EVALUATION OF PATIENT DOSE DURING
FLUOROSCOPICALLY GUIDED CERVICAL SPINAL FUSION

Vasileios I. Metaxas
Medical Physicist

Ph.D. Thesis

Patras 2017
ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ

ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ

ΑΞΙΟΛΟΓΗΣΗ ΔΟΣΗΣ ΑΣΘΕΝΟΥΣ ΚΑΤΑ ΤΗΝ ΑΚΤΙΝΟΣΚΟΠΙΚΑ ΚΑΘΟΔΗΓΟΥΜΕΝΗ ΑΥΧΕΝΙΚΗ ΣΠΟΝΔΥΛΟΔΕΣΙΑ

Βασίλειος Ι. Μεταξάς

Φυσικός Νοσοκομείων - Ακτινοβολικός Ιατρικής

Διδακτορική Διατριβή

Πάτρα 2017
THREE MEMBERS ADVISORY COMMITTEE

Professor George Panayiotakis  Supervisor
Assoc. Professor George Gatzounis  Member of the Advisory Committee
Professor Efstathios Efstathopoulos  Member of the Advisory Committee

SEVEN MEMBERS EXAMINING COMMITTEE

Professor George Panayiotakis  Supervisor
Professor Lena Costaridou  Member of the Examining Committee
Professor Efstathios Efstathopoulos  Member of the Advisory Committee
Assoc. Professor George Gatzounis  Member of the Advisory Committee
Assoc. Professor George Sakellaropoulos  Member of the Examining Committee
Assoc. Professor George Kagadis  Member of the Examining Committee
Assoc. Professor Aikaterini Solomou  Member of the Examining Committee
ACKNOWLEDGEMENTS

I feel deeply obliged to my supervisor, Professor George Panayiotakis, for his availability, continuous support, valuable guidelines, and encouragement during this PhD Thesis. His critical reading of the text and insightful comments is greatly acknowledged.

I am indebted to Associate Professor George Gatzounis for his scientific support and useful advices in all stages of this Thesis.

I am indebted to Professor Theodore Petsas, director of the Department of Radiology of University Hospital of Patras, for giving me the opportunity to use the C-arm fluoroscopy system available in the Neurosurgery Department.

I would like to thank the Division of Medical Physics of University Hospital of Patras for providing the quality assurance equipment used throughout this Thesis.

I would like to thank the staff of the Surgery Department of University Hospital of Patras for always helping me and especially for the co-operation during the procedures.

I am grateful to medical physicists of the University Hospital of Patras Zeta Malatara, Spyros Papatheodorou, Theodoros Skouras and Gerasimos Messaris for their valuable friendship, scientific support and best co-operation the last five years.

I would like also to thank all my colleagues of the Department of Medical Physics for their help and valuable discussions.

Last but not least, the greatest thanks go to my family, not only for the opportunity that gave me to continue my studies at the University of Patras, but also for their support and interest in my future career. Especially, would like to thank my wife for her patience and support the last five years.
# TABLE OF CONTENTS

Table of Contents............................................................................................................................ i  
List of Figures .................................................................................................................................... ix  
List of Tables ....................................................................................................................................... xvii  
List of Abbreviations.......................................................................................................................... xxi

## Chapter 1 Introduction

1.1 Introduction ..................................................................................................................................... 1  
1.2 The problem ................................................................................................................................. 2  
1.3 Thesis originality ........................................................................................................................... 6  
1.4 Publications .................................................................................................................................... 7  
1.5 Thesis layout................................................................................................................................... 7

## Chapter 2 Cervical myelopathy: pathophysiology and treatment

2.1 Introduction ..................................................................................................................................... 9  
2.2 Functional anatomy of the spine ..................................................................................................... 10  
2.3 Pathophysiology of cervical myelopathy ....................................................................................... 15  
2.4 Surgical management of cervical myelopathy ............................................................................... 16  
2.4.1 Multilevel cervical discectomy ................................................................................................. 17  
2.4.1.1 Indications........................................................................................................................... 17  
2.4.1.2 Preparation and position of patient ...................................................................................... 18  
2.4.1.3 Fluoroscopic exposure of the anterior cervical spine .......................................................... 19  
2.4.1.4 Removal of disc and preparation of end plates ................................................................. 21  
2.4.1.5 Decompression of the spinal canal and foramen ............................................................... 22  
2.4.1.6 Graft selection and insertion ............................................................................................ 24  
2.4.1.7 Plating and screw placement ............................................................................................. 25  
2.4.1.8 Closure ............................................................................................................................... 26  
2.4.2 Multilevel laminectomy and fusion ......................................................................................... 27  
2.4.2.1 Indications for multilevel cervical laminectomy ............................................................... 27
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4.2.2 Indications for posterior cervical fusion</td>
<td>28</td>
</tr>
<tr>
<td>2.4.2.3 Contraindications for the posterior approach</td>
<td>29</td>
</tr>
<tr>
<td>2.4.2.4 Patient positioning - Operative set-up</td>
<td>30</td>
</tr>
<tr>
<td>2.4.2.5 Multilevel laminectomy</td>
<td>30</td>
</tr>
<tr>
<td>2.4.2.6 Posterior cervical stabilization and fusion</td>
<td>32</td>
</tr>
<tr>
<td>2.4.2.7 Lateral mass fixation</td>
<td>34</td>
</tr>
<tr>
<td>2.4.2.8 Cervical pedicle screws</td>
<td>39</td>
</tr>
</tbody>
</table>

**Chapter 3 Health effects of ionising radiation**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Introduction</td>
<td>41</td>
</tr>
<tr>
<td>3.2 Classification of radiation qualities in radiological protection</td>
<td>42</td>
</tr>
<tr>
<td>3.3 Health effects</td>
<td>42</td>
</tr>
<tr>
<td>3.3.1 Somatic and genetic effects</td>
<td>43</td>
</tr>
<tr>
<td>3.3.2 Stochastic effects</td>
<td>43</td>
</tr>
<tr>
<td>3.3.3 Tissue reactions</td>
<td>44</td>
</tr>
<tr>
<td>3.3.4 Direct and indirect effects of radiation</td>
<td>47</td>
</tr>
<tr>
<td>3.4 Dose response curves</td>
<td>48</td>
</tr>
<tr>
<td>3.5 Relative biological effectiveness (RBE)</td>
<td>48</td>
</tr>
<tr>
<td>3.6 International organizations on radiation effects</td>
<td>49</td>
</tr>
<tr>
<td>3.7 Risk estimates from exposure to low level ionising radiation</td>
<td>49</td>
</tr>
<tr>
<td>3.7.1 Risk models for cancer</td>
<td>50</td>
</tr>
<tr>
<td>3.7.2 Time course and latency period</td>
<td>50</td>
</tr>
<tr>
<td>3.7.3 Dose-response relationship for cancer</td>
<td>51</td>
</tr>
<tr>
<td>3.7.4 Dose and dose rate effectiveness factor</td>
<td>51</td>
</tr>
<tr>
<td>3.7.5 Cancer risk</td>
<td>52</td>
</tr>
<tr>
<td>3.8 Radiation safety standards</td>
<td>55</td>
</tr>
</tbody>
</table>

**Chapter 4 Dosimetric quantities and units**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Introduction</td>
<td>57</td>
</tr>
<tr>
<td>4.2 Basic dosimetric quantities</td>
<td>58</td>
</tr>
<tr>
<td>4.2.1 Fluence</td>
<td>58</td>
</tr>
</tbody>
</table>
Table of contents

4.2.2 Energy fluence .......................................................................................................... 59
4.2.3 Kerma and kerma rate ........................................................................................... 59
4.2.4 Energy imparted ..................................................................................................... 60
4.2.5 Absorbed dose ....................................................................................................... 60
4.2.6 Kerma and absorbed dose .................................................................................... 61
4.3 Application specific dosimetric quantities .............................................................. 61
  4.3.1 Incident air kerma ............................................................................................... 62
  4.3.2 Entrance surface air kerma ................................................................................ 63
  4.3.3 X-ray tube output ............................................................................................... 64
  4.3.4 Air kerma-area product ..................................................................................... 64
4.4 Quantities related to stochastic and deterministic effects ....................................... 65
  4.4.1 Organ and tissue dose ....................................................................................... 65
  4.4.2 Equivalent dose ................................................................................................. 66
  4.4.3 Effective dose .................................................................................................... 68
4.5 Relationship between dosimetric quantities .......................................................... 69
4.6 Conversion coefficients for the evaluation of organ and tissue doses .................... 70

Chapter 5 Instrumentation for dosimetry

5.1 Introduction ............................................................................................................... 71
5.2 Selection of instrumentation for dosimetry ............................................................. 72
  5.2.1 Ionisation chambers .......................................................................................... 73
    5.2.1.1 Free air chambers ................................................................................... 73
    5.2.1.2 Cylindrical and parallel plate chambers ............................................. 74
    5.2.1.3 Transmission ionisation chambers ..................................................... 75
  5.2.2 Solid state dosimeters ....................................................................................... 76
    5.2.2.1 TLDs ...................................................................................................... 76
    5.2.2.2 Semiconductor dosimeters .................................................................. 78
  5.2.3 Film dosimetry .................................................................................................. 79
    5.2.3.1 Radiographic film ............................................................................... 79
    5.2.3.2 Radiochromic film ............................................................................... 81
5.3 Summary of properties of common dosimetric systems ....................................... 82
5.4 Summary of characteristics of diagnostic dosimeters .......................................... 83
5.5 Calibration of instrumentation

5.5.1 Specification of the X-ray beams

5.5.2 Calibration facilities

5.5.3 Radiation qualities for calibration

5.5.4 Requirements for equipment used for calibration

5.5.5 Calibration of the instrumentation

5.6 Instruments for measurement of tube voltage and time

Chapter 6 Fundamentals of image quality

6.1 Introduction

6.2 Primary image quality indices

6.2.1 Contrast

6.2.2 Unsharpness

6.2.2.1 Limiting spatial resolution

6.2.2.2 Modulation transfer function (MTF)

6.2.3 Noise

6.2.3.1 Measures of variance and covariance

6.2.3.2 Noise Power Spectrum (NPS) (Wiener Spectrum)

6.2.3.3 Cascade of image noise

6.2.3.4 Image subtraction

6.3 Overall performance

6.3.1 Signal to noise ratio (SNR)

6.3.2 Detective Quantum Efficiency (DQE)

6.3.3 Noise Equivalent Quanta (NEQ)

6.3.4 Figure of Merit (FOM)

6.4 Artefacts

6.5 Methodologies for evaluation of observer performance

6.5.1 Contrast detail experiments

6.5.2 Forced choice experiments

6.5.3 Receiver operating characteristic (ROC) analysis

6.5.3.1 Statistical decision theory

6.5.3.2 Receiver operating characteristic (ROC) experiments
## Table of contents

6.5.4 Viewing conditions ........................................................................................................ 115
6.5.5 Limitations of observer performance studies .......................................................... 115

### Chapter 7 Patient dosimetry issues

7.1 Introduction .................................................................................................................... 117
7.2 Dosimetric quantities in fluoroscopy ......................................................................... 119
7.3 Uncertainties in dosimetric quantities ........................................................................ 120
  7.3.1 Uncertainties in quantities directly measured with dosimeters ...................... 120
  7.3.2 Uncertainties in quantities derived from directly measured quantities ............. 122
7.4 Dosimetry in fluoroscopy ......................................................................................... 122
  7.4.1 Measurements using phantoms ........................................................................ 123
    7.4.1.1 Equipment for measurements using phantoms ........................................ 125
    7.4.1.2 Aspects for measurements using phantoms ........................................... 126
    7.4.1.3 Measurement of the tube output .............................................................. 128
  7.4.2 Patient dose measurements .............................................................................. 130
    7.4.2.1 Equipment for patient dosimetry ......................................................... 131
    7.4.2.2 Aspects for patient dosimetry .............................................................. 131
7.5 Estimation of organ doses ....................................................................................... 135
  7.5.1 Monte Carlo simulation .................................................................................... 135
  7.5.2 Anthropomorphic phantom measurements .................................................... 137
7.6 Estimation of effective dose utilizing Monte Carlo simulation ............................... 138
7.7 Radiation safety considerations ............................................................................... 139
  7.7.1 Patient protection ............................................................................................ 139
  7.7.2 Operator protection ......................................................................................... 140

### Chapter 8 Optimization in clinical practice

8.1 Introduction .................................................................................................................. 141
8.2 Quality and patient safety in medical imaging ....................................................... 142
  8.2.1 Improve quality by radiation protection ............................................................ 144
    8.2.1.1 Impact of ICRP recommendations ......................................................... 144
    8.2.1.2 European Commission actions ................................................................. 145
<table>
<thead>
<tr>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2.2 Radiation protection actions in quality programs</td>
</tr>
<tr>
<td>8.3 Dose recording and monitoring</td>
</tr>
<tr>
<td>8.3.1 Population based dose surveys</td>
</tr>
<tr>
<td>8.3.2 Local dose audit</td>
</tr>
<tr>
<td>8.3.3 Role of the medical physicist</td>
</tr>
<tr>
<td>8.4 The three principles of radiological protection</td>
</tr>
<tr>
<td>8.4.1 Justification of a practice</td>
</tr>
<tr>
<td>8.4.1.1 Referral guidelines and radiation protection</td>
</tr>
<tr>
<td>8.4.1.2 Sensitive populations</td>
</tr>
<tr>
<td>8.4.1.3 High skin dose examinations</td>
</tr>
<tr>
<td>8.4.1.4 Informed consent</td>
</tr>
<tr>
<td>8.4.2 Optimization of protection</td>
</tr>
<tr>
<td>8.4.2.1 Aspects to optimize quality and minimize exposure</td>
</tr>
<tr>
<td>8.4.2.2 How optimization affects justification</td>
</tr>
<tr>
<td>8.4.2.3 Strategies for ALARA in Fluoroscopy: Dose reduction and image quality</td>
</tr>
<tr>
<td>8.4.2.4 Aspects of good practice</td>
</tr>
<tr>
<td>8.4.3 Dose limits</td>
</tr>
<tr>
<td>8.5 Diagnostic Reference Levels (DRLs)</td>
</tr>
<tr>
<td>8.5.1 Definition</td>
</tr>
<tr>
<td>8.5.2 Use of diagnostic reference levels to reduce patient dose</td>
</tr>
<tr>
<td>8.6 Radiation protection for patients and staff</td>
</tr>
<tr>
<td>8.7 Education, training and optimization strategies</td>
</tr>
</tbody>
</table>

Chapter 9 Evaluation of patient dose in fluoroscopically guided cervical discectomy and fusion

<table>
<thead>
<tr>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1 Introduction</td>
</tr>
<tr>
<td>9.2 Materials and methods</td>
</tr>
<tr>
<td>9.2.1 Fluoroscopy equipment</td>
</tr>
<tr>
<td>9.2.2 Patients and CDF technique</td>
</tr>
<tr>
<td>9.2.3 Dose calculations</td>
</tr>
<tr>
<td>9.3 Results</td>
</tr>
<tr>
<td>9.4 Discussion</td>
</tr>
</tbody>
</table>
Chapter 10 Optimization of patient dose and image quality in fluoroscopically guided cervical spine surgery: a phantom based study

10.1 Introduction .................................................................................................................. 185
10.2 Materials and methods .............................................................................................. 187
  10.2.1 Fluoroscopy system description ........................................................................... 187
  10.2.2 Dose evaluation .................................................................................................... 188
  10.2.3 Image quality evaluation and FOM ...................................................................... 190
  10.2.4 Statistical analysis ................................................................................................. 192
10.3 Results ......................................................................................................................... 193
10.4 Discussion .................................................................................................................... 199
  10.4.1 Radiation dose ...................................................................................................... 199
  10.4.2 Image quality and FOM ........................................................................................ 200
10.5 Conclusion .................................................................................................................... 208

Chapter 11 Institutional (local) diagnostic reference levels in fluoroscopically guided spine surgery

11.1 Introduction .................................................................................................................. 209
11.2 Materials and methods .............................................................................................. 212
  11.2.1 Dosimetric quantities ............................................................................................ 212
  11.2.2 Fluoroscopy system .............................................................................................. 212
  11.2.3 Calibration of the KAP meter ............................................................................... 213
  11.2.4 Patients and data collection .................................................................................. 214
  11.2.5 Dose calculations .................................................................................................. 215
  11.2.6 Reference Levels (RLs) ........................................................................................ 216
11.3 Results and discussion .................................................................................................. 217
11.4 Conclusion .................................................................................................................... 230
Chapter 12 General discussion, conclusions and future work

12.1 General discussion........................................................................................................ 231
12.2 Recommendations and conclusions.............................................................................. 254
12.3 Limitations and future work ......................................................................................... 258

References ........................................................................................................................... 261

List of Appendices

Appendix A: User guide for CALDOSE_X 5.0 software .............................................. 313
Appendix B: Spinal surgery basic instrumentation........................................................... 321
Appendix C: Calibration of KAP meter ......................................................................... 333
Summary ............................................................................................................................. 341
Περίληψη ........................................................................................................................... 343
LIST OF FIGURES

Figure 2.1  Lateral view of the vertebral column, showing the spinal curvatures.
Figure 2.2  A typical human vertebra. A. superior and B. lateral view.
Figure 2.3  Structure of the intervertebral disc.
Figure 2.4  Lateral view of major ligaments of the spine, illustrating the ligamentum flava, supraspinous, interspinous, and anterior and posterior longitudinal ligaments.
Figure 2.5  (A) Anterior surface of the spine showing the midline marked in the ALL above and below the level of fusion. (B) The periosteum, anterior longitudinal ligament and longus colli structures are elevated with a Key periosteal elevator. (C) Self-retaining retractors are placed under the longus colli muscles, and the distractor is inserted over the distraction pins at the upper level in preparation for the decompression.
Figure 2.6  Distraction posts placement for a two-level procedure. The posts are placed above and below the midpoints of the respective vertebrae. They are placed perpendicular to the end plate and will not be parallel until distraction is applied (bottom).
Figure 2.7  Sequential steps in the multilevel discectomy and fusion procedure. (A) Initial view. (B) Anterior osteophyte removal. (C and D) Flattening of superior end plate of upper vertebra. (E) Contouring of inferior end plate to the superior vertebra. (F) Undercutting of marginal osteophyte. (G) Assessing end plates for parallelism with caliper and measuring dimensions for grafting. (H) View is obtained coaxial with the vertebra (*) rather than obliquely (#) to perfect end plate flattening. (I and J) Curetting residual osteophytes behind the vertebra. (K) Graft placement.
Figure 2.8  The en bloc laminectomy approach avoids placement of instruments into the central canal before the decompression. Bilateral troughs are drilled at the lamina-facet junction with the drill bit oriented perpendicular to the dorsal surface of the lamina to avoid violation of the lateral mass.
Figure 2.9  The lamina and spinous processes are resected en bloc making sure the rostral and caudal ends are simultaneously elevated to avoid leveraging into the spinal canal. Curettes or rongeurs are inserted into the troughs to release any ligamentous tissue tethering the lamina.
**Figure 2.10** Wiring techniques used to stabilize the cervical spine after a multilevel laminectomy include passage of the wire between adjacent facets, securing individual wires to a structural graft, or to a rigid rod, such as the Hartshill rectangle.

**Figure 2.11** A radiograph demonstrating how plate constructs have a limited ability to conform to the surgical anatomy. The right sided screw hole second from the top is positioned over the facet joint, eliminating the possibility for screw placement.

**Figure 2.12** The entry site for the screw with the Roy-Camille method is the midpoint of the lateral mass, perpendicular to the dorsal cortex in the sagittal plane. The screw is directed laterally by 10°. Using the Magerl technique the screw entry site is located slightly medial and cranial to the midpoint of the lateral mass. The screw trajectory is parallel to the facet joint in the sagittal plane and directed 25° laterally in the transverse plane. The entry site for the Anderson technique is located approximately 1 mm medial to the lateral mass midpoint with a rostral angulation of 30-40° and a lateral angle of 10°. The An technique uses an entry site similar to the Anderson technique but only 15° of rostral angulation and a lateral angulation of 30°.

**Figure 2.13** The general trajectory required for safe lateral mass screw placement. A lateral trajectory directs the screw away from the transverse foramen and vertebral artery, while the rostral angle avoids the nerve root traversing deep to the superior facet of the caudal spinal segment. Bone volume is sufficient with this trajectory to enhance screw purchase.

**Figure 2.14** Lamina are left intact during drilling of the lateral masses to act as a protective barrier. The prominent spinous processes can obstruct the trajectory for appropriate lateral mass drilling; therefore resection will allow the optimal screw trajectory. Once drilling of the lateral masses is completed, the lamina is resected.

**Figure 2.15** Once the decompression is completed, the lateral mass screws are inserted with a rostral and lateral angulation with respect to the lateral mass. The computed tomographic image demonstrates appropriately placed screws and their relationship to the transverse foramen.
Figure 2.16 The final stabilization construct is depicted in the schematic and intraoperative photograph. The lateral masses and facet joints are decorticated and the bone graft impacted along these surfaces. To enhance stability, the newer generation screw-rod constructs allow insertion of cross-links to create a rectangular construct. Placing bone graft along the exposed dural surfaces, especially along a decompressed nerve root, should be avoided to prevent the possibility of recurrent stenosis.

Figure 2.17 The trajectories required for appropriate cervical pedicle screw placement in both the sagittal and axial planes. A steep lateral to medial inclination and the significant variability of the pedicle trajectory make the insertion of cervical pedicle screws technically demanding. Potential for neurovascular injury exists because of the proximity of the vertebral artery, nerve root, and spinal cord.

Figure 3.1 Moist desquamation erythema after radiofrequency catheter ablation.

Figure 3.2 Secondary ulceration after two angioplasties of the left coronary artery.

Figure 3.3 Typical dose response curves for cancer development (curves A, B, C and D) and for tissue response (curve E).

Figure 3.4 The lifetime attributable risk from a single small dose as a function of age at the time of exposure.

Figure 4.1 Definition of fluence and energy fluence utilizing a spherical surface, S.

Figure 4.2 Diagram of the measuring geometry for the dosimetric quantities.

Figure 4.3 Radiation weighting factor, $w_R$, for neutrons. Step function and continuous function given in ICRP 60 and function adopted in ICRP 103 Recommendations.

Figure 4.4 Relationship between physical protection and operational quantities.

Figure 5.1 Basic design of a parallel-plate ionisation chamber. 1: polarizing electrode, 2: measuring electrode, 3: guard ring, a: height (electrode separation) of the air cavity, d: diameter of the polarizing electrode, m: diameter of the collecting electrode, g: width of the guard ring.

Figure 5.2 Basic design of a cylindrical ionisation chamber.

Figure 5.3 A typical TLD glow curve of LiF:Mg,Ti obtained at a low heating rate.

Figure 5.4 Typical H&D curve for a radiographic film. The OD is plotted against the log of the exposure.
Figure 5.5 Typical waveform for a three phase six pulse generator operating at 80 kV and 165 ms exposure time.

Figure 6.1 X-ray spectral shaping: Influence of tube loading and Cu filtration.

Figure 6.2 Typical dose control curves for fluoroscopy.

Figure 6.3 A point object is blurred with increasingly larger kernels. The larger the kernel, the greater the blurring and the lower the contrast of small objects.

Figure 6.4 The overall MTF is the product of the MTFs of the three sub-components A, B and C.

Figure 6.5 (a) A radiograph of a bar pattern is presented, (b) In the magnified region of the pattern, the limiting resolution is 3.4 LP/mm.

Figure 6.6 The ability to detect an object depends on both the contrast of the object and the noise presented in the image.

Figure 6.7 Right: A uniform disk (a) is presented on a uniform background (b); Left: The SNR is calculated using the mean signals and noise in the background in Eq. (6.4).

Figure 6.8 (a) Pincushion distortion (b); S distortion.

Figure 6.9 TOR 18FG test object.

Figure 6.10 Schematic representation of CDRAD 2.0 contrast detail phantom.

Figure 6.11 Contrast detail curve obtained with the CDRAD 2.0 phantom.

Figure 6.12 Decision outcomes in statistical ‘decision theory’.

Figure 6.13 Decision thresholds for probability density functions.

Figure 6.14 ROC curves are symmetrical since the underlying probability density functions have equal variance.

Figure 7.1 Water phantom for measurements of ESAK in fluoroscopy.

Figure 7.2 Configurations for measurement of patient ESAK (a) an under couch installation, (b) an over couch installation, (c) a C-arm unit, (d) C-arm unit, lateral exposures.

Figure 7.3 Geometry for measurement of the tube output using a solid state dosimeter.

Figure 7.4 A schematic of the IRP.

Figure 8.1 A case of radiodermatitis after percutaneous coronary interventions.

Figure 9.1 Correlation of KAP and CD with FT values obtained during CDF procedures.

Figure 10.1 Dose control (kV/mA) curves for the six default fluoroscopy modes of the fluoroscopy system.
Figure 10.2 Graphical representation of the irradiation geometry, showing the TOR-18FG test object at the isocentre (in the middle of the PMMA phantom).

Figure 10.3 A typical radiograph of the TOR 18FG test object acquired with the continuous LDF mode and FOV of 23 cm, indicating the ROIs used for the calculation of the image quality indices.

Figure 10.4 Phantom ESD rate for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.

Figure 10.5 $FOM_{SNR}$ values for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.

Figure 10.6 $FOM_{HCSR}$ values for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.

Figure 11.1 Histograms of the total distribution of KAP and CD values for (a) cervical and (b) thoraco-lumbar interventions.

Figure 11.2 Fitting curves describing the relationship between KAP and CD values with FT for (a) cervical and (b) thoraco-lumbar interventions.

Figure 11.3 Experimental determination of k-factor used for patient size corrections.

Figure 12.1 Influence of BMI to patient ESD and ED for cervical interventions.

Figure 12.2 Influence of BMI to patient ESD and ED for thoraco-lumbar interventions.

Figure 12.3 Patient dose in terms of KAP and CD values plotted against patient weight for thoraco-lumbar interventions. The crosses and solid show the uncorrected results and the circles and dotted lines the size-corrected results.

Figure 12.4 Graphs show correlation between MSD and FT, WFP as well as KAP and WFP in cervical interventions.

Figure 12.5 Graphs show correlation between ESD and FT, WFP in thoraco-lumbar interventions.

Figure A.1 CALDose_X 5.0 cover image.

Figure A.2 Definition of the X-Ray examination.

Figure A.3 Definition of patient data, sex, posture and view of available X-ray examinations.

Figure A.4 Selection of Cervical Spine examination, right lateral (RLAT) projection, FDD = 100 cm, 10 mAs and 65 kV for standard field position.

Figure A.5 Selection of the theoretical output curve for 2.5 mm Al filtration provided by the CALDose_X 5.0.
Figure A.6  Theoretical output curve, INAK, ESAK and the BSF values.
Figure A.7  Visualization of the selected Cervical Spine RLAT examination.
Figure A.8  Selection of the output mode for calculations and normalization quantity: organ and tissue absorbed doses based on ESAK values.
Figure A.9  Selection of the output mode for calculations and normalization quantity: organ and tissue absorbed doses CCs based on ESAK values.

Figure B.1  Weitlaner retractor.
Figure B.2  Derrico retractor.
Figure B.3  Adson Cerebellar retractor.
Figure B.4  Hand-held Meyerding retractor.
Figure B.5  Taylor retractor.
Figure B.6  Top: Caspar nerve root retractor; Bottom: Derrico nerve root retractor.
Figure B.7  Micro Williams retractor.
Figure B.8  Hoen Sedilot elevator.
Figure B.9  Cobb elevator.
Figure B.10 Penfield 4 elevator.
Figure B.11 Stille-Luer Horsley rongeur.
Figure B.12 Leksell rongeur.
Figure B.13 Duckbill rongeur.
Figure B.14 Kerrison rongeur.
Figure B.15 Pituitary rongeur.
Figure B.16 Caspar serrated pituitary rongeur.
Figure B.17 Micro straight pituitary rongeur.
Figure B.18 Peapod pituitary rongeur.
Figure B.19 Micro Williams pituitary rongeur.
Figure B.20 Dandy blunt nerve hook.
Figure B.21 Cushing Gasserian nerve hook.
Figure B.22 Weary Black nerve hook.
Figure B.23 Malis (micro) nerve hook.
Figure B.24 Angled curette.
Figure B.25 Straight curette.
Figure B.26 Epstein curette.
List of figures

Figure C.1  Set-up for calibration of KAP meter using diagnostic dosimeter: (a) over couch installation, (b) under couch installation.

Figure C.2  Set-up for calibration of KAP meter using reference KAP meter, according to IAEA method: (a) over couch installation, (b) under couch installation.

Figure C.3  Set-up for calibration of KAP meter using tandem method.
LIST OF TABLES

Table 2.1  Pathophysiologica factors involved in cervical myelopathy.
Table 2.2  Indications for anterior and posterior approaches for cervical myelopathy.
Table 3.1  Radiation induced skin reactions after a single exposure.
Table 3.2  Nominal probability coefficients for stochastic effects in ICRP 60 (10\(^{-2}\) Sv\(^{-1}\)).
Table 3.3  Detriment-adjusted risk coefficients for stochastic effects in ICRP 103 (10\(^{-2}\) Sv\(^{-1}\)).
Table 3.4  Lifetime attributable risk for cancer incidence.
Table 3.5  Lifetime attributable risk for cancer mortality.
Table 4.1  Recommended application specific quantities in X-ray medical imaging.
Table 4.2  Radiation weighting factors in the 1990 recommendations.
Table 4.3  Radiation weighting factors in the 2007 recommendations.
Table 4.4  Tissue weighting factors w\(_T\) according to the ICRP.
Table 5.1  Advantages and disadvantages of the four most common dosimetric systems.
Table 5.2  Basic characteristics of diagnostic dosimeters.
Table 5.3  Radiation qualities for the calibration of diagnostic dosimeters.
Table 5.4  Maximum variation of energy response for ionisation chambers used at SSDLs.
Table 5.5  Uncertainty for different types of instruments for an SSDL.
Table 6.1  Decision outcomes of a detection task.
Table 7.1  Dosimetry quantities and measurement methodology for different modalities.
Table 7.2  Typical uncertainty budgets for quantities directly measured with dosimeters.
Table 7.3  Estimation of additional uncertainty in the measurement of ESAK rate in fluoroscopy.
Table 8.1  Annual dose limits in according to the Greek radiation protection regulations.
Table 9.1  Operating and exposure parameters obtained from the CDF procedures.
Table 9.2  Organ dose CCs normalized over KAP values, for male and female patients undergoing a CDF procedure.
Table 9.3  Patient ESD and ED values as a function of the sex during CDF procedures.
Table 9.4  FT, KAP, CD, ESD and ED values for single and multiple level CDF procedures.
Table 9.5  Comparison of our results with corresponding values reported in previous studies.
Table 10.1 Technical specifications of the fluoroscopy system, Philips BV Endura.

Table 10.2 II ESD rate for all fluoroscopy modes, FOVs and phantom thicknesses used.

Table 10.3 LCD and HCR for all fluoroscopy modes, FOVs and phantom thicknesses used.

Table 10.4 Exposure parameters (TV and TC), KAP rate and CD rate values corresponding to all fluoroscopy modes, phantom thicknesses and FOVs used.

Table 10.5 SNR, CNR and HCSR values for all fluoroscopy modes, phantom thicknesses and FOVs used.

Table 10.6 Dosimetric and imaging performance for all fluoroscopy modes and FOVs, for the 20 cm phantom and two geometric magnifications.

Table 11.1 Patients’ characteristics.

Table 11.2 FT, KAP and CD values per treated level for cervical and thoraco-lumbar interventions.

Table 11.3 Mean, median, range, 10th, 25th, 75th percentile of the total distribution of FT, KAP and CD values for cervical and thoraco-lumbar interventions.

Table 11.4 Association of the LDRLs with the investigated anatomical, clinical and technical factors influencing procedure complexity.

Table 11.5 Mean, median, range, 10th, 25th, 75th percentile of FT, KAP and CD values, for cervical and thoraco-lumbar interventions, obtained from weight banding method.

Table 11.6 Mean, median, range, 10th, 25th, 75th percentile of FT, KAP and CD values for thoraco-lumbar interventions, obtained with size correction method.

Table 11.7 Patient ESD, ED, thyroid absorbed dose and gonadal dose values for cervical and thoraco-lumbar interventions.

Table 12.1 Influence of patient BMI in FT, KAP and CD values during thoraco-lumbar interventions.

Table 12.2 Gradients of the linear regression lines for KAP and CD values against patient weight shown in Figure 12.3.

Table 12.3 Feasibility of CD values as skin dose indicator for cervical and thoracolumbar interventions.

Table 12.4 FT, KAP and CD values for each operator in thoraco-lumbar interventions.

Table A.1 CALDose_X 5.0 organ and tissue absorbed doses, as well as associated cancer risks for the selected examination.
Table A.2  CALDose_X 5.0 conversion coefficients between organ and tissue absorbed doses and ESAK for the selected examination and exposure parameters.
#### LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAPM</td>
<td>American Association of Physicists in Medicine</td>
</tr>
<tr>
<td>ABC</td>
<td>automatic brightness control</td>
</tr>
<tr>
<td>ACR</td>
<td>American College of Radiology</td>
</tr>
<tr>
<td>AEC</td>
<td>automatic exposure control</td>
</tr>
<tr>
<td>AFC</td>
<td>alternative forced choice</td>
</tr>
<tr>
<td>AFROC</td>
<td>alternative free response receiver operating characteristic</td>
</tr>
<tr>
<td>AHARA</td>
<td>as high as reasonably achievable</td>
</tr>
<tr>
<td>ALs</td>
<td>action levels</td>
</tr>
<tr>
<td>ALARA</td>
<td>as low as reasonably achievable</td>
</tr>
<tr>
<td>ALL</td>
<td>anterior longitudinal ligament</td>
</tr>
<tr>
<td>APF</td>
<td>automatic programmed fluoroscopy</td>
</tr>
<tr>
<td>ASARA</td>
<td>as safe as reasonably achievable</td>
</tr>
<tr>
<td>AUC</td>
<td>area under curve</td>
</tr>
<tr>
<td>BEIR</td>
<td>biologic effects of ionizing radiation</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>BSC</td>
<td>bone surface cells</td>
</tr>
<tr>
<td>BSF</td>
<td>backscatter factor</td>
</tr>
<tr>
<td>BSS</td>
<td>Basic Safety Standards</td>
</tr>
<tr>
<td>CC</td>
<td>conversion coefficient</td>
</tr>
<tr>
<td>CD</td>
<td>cumulative dose</td>
</tr>
<tr>
<td>CDF</td>
<td>cervical discectomy and fusion</td>
</tr>
<tr>
<td>CIRCE</td>
<td>Cardiovascular and Interventional Radiological Society of Europe</td>
</tr>
<tr>
<td>CNR</td>
<td>contrast to noise ratio</td>
</tr>
<tr>
<td>COR</td>
<td>correct observation ratio</td>
</tr>
<tr>
<td>CRCPD</td>
<td>Conference of Radiation Control Program Directors</td>
</tr>
<tr>
<td>CSF</td>
<td>cervical spine fusion</td>
</tr>
<tr>
<td>CSS</td>
<td>cervical spine surgery</td>
</tr>
<tr>
<td>DAP</td>
<td>dose area product</td>
</tr>
<tr>
<td>DDREF</td>
<td>dose and dose rate effectiveness factor</td>
</tr>
<tr>
<td>DICOM</td>
<td>digital imaging and communication in medicine</td>
</tr>
<tr>
<td>DQE</td>
<td>detective quantum efficiency</td>
</tr>
</tbody>
</table>
List of abbreviations

**DRLs**: diagnostic reference levels  
**DSA**: digital subtraction angiography  
**EAK**: entrance air kerma  
**EAR**: excess absolute risk  
**EC**: European Commission  
**ED**: effective dose  
**ERR**: excess relative risk  
**ESAK**: entrance surface air kerma  
**ESD**: entrance surface dose  
**ESE**: exposure at skin entrance  
**ESR**: European Society of Radiology  
**FASH**: female adult mesh  
**FDA**: Food and Drug Administration  
**FDD**: focus detector distance  
**FG**: fluoroscopically guided  
**FN**: false negative  
**FOM**: figure of merit  
**FOV**: field of view  
**FP**: false positive  
**FPF**: false positive fraction  
**FP**: flat panel  
**FROC**: free response receiver operating characteristic  
**FSD**: focus skin distance  
**FT**: fluoroscopy time  
**GAEC**: Greek Atomic Energy Commission  
**GSF**: National Research Center for Environment and Health  
**HCR**: high-contrast resolution  
**HCSR**: high contrast spatial resolution  
**HDF**: high definition fluoroscopy  
**HPA**: Health Protection Agency  
**HVL**: half value layer  
**IAEA**: International Atomic Energy Agency  
**IC**: interventional cardiology
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICRP</td>
<td>International Commission on Radiological Protection</td>
</tr>
<tr>
<td>ICRU</td>
<td>International Commission on Radiation Units and Measurements</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>II</td>
<td>image intensifier</td>
</tr>
<tr>
<td>INAK</td>
<td>incident air kerma</td>
</tr>
<tr>
<td>IOMP</td>
<td>International Organization for Medical Physics</td>
</tr>
<tr>
<td>IQ</td>
<td>image quality</td>
</tr>
<tr>
<td>IQF</td>
<td>image quality figure</td>
</tr>
<tr>
<td>IQF&lt;sub&gt;inv&lt;/sub&gt;</td>
<td>inverse image quality figure</td>
</tr>
<tr>
<td>IR</td>
<td>interventional radiology</td>
</tr>
<tr>
<td>IRP</td>
<td>interventional reference point</td>
</tr>
<tr>
<td>ISSRT</td>
<td>International Society of Radiographers and Radiological Technologists</td>
</tr>
<tr>
<td>IV</td>
<td>intervertebral</td>
</tr>
<tr>
<td>KAP</td>
<td>kerma area product</td>
</tr>
<tr>
<td>LCD</td>
<td>low-contrast detectability</td>
</tr>
<tr>
<td>LDF</td>
<td>low dose fluoroscopy</td>
</tr>
<tr>
<td>LDRLs</td>
<td>local diagnostic reference levels</td>
</tr>
<tr>
<td>LET</td>
<td>linear energy transfer</td>
</tr>
<tr>
<td>LLAT</td>
<td>left lateral</td>
</tr>
<tr>
<td>LNT</td>
<td>linear non threshold</td>
</tr>
<tr>
<td>LPs</td>
<td>line pairs</td>
</tr>
<tr>
<td>LROC</td>
<td>location receiver operating characteristic</td>
</tr>
<tr>
<td>LSF</td>
<td>lumbar spine fusion</td>
</tr>
<tr>
<td>MASH</td>
<td>female adult mesh</td>
</tr>
<tr>
<td>MC</td>
<td>Monte Carlo</td>
</tr>
<tr>
<td>MED</td>
<td>Medical Exposure Directive</td>
</tr>
<tr>
<td>MPE</td>
<td>medical physics expert</td>
</tr>
<tr>
<td>MRI</td>
<td>magnetic resonance imaging</td>
</tr>
<tr>
<td>MSD</td>
<td>maximum skin distance</td>
</tr>
<tr>
<td>MTF</td>
<td>modulation transfer function</td>
</tr>
<tr>
<td>NCRP</td>
<td>National Council on Radiation Protection and Measurements</td>
</tr>
<tr>
<td>NDRLs</td>
<td>national diagnostic reference levels</td>
</tr>
<tr>
<td>NEQ</td>
<td>noise equivalent quanta</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>NPS</td>
<td>noise power spectrum</td>
</tr>
<tr>
<td>NPV</td>
<td>negative predictive value</td>
</tr>
<tr>
<td>OD</td>
<td>optical density</td>
</tr>
<tr>
<td>PACS</td>
<td>picture archiving and communication system</td>
</tr>
<tr>
<td>PC</td>
<td>percentage correct scores</td>
</tr>
<tr>
<td>PLL</td>
<td>posterior longitudinal ligament</td>
</tr>
<tr>
<td>PMMA</td>
<td>polymethyl methacrylate</td>
</tr>
<tr>
<td>pps</td>
<td>pulses per second</td>
</tr>
<tr>
<td>PPV</td>
<td>positive predictive value</td>
</tr>
<tr>
<td>PSDL</td>
<td>primary standards dosimetry laboratory</td>
</tr>
<tr>
<td>QA</td>
<td>quality assurance</td>
</tr>
<tr>
<td>QC</td>
<td>quality control</td>
</tr>
<tr>
<td>RBE</td>
<td>relative biological effectiveness</td>
</tr>
<tr>
<td>RBM</td>
<td>red bone marrow</td>
</tr>
<tr>
<td>RDSR</td>
<td>radiation dose structured reports</td>
</tr>
<tr>
<td>RIS</td>
<td>radiology information system</td>
</tr>
<tr>
<td>RLs</td>
<td>reference levels</td>
</tr>
<tr>
<td>RLAT</td>
<td>right lateral</td>
</tr>
<tr>
<td>ROC</td>
<td>receiver operating characteristic</td>
</tr>
<tr>
<td>ROI</td>
<td>region of interest</td>
</tr>
<tr>
<td>RR</td>
<td>relative risk</td>
</tr>
<tr>
<td>SIR</td>
<td>Society of Interventional Radiology</td>
</tr>
<tr>
<td>SNR</td>
<td>signal-to-noise-ratio</td>
</tr>
<tr>
<td>SSDL</td>
<td>secondary standards dosimetry laboratory</td>
</tr>
<tr>
<td>STD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>STUK</td>
<td>Radiation and Nuclear Safety Authority</td>
</tr>
<tr>
<td>TC</td>
<td>tube current</td>
</tr>
<tr>
<td>TDR</td>
<td>total disk replacement</td>
</tr>
<tr>
<td>TLD</td>
<td>thermoluminescent detector</td>
</tr>
<tr>
<td>TN</td>
<td>true negative</td>
</tr>
<tr>
<td>TP</td>
<td>true positive</td>
</tr>
<tr>
<td>TPF</td>
<td>true positive fraction</td>
</tr>
<tr>
<td>TV</td>
<td>tube voltage</td>
</tr>
</tbody>
</table>
List of abbreviations

**UNSCER**: United Nations Scientific Committee on the Effects of Atomic Radiation  
**WFP**: weight fluoroscopy time product  
**WHO**: World Health Organization
1.1 Introduction

In this chapter, the problem, methodological approach and the research studies are outlined. The present thesis was developed to address a number of radiological protection issues related to certain fluoroscopically guided procedures performed at the neurosurgery operating theatre, in view of the fact that there has been general neglect of radiological protection considerations and insufficient training and awareness, resulting in increased risks to both medical staff and patients. Firstly, a survey was conducted to evaluate patient dose during cervical discectomy and fusion (CDF) procedures. Then, an experimental study simulating cervical spine surgery conditions is carried out, utilizing a polymethyl methacrylate (PMMA) phantom and the TOR 18FG test object, in order to optimize patient dose, image quality and figure of merit (FOM) with respect to patient size, simply by varying several technical parameters. A preliminary protocol was developed to help the neurosurgeons in the selection of the optimal settings of the fluoroscopy system according to the size of the patient to be treated. Subsequently, institutional (local) diagnostic reference levels (DRLs) and action levels (ALs) are estimated for both cervical and thoraco-lumbar interventions based on weight banding method and size correction method, in order to further optimize spine interventional procedures. Practical hints are also provided, in order to reduce both patient and staff doses during such procedures. Due to the lack of national DRLs, the latter values could contribute towards this direction and increasing neurosurgeons awareness regarding patient dose and radiation protection culture.
Chapter 1

Introduction

1.2 The problem

In recent years, an increasing number of interventional procedures, such as anterior cervical discectomy and fusion, cervical total disc replacement, transforaminal lumbar interbody fusion, lumbar discectomy and fusion, e.t.c., have been introduced into the field of neurosurgery [1-13]. They are considered as the standard treatment of various degenerative spinal pathologies and have been proven effective in structural rehabilitation of the spine [14-19]. Fluoroscopy is considered an effective technique for localizing the surgical level and assisting the correct placement of the appropriate instrumentation (cages, screws, plates, rods) [20-23]. In contrast to invasive open surgery, interventional procedures require only a small incision to be made for the introduction of instruments into the body - greatly reducing the risks of infections, complications, and recovery times. However, there has been a long discussion about the benefits and risks (stochastic or deterministic) arising from the intraoperative use of ionising radiation [8-13, 24, 25]. Thus, it is of critical importance to optimise these procedures aiming to get the best possible image quality while keeping the patient dose as low as reasonably achievable [26-34].

In general, most of these procedures are performed outside the imaging department by non-radiologist professionals, usually with insufficient knowledge training and awareness of radiation protection [35-37]. Additionally, these procedures are complex and surgeon-dependent, involving prolonged fluoroscopic exposures that may result not only to significant dose to the patient, but also to the medical staff and neurosurgeon [1-13, 38-106]. There are also a number of clinical situations where the X-ray beam is targeted at a fixed entrance surface area for a lengthy period throughout the procedure, increasing the risk for skin injuries [25]. These, combined with the increased number of interventions performed annually, multiple projections as well as repeat procedures pose questions that require documented responses regarding the detrimental effects of ionising radiation [8-13, 24, 25, 30, 107-109], especially when younger patients are involved and in cases where highly radiosensitive organs are inside the X-ray field. This can be achieved through patient dose recording and tracking which consist part of a quality assurance (QA) program [26-34, 110-113]. This is also prompted strong recommendations from scientific, medical, and legislative communities to encourage patient specific tracking of medical doses for inclusion in medical records [30-32].

Several quantities have been proposed so far in order to quantify the patient dose and the corresponding image quality. As far as the dose is concerned, a variety of tracking systems
have been developed to indirectly or directly quantify the organ and skin dose. These methods include the use of fluoroscopy time (FT), kerma area product (KAP), cumulative dose (CD) at the interventional reference point (IRP) included in the dosimetric report of the system and the use of thermoluminescent dosimeters (TLDs) and film dosimetry. FT is the simplest dose metric employed by fluoroscopy systems for clinical patient monitoring. However, it is also arguably the most inadequate indicator of patient dose, since it completely disregards the contribution of important dose parameters, such as radiation quality, dose rate, image acquisitions, beam’s entrance port and variations in patients’ size [114]. The KAP, is defined as the air-kerma integrated over the beam area and is directly measured with the use of a transmission ionization chamber mounted on the collimator housing or through a software using tabulated exposure parameters and collimator settings. It is closely related to the energy imparted to the patient and effective dose (ED) and is a better indicator of maximum skin dose than total FT; however this estimation is not straightforward, since fails to account for field non-uniformity effects, field size, altering of exposure parameters and projection angle during the procedure [114, 115]. An alternative approach to measure the incident air kerma (INAK) is the CD at the IRP [116], which is a point 15 cm from the isocentre towards the X-ray source. This value is derived from measurements obtained with a detector placed at the beam port. Both the KAP and CD values fail to account for the dynamic nature of fluoroscopically guided procedures and have allowable uncertainties of up to ±35% [114]. In situations where the exposure parameters are known, the INAK can be calculated directly from knowledge of these parameters and measurements of the X-ray tube output [117, 118]. TLD chips can provide a direct measure of entrance surface dose (ESD) under proper calibration and when applied prior to the procedure on the patient's skin, which makes difficult their practical application. Another way is to use a low sensitivity film, properly calibrated and positioned close to the patient’s skin. Film dosimetry can provide great spatial knowledge with regards to the dose distribution on the patient’s skin; however the optical density of this type of film saturates at a dose of about 1-2 Gy and thus it is not capable of determining the maximum skin dose in some cases [119, 120]. This can be overcome by using radiochromic film, the sensitivity of which is adequate even for high dose interventional procedures [121].

In most situations, it is not possible or practicable to measure organs’ absorbed dose directly. The estimation of the organs’ absorbed doses can be achieved with measurements using either anthropomorphic phantoms [8, 10-12, 122], or tabulated conversion coefficients
(CCs) that relate organ absorbed dose to readily measurable quantities, such as KAP, ESD, generated using Monte Carlo (MC) simulation methods [123]. In view of the fact that only a few studies provided dosimetric data for CDF procedures, this study focused to the reporting all the above mentioned quantities (FT, KAP, CD, ESD, ED), as well as thyroid absorbed dose which is the most radiosensitive organ inside the X-ray field. From the point of view of radiation protection, the calculation of KAP to organ’s absorbed dose CCs becomes even more important.

Regarding the image quality, signal to noise ratio (SNR), contrast to noise ratio (CNR) and high contrast spatial resolution (HCSR) are the most common physical quantities considered by the most of the authors [124-137]. These are directly related to operator selectable parameters (fluoroscopy mode, field of view (FOV), geometric magnification, exposure factors, focus skin distance and collimation). Nowadays, a lot of effort has been placed in finding the optimal settings of the fluoroscopy systems, in order to obtain clinically acceptable image quality while minimizing patient dose during the procedures with respect to the patient’s body size and clinical conditions. Evaluation of image quality could also be performed by means of observer performance studies utilizing phantoms containing objects for the measurement of physical characteristics, such as low-contrast detectability (LCD) and high contrast resolution (HCR). Experimental studies using simple test objects (such as TOR 18FG) and PMMA phantoms to simulate patients of different sizes are usually used towards this direction. In general, such phantoms are used for dose and quantitative image quality assessment, as well as for performance testing of the fluoroscopic equipment [124-151]. The characterization of the overall performance of a fluoroscopy system can be described by estimating a FOM, which combines image and dose indices during implementation of different operating modes [129-137]. However, only a few experimental data are available, considering the radiation dose and image quality indices during intraoperative fluoroscopy in spinal surgery [69, 106]. This makes the propose of a protocol maximizing the FOM values, with respect to the patient’s size even more important.

The concept of DRLs was introduced by the International Commission on Radiological Protection (ICRP) as a practical tool for optimisation of radiation protection for certain types of diagnostic examinations [152]. The radiation protection scheme used across the Europe (and worldwide) is based on the recommendations of the ICRP [24, 153, 154]. Some refinements were made to the medical use of radiation by recommending the use of DRLs for interventional procedures [155]. Achieving acceptable image quality consistent with the
medical task is the overriding clinical objective. DRLs are used to help manage the dose delivered to the patients so that the dose is commensurate with the clinical purpose. They should be used as an investigation level to identify unusually high dose levels. If they are consistently exceeded, a local review usually takes place. DRLs are not intended for regulatory purposes, nor do they represent a dose constraint, nor are they linked to limits or constraints [156]. The ICRP states [155] that it is not appropriate to set dose limits or constraints for patient exposures because the medical condition is invariably more significant than the potential for radiation harms arising from any justified examination. Instead, the ICRP recommends that justification of each procedure and dose optimization be used as the primary tools for radiation protection of the patient. Dose monitoring is implicit in the optimization task. Patient doses can only be successfully monitored if information is available on the magnitude and range of doses occurred in clinical practice, and DRLs are based on these data. Local practice can then be improved by comparison with the appropriate DRLs. Several authorized bodies have also provided guidance on monitoring patient dose and setting DRLs for both diagnostic and interventional procedures [156-161]. The Radiation Protection 109 document published by the European Commission (EC) document highlighting the importance of establishing DRLs for high-dose interventional procedures and recommends that they should be based on dose distributions measured in various types of hospitals, clinics and practices and not only in well-equipped hospitals [158]. The DRLs should represent the 75th percentile of the KAP values, since this dose metric offers the ability to monitor the entire examination without interfering with the patient and the procedure. On the other hand, overzealous dose reduction may lead to poor images and be detrimental to the clinical outcome. Low dose ALs can help to trigger investigation as to whether too poor images are been used [157]. However, the DRLs is somewhat different from reference Levels (RLs), which can either be defined taking into consideration the complexity of the procedure [157, 162-167] or with a dose audit approach [29, 168-170]. In order to obtain a reliable value of DRL for an interventional procedure, size-corrected or weight banded KAP distributions have to be used [168-171]. Also the EC has strengthened the importance of DRLs in the recently published Council Directive 2013/59/EURATOM [172], laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. According to this Directive, all member states shall ensure the establishment, regular review and use of DRLs for radiodiagnostic examinations, having regard to the recommended European DRLs where available. The use of DRLs generates
complementary information and thus supports professional judgment. The use of DRLs is important to promote the review of practice in local sites. The establishment of DRLs at local level should be implemented with the involvement of radiologists, radiographers and medical physicists and should be regularly reviewed to improve best practice at lower doses. In Greece, the Greek Atomic Energy Commission (GAEC) has recently published national DRLs including interventional cardiology procedures [173]. However, there is lack of reference data concerning spine interventions. In the literature, only a few DRL values dealing with spine interventions have been reported [174, 175]. Therefore, monitoring and reporting DRL and AL values regarding spine interventions is critical, since there is a substantial need to provide reference dose data in view of their increased usage, as well as optimization of radiation protection during such procedures.

1.3 Thesis originality

The originality of this thesis consists in:

- A survey to evaluate patient dose in terms of FT, KAP and CD, as well as ESD, thyroid or gonadal absorbed dose and ED during single or multilevel, cervical or thoraco-lumbar discectomy and fusion procedures.
- The calculation of total KAP to organ/tissue absorbed dose CCs, as well as for male and female patients undergoing CDF procedures, utilizing a MC based software, the CALDoseX 5.0.
- The investigation of the influence of operator-selectable parameters (fluoroscopy mode, FOV, geometric magnification) on patient dose and image quality in an experimental study simulating CDF procedures, aiming to propose an exposure protocol maximizing the quality of images while keeping patient dose as low as reasonably achievable, with respect to the patient’s size and clinical conditions.
- The evaluation of image quality in terms of subjective (LCD and HCR) and objective measurements (SNR, CNR, HCSR), under conditions simulating CDF procedures aiming to define a FOM for optimization purposes.
- The establishment of local DRLs and ALs for cervical and thoraco-lumbar interventions, utilizing the weight banding method and size correction method. These results could contribute in the effort to establish national reference levels and increase neurosurgeons awareness regarding radiation protection issues.
The investigation of the influence of anatomical, technical and clinical factors affecting the complexity of each procedure on the calculated reference levels.

The evaluation of the influence of patient’s body habitus and surgeon’s skills on radiation dose for both cervical and thoraco-lumbar interventions.

1.4 Publications

This work resulted in the following publications in international peer reviewed journals:


1.5 Thesis layout

The layout of this thesis has been built as following:

Theoretical information will be discussed during the next seven chapters. *Chapter 2* provides an overview to the functional anatomy of the spine with the discussion of some aspects concerning the most significant pathophysiological processes involved in cervical myelopathy, as well as on the main indications and techniques for its surgical management. *Chapter 3* describes the health effects arising from exposures to ionising radiation, as well as their place in assessing radiation-induced risk, setting radiation safety standards and applying principles and systems of radiation protection. *Chapter 4* is an introduction to the dosimetric quantities utilized in the study along with some background information that must be addressed when using these quantities, while the basic equipment required for the measurement of radiation, as well as some special requirements for its calibration are summarized in *Chapter 5*. The basic indices concerning image quality, along with
quantitative and qualitative methods for its evaluation are introduced in Chapter 6. Chapter 7 provides information on practical patient dosimetry issues along with the description of the methodology for both phantom and clinical measurements on patients accompanied by a discussion describing the appropriate dosimetric quantities and the equipment used. In chapter 8, the basic aspects for the optimization of radiation protection during interventional procedures are described, focusing on the use of DRLs and patient dose recording and tracking.

Some representative results of the studies carried out in the framework of this thesis are presented in the following three chapters. In chapter 9, dose to patients undergoing single or multilevel fluoroscopically guided CDF procedures is evaluated in terms of FT, KAP and CD, as well as ESD, thyroid absorbed dose and ED, utilizing a MC based software, the CALDoseX 5.0. CCs relating the mean organ/tissue absorbed doses to readily measurable KAP values were also estimated. Chapter 10 includes the results concerning the dosimetric and imaging performance of the fluoroscopy system both in terms of subjective (LCD and HCR) and objective measurements (SNR, CNR, HCSR), during an experimental study simulating cervical spine surgery conditions, utilizing a PMMA phantom and the TOR 18FG test object, in order to optimize patient dose, image quality and FOM with respect to ‘patient’ thickness, simply by varying the operator selectable parameters (fluoroscopy modes, FOVs and two geometric magnifications). In Chapter 11, institutional (local) DRLs and ALs in terms of FT, KAP and CD are reported both for cervical and thoraco-lumbar interventions, utilizing the weight banding method and the size correction method. The influence of complexity factors (anatomical, clinical and technical factors) on the reference levels was investigated. Patient ESD, ED, thyroid absorbed dose and gonadal dose were also estimated. The results of all three studies were compared to corresponding results reported in the literature, while discussion concerning their limitations is also included.

Finally, some additional discussion concerning the results produced during the course of this study, including the evaluation of the influence of surgeon’s skills and patient’s body habitus on radiation dose are being presented in Chapter 12, followed by some conclusions and practical recommendations for optimization of radiation protection as well as some suggestions for future work that could contribute further in the effort to optimize the specific procedures.
CHAPTER 2

CERVICAL MYELOPATHY:
PATHOPHYSIOLOGY AND TREATMENT

2.1 Introduction

The vertebral column is comprised of alternating vertebrae and intervertebral (IV) discs supported by robust spinal ligaments and muscles. All these elements (bony, cartilaginous, ligamentous and muscular) are essential to the structural integrity of the spine. The spine serves three vital functions: protecting the spinal cord and spinal nerves, transmitting the weight of the body, and providing a flexible axis for movements of the head and the torso. The vertebral column is capable of extension, flexion, lateral flexion, and rotation. The degree to which the spine is capable of these movements depending on the region. These regions are the cervical, thoracic, lumbar, and the sacroccocygeal spine and form four curvatures. Congenital defects and degenerative diseases can result in excessive, abnormal curvatures. A typical vertebra consists of two parts: the body and the vertebral (neural) arch. The vertebral body is located anteriorly and articulates with the adjacent IV discs. Together, the vertebral body and the arch form a central, vertebral foramen, and, collectively, the foramina create a vertebral canal, protecting the spinal cord.

Cervical myelopathy is a group of closely related disorders usually caused by spondylosis or by ossification of the posterior longitudinal ligament and is characterized by compression of the cervical spinal cord or nerve roots by varying degrees and number of levels. The decrease in diameter of the vertebral canal secondary to disc degeneration and osteophytes compresses the spinal cord and nerve roots at one or several levels, producing direct damage and often secondary ischemic changes.

Surgery is usually required for treatment of cervical myelopathy to decompress the structures, restore lordosis (inward curvature), and stabilize the spine. By addressing these problems, the associated neurological deficit may be halted. Decompression is achieved via
discectomy and subsequent removal of the osteophytes using a curettage technique. Preparation of end plates in a parallel fashion allows for gapless grafting of allograft bone for enhancement of fusion. A plate and screw system reinforces the construct. Multilevel cervical discectomy and fusion is especially useful in cases of spondylosis that have a kyphotic deformity (outward curvature) because, in addition to anterior decompression, it allows reconstruction of the spine to restore a lordotic curvature.

In this chapter, we will focus on the functional anatomy of the adult’s spine (vertebrae and IV discs), the most significant pathophysiological processes involved in cervical myelopathy as well as on the main indications and techniques for its surgical management.

### 2.2 Functional anatomy of the spine

The vertebral bodies consist of a shell of compact bone surrounding a core of trabecular bone and red marrow. Additionally, hyaline cartilage forms vertebral end plates on the superior and inferior surfaces of each body. The vertebral bodies, in conjunction with the IV discs, bear and transmit weight of the human body. Thus the vertebral bodies increase in size from the cervical to the lumbar region (Figure 2.1). However, as weight is transferred to the lower extremities via the sacrum, the vertebral bodies decrease in size [176].

The vertebral arch is located posterior to the vertebral body and consists of two pedicles and two laminae (Figure 2.2a). The superior and inferior notches of adjacent pedicles form the intervertebral foramina, which transmit the spinal nerves (Figures 2.2b). Disruption of these foramina (for example by a herniated disc) can compress the spinal nerves, resulting in both sensory and motor deficits. In addition to protecting the spinal cord and spinal nerves, the vertebral arch also has a number of processes that provide sites for muscle and ligament attachment. The spinous processes, located at the junction of the laminae, and the transverse processes, located at the pedicle-lamina junctions, provide attachment sites for ligaments as well as the erector spinae and transversospinalis muscle groups (Figure 2.2). The transverse processes articulate with the costal tubercles to form the costovertebral joints. The superior and the inferior articular processes of adjacent vertebrae interlock to form the zygapophysial (facet) joints (Figure 2.3). These joints permit gliding movements and their orientation significantly determines the ranges of motion that are possible between adjacent vertebrae [176].
The morphology and the functions of the vertebrae vary by region. The cervical spine is composed of seven vertebrae (Figure 2.1). The bodies are small, reflecting their relatively minor weight-bearing role, while transverse foramina are present for the passage of the vertebral arteries and veins. The articular facets on the superior and the inferior articular processes face superiorly and inferiorly, promoting flexion, extension, lateral flexion, and rotation at the cervical facet joints. This region also includes two particular elements, the C1 and C2 vertebrae. The C1 vertebra (atlas) lacks a body and spinous process. Instead, it supports two lateral masses joined by an anterior and a posterior vertebral arch. The superior articular facets of the atlas articulate with the occipital condyles of the skull to form the

Figure 2.1 Lateral view of the vertebral column, showing the spinal curvatures [176].
atlanto-occipital joints. These joints allow for flexion and extension of the head. The C2 vertebra (axis) features an odontoid process, which articulates with the anterior arch of the atlas to form the median atlanto-axial joint, while the facet joints between the C1 and C2 vertebrae form the lateral atlanto-axial joints. Together, these joints allow for rotation of the head.

![Figure 2.2](image-url) A typical human vertebra. A. superior and B. lateral view [176].

The 12 thoracic vertebrae are distinct in featuring lateral facets on their bodies and transverse processes. Typically, a thoracic vertebral body articulates with two costal heads, while the transverse process articulates with the tubercle of one of these ribs. Altogether these articulations form the costovertebral joints. These joints serve to elevate and depress the ribs, thus increasing the anterior-posterior and transverse diameters of the thoracic cavity during respiration. In the thoracic spine, the superior and inferior articular facets face anteriorly and posteriorly, permitting rotation and some lateral flexion. However, the orientation of these facets, as well as the inferiorly directed spinous processes and the costovertebral joints, severely restricts flexion and extension of the thoracic spine.

In contrast, the medially and laterally facing articular facets of the five lumbar vertebrae allow for a large flexion and extension, but restrict rotation. The lumbar vertebrae exhibit robust vertebral bodies and well-developed spinous, transverse, and superior articular processes providing attachment sites for ligaments as well as the erector spinae and transversospinalis muscle groups.

The sacrum is typically formed by the fusion of five sacral vertebrae (Figure 2.1). The sacral canal transmits the spinal roots of the cauda equina and ends at the sacral hiatus, an important landmark for administering a caudal epidural. In addition, four pairs of sacral foramina transmit the ventral and dorsal rami of the sacral spinal nerves. The sacrum plays
an important role in transmitting the weight of the body from the spine to the lower extremities. As a result, the sacroiliac joints are protected by extremely robust ligaments.

Similar to the sacrum, the coccyx is typically formed by the fusion of four coccygeal vertebrae (Figure 2.1). Although the coccyx is rudimentary in humans, it serves as a focal point for the attachment of the muscles of the pelvic floor as well as the sacrotuberous and sacrospinous ligaments [176].

Most of the vertebral bodies articulate superiorly and inferiorly with IV discs, forming secondary cartilaginous joints (symphyses) (Figure 2.3). However, an IV disc is not present between the atlas and the axis, and the sacral and coccygeal IV discs ossify progressively into adulthood. Representing up to 25% of the total length of the spine, the IV discs act as shock absorbers and enhance spinal flexibility, particularly in the cervical and lumbar regions. The IV discs are responsible for resisting compressive loads due to weight bearing as well as tensile and shearing stresses that arise from movements of the vertebral column, such as rotation and lateral flexion. The thoracic IV discs are relatively thin and uniform in shape, while the cervical and lumbar IV discs are wedge-shaped, contributing to the curvatures of the vertebral column. Each IV disc is composed of an outer fibrocartilaginous ring, the anulus fibrosus, and a central gelatinous core, the nucleus pulposus (Figure 2.3). Composed primarily of collagen fibers, the anulus fibrosus is characterized by a series of concentric layers (lamellae). The lamellae serve to resist the expansion of the nucleus pulposus during compression. The nucleus pulposus is composed of water, proteoglycans, and scattered collagen fibers [176].

Figure 2.3 Structure of the intervertebral disc [176].
The vertebrae and IV discs are stabilized by robust spinal ligaments which function to restrict movements and to minimize the need for continuous muscular contraction. The major spinal ligaments are illustrated in Figure 2.4. The broad anterior longitudinal ligament is situated on the anterior surface of the vertebral bodies and IV discs and extends from the sacrum to the occipital bone. This ligament prevents hyperextension of the spine and anterior herniation of the nucleus pulposus. The posterior longitudinal ligament is thinner compared to its counterpart. It lies within the vertebral canal, on the posterior surface of the vertebral bodies and IV discs. This ligament prevents hyperflexion of the vertebral column and posterior herniation of the nucleus pulposus. In fact, due to the presence of the posterior longitudinal ligament, the nucleus pulposus tends to herniate in a posterolateral direction.

![Figure 2.4 Lateral view of major ligaments of the spine, illustrating the ligamentum flava, supraspinous, interspinous, and anterior and posterior longitudinal ligaments [176].](image)

While the anterior and posterior longitudinal ligaments traverse the length of the spine, the ligamenta flava connect the laminae of adjacent vertebrae (Figure 2.4). These ligaments contribute to the posterior wall of the vertebral canal, helping to protect the spinal cord. The ligamenta flava are highly elastic. They support the normal curvatures of the spine, resist separation of the laminae during flexion, and assist in extending the spine from a flexed position. The vertebrae are also held together by the intertransverse and interspinous ligaments, which connect adjacent transverse and spinous processes, respectively. More superficially, the robust supraspinous ligament binds the spinous processes together. In the neck, the supraspinous ligament merges with the ligamentum nuchae, a fibroelastic structure that extends from the cervical spinous processes to the occiput, forming a midline raphe for muscle attachment. The intertransverse, interspinous, and supraspinous ligaments help to prevent hyperflexion and extreme lateral flexion of the vertebral column [176].
2.3 Pathophysiology of cervical myelopathy

Cervical myelopathy is the most serious condition of cervical spondylosis and is the most common cause of spinal cord dysfunction among those aged over 55 years [177]. This disorder was originally described by Stookey in 1928 and was attributed to compression of the cord by cartilaginous nodules of degenerated disc material [178]. It evolves from desiccation of the IV that leads to reduced disc height and bulging of the disc posteriorly into the spinal canal. The bulging disc may then calcify and, along with marginal osteophyte formation and uncovertebral spurring, narrow the spinal canal. The resultant foraminal and spinal canal stenosis produces radiculopathy and myelopathy, respectively [179, 180]. The symptoms and signs with which myelopathy patients present are dependent on the relative degree to which the posterior, dorsolateral and ventrolateral columns, the ventral horns, and the cervical nerve root of the spinal cord are involved [181]. In most cases, patients present with more than one of the aforementioned structures being affected [182]. These symptoms are due to impaired motor and sensory functionality. They include clumsiness of the hand, difficulty walking, impaired balance and coordination, and sensory complaints of numbness or tingling sensation in the hands and feet [183].

Although the exact pathophysiology underlying cervical myelopathy remains uncertain, it is largely accepted to be a disorder that involves compressive forces on the spine, likely due to multiple factors. Cervical cord compression can occur as a result of a disc herniation alone; degenerative changes that occur in the spine such as degeneration of the joints, intervertebral discs, ligaments, and connective tissue of the cervical vertebrae; and bone spur growth in the spinal canal (spondylosis). Posteriorly, infolding of the ligamentum flavum and facet joint capsule can create decreased space within the spinal canal and foraminal dimensions [184]. Conversely one is placed at increased risk for developing cervical cord compression and myelopathy as the space within the spinal canal narrows (stenosis).

The pathophysiology of cervical myelopathy involves static factors, which result in acquired or developmental stenosis of the cervical canal, and dynamic factors, which involve repetitive injury to the cervical cord. These mechanical factors in turn result in direct injury to neurons and glia as well as a secondary cascade of events including ischemia, excitotoxicity, and apoptosis (Table 2.1). Further research is required to elucidate the mechanisms underlying progressive cell death in cervical myelopathy. Indeed, the pathobiology of cervical myelopathy bears many similarities to traumatic spinal cord injury [176, 185]. With an increased understanding of the pathophysiological mechanisms involved
in cervical myelopathy, there will be improved reparative and regenerative strategies that can be developed to relieve spinal cord and nerve root compression [186].

Table 2.1 Pathophysiologic factors involved in cervical myelopathy [186].

<table>
<thead>
<tr>
<th>Static factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spondylosis</td>
</tr>
<tr>
<td>Disc degeneration</td>
</tr>
<tr>
<td>Ossification of the posterior longitudinal ligament</td>
</tr>
<tr>
<td>Ossification of the ligamentum flavum</td>
</tr>
<tr>
<td>Congenital stenosis</td>
</tr>
<tr>
<td>Other acquired compressive pathology (e.g., tumors and calcification)</td>
</tr>
<tr>
<td>Dynamic factors</td>
</tr>
<tr>
<td>Changes in neck flexion/extension, which narrow the cervical spinal canal dynamically and place increased strain and shear forces on the spinal cord</td>
</tr>
<tr>
<td>Biologic factors</td>
</tr>
<tr>
<td>Ischemic injury due to chronic compression of spinal cord vasculature</td>
</tr>
<tr>
<td>Glutamate-mediated excitotoxicity</td>
</tr>
<tr>
<td>Oligodendrocyte and neuronal apoptosis</td>
</tr>
</tbody>
</table>

2.4 Surgical management of cervical myelopathy

A variety of surgical techniques have been used to decompress the neural elements, restore lordosis, and stabilize the spine to prevent the evolution of the degeneration at the affected level. Surgery for cervical myelopathy has been performed by both posterior (laminectomy, laminoplasty) and anterior (multilevel discectomy, corpectomy) approaches, each with unique advantages and disadvantages [18].

Although the surgeon preference will necessarily be involved, some principles can also help in the selection of the appropriate approach. The location of the stenosis and the alignment of the cervical spine should be evaluated when selecting between an anterior and a posterior approach. If the compression is posterior and related primarily to facet hypertrophy or buckling of the ligamentum flavum, a posterior decompression should be considered [187]. The ligamentum infolding can also be corrected indirectly by restoring disc space height anteriorly; however, this factor alone is not weighted heavily when deciding on an approach. If the compression is from anterior osteophytes or disc herniations, an anterior approach through either multilevel discectomy or corpectomy offers the ability to decompress the spinal cord directly and should be considered [18].
Chapter 2  

Cervical myelopathy: pathophysiology and treatment

The alignment of the patient’s spine should also be considered. If the spine is lordotic, a posterior procedure can achieve an indirect decompression and may be an excellent alternative to anterior decompression. If the spine is kyphotic, however, a posterior approach may be contraindicated because the spinal cord cannot displace dorsally from the anterior compressive structures. In such cases, a ventral approach is indicated. A ventral approach not only allows direct decompression, but the proper use of intraoperative distraction often can also help to restore alignment. This cannot usually be accomplished by a posterior approach. If the patient’s spine is straight, either procedure can be used [188].

Other considerations when selecting the approach are the extent of the degenerative disease (the number of levels involved), the patient’s age and the overall medical condition. Anterior surgery is more prolonged, and patients with multiple levels will be more likely to have dysphagia and voice problems postoperatively. Therefore, for an older or unstable patient, posterior surgery may be preferable if the alignment is not kyphotic [18].

2.4.1 Multilevel cervical discectomy

2.4.1.1 Indications

Multilevel cervical discectomy is indicated for decompression of cervical myelopathy in cases in which the compressing pathology is located anterior to the spinal cord. An anterior approach provides the most direct access to central, broad-based disc herniations and large osteophytes at or adjacent to the level of the disc space. It also provides access in cases of segmental ossification of the posterior longitudinal ligament (PLL) in which the ligamental ossification is confined primarily to the disc space region and is not continuous or extending extensively behind the vertebral body [18].

Multilevel cervical discectomy has several advantages compared to single or multilevel corpectomies. It can achieve the goal of decompression as well as corpectomy when proper technique is used to remove the posterior osteophytic projection invading on the spinal canal and neural foramen. However, by sparing the vertebral bodies, multiple points of fixation exist, allowing for restoration of lordosis, which is maintained by the interbody grafting technique [189]. The spine is stabilized with an anterior cervical plate. In a multilevel cervical discectomy, the grafts are shorter than those used in a corpectomy. This may
increase the rate of fusion and avoid late failures by decreasing the distance across which fusion and bone replacement by creeping substitution must occur.

Multilevel cervical discectomy and fusion is especially indicated for patients with cervical spondylosis who do not have a lordotic spine. Posterior operations usually cannot restore lordosis and, if they do not, posterior decompression is not adequate to decompress a cord draped over the residual anterior osteophyte. Addressing the problem from the front also allows the surgeon to distract and restore disc height, which corrects the in-buckling of the elastic ligamentum flavum. A multilevel discectomy and fusion also provides multiple distraction points and therefore can restore lordosis more effectively than if a multilevel corpectomy approach is used. Lordosis is better achieved with interbody grafting, especially in comparison with a long, straight corpectomy graft such as fibular bone. The trade-off here is that removal of the osteophyte that extends behind the vertebral body is more difficult and time consuming when an interbody approach is used. However, the same degree of decompression as is achieved with a corpectomy can be reliably achieved using cervical discectomy [18].

2.4.1.2 Preparation and position of patient

A dose of antibiotics is given before the start of the operation. If direct laryngoscopy for intubation cannot be easily accomplished without hyperextension of the neck, which can worsen myelopathy, indirect techniques, such as fiberoptic intubation, should be used. The patient is positioned supine with the head of the bed elevated to place the neck above the heart level. This enhances venous drainage and reduces bleeding. The table is flexed so the patient does not slide down, and the legs are kept level to avoid venous pooling. Both arms are secured with tape starting at the shoulders and wrapped to the end of the hands. This results in steady traction to allow for consistent fluoroscopic visualization of the inferior end of the cervical spine.

The fluoroscopy system (C-arm) is positioned for lateral imaging of the cervical spine and left in place during the whole procedure. The surgeon stands alongside the patient at the level of the torso just caudal to the fluoroscopy system with the assistant surgeon on the opposite side. This geometry allows for instantaneous fluoroscopic images throughout any stage of the operation. The microscope base is positioned on the cranial side of the C-arm system and set up with a side observer tube rather than opposing viewing positions. Thus,
the surgeon and his assistant have access to the field at approximately a 45° angle to the sagittal plane for both the macroscopic and the microscopic stages of the operation.

2.4.1.3 Fluoroscopic exposure of the anterior cervical spine

Fluoroscopic exposure is used to identify the level for the surgical incision. A skin crease closest to the desired incision level is identified. A horizontal incision will allow access to multiple disc levels by opening the sternocleidomastoid fascia widely. The retractor system is then repositioned in order to access the specific levels. A vertical incision along the sternocleidomastoid can also be used in difficult necks, although this is not as cosmetic.

The skin is prepared and draped in the usual manner. Local anesthetic is used to infiltrate the skin. After the skin incision and dissection of the subcutaneous fat, a Weitlaner retractor is used to retract the skin incision. Then, the platysma is identified, elevated with a curved clamp, and incised with electrocautery. The sternocleidomastoid is identified, and the superficial cervical fascia along its medial border is sharply incised. Extending this opening of the fascia superiorly and inferiorly as far as possible is the key to adequate multilevel vertebral exposure. Blunt dissection is then performed in the natural tissue plane between the carotid sheath laterally and the esophagus and trachea medially down to the anterior spine.

The appropriate levels of the disc spaces are confirmed with the fluoroscopy system. The midline can be identified by reference to the medial edge of the two longus colli muscles. By marking the midline with monopolar cautery and reinforcing this with a marking pen above and below the extent of the anterior longitudinal ligament (ALL) that will be incised and retracted (Figure 2.5, A), it can be identified throughout the procedure. This will help proper positioning of the plate later in the operation.

An incision in the midline is then made with the monopolar cautery through the ALL down to the vertebral body. A periosteal elevator is then used to elevate the ALL and longus colli muscle subperiosteally from the middle of the vertebral bodies laterally to allow for placement of the retractor system (Figure 2.5, B). The mobilization of the longus colli muscle should extend over the majority of the vertebral bodies above and below the disc levels to be treated to allow for placement of the instrumentation. The ligament, muscle, and periosteum are elevated together over the entire anterior surface of the vertebral body. Care should be taken to minimize shredding of the periosteum, especially if it is adherent to anterior osteophytes that may be present.
Figure 2.5 (A) Anterior surface of the spine showing the midline marked in the ALL above and below the level of fusion. (B) The periosteum, anterior longitudinal ligament and longus colli structures are elevated with a Key periosteal elevator. (C) Self-retaining retractors are placed under the longus colli muscles, and the distractor is inserted over the distraction pins at the upper level in preparation for the decompression [18].

A Caspar retractor system using sharp-toothed blades of the shortest length possible is then inserted beneath the longus colli muscle on either side and opened to expand the working field further (Figure 2.5, C). Sharp-toothed blades will engage tightly into the preserved periosteum, longus colli and ALL layer and are less likely than blunter blades to slip and compress the trachea and esophagus medially and the carotid arteries laterally. Before the distraction pins are placed, the anterior osteophytes are removed using bone rongeurs or a high-speed drill. Lateral fluoroscopy is helpful in determining the extent of osteophyte removal down to the anterior margin of the vertebral body. The Caspar distraction posts are then placed under fluoroscopic guidance, aiming perpendicular to the posterior margin of the vertebral body and choosing a length to engage as much of the vertebra as can safely be achieved (Figure 2.6, top). The cranial distraction pins are usually positioned at the upper third of the vertebral body to be fused and the caudal pins are placed at the lower third of the vertebral body, thereby avoiding any overlap in the permanent screw positions. The pins will often not be parallel to one another because of the degeneration of the spine. After the disc space is emptied, cervical lordosis will be restored as distraction is applied (Figure 2.6, bottom).

The distraction pins is an important and powerful tool since their use increases disc space height (and hence access), as well as restores lordosis. The distraction posts also help retract the soft tissues at the edges of the incision, so it is not need to use cranial-caudal retractors. For extensive multilevel exposure, three posts are placed in order to treat two interspaces
including grafting, then move to the other interspaces, removing the initial posts and placing the remaining ones as needed.

**Figure 2.6** Distraction posts placement for a two-level procedure. The posts are placed above and below the midpoints of the respective vertebrae. They are placed perpendicular to the end plate and will not be parallel until distraction is applied (bottom) [18].

### 2.4.1.4 Removal of disc and preparation of end plates

The discectomy begins at the highest disc level to be addressed and proceed inferiorly. The distractor is placed over the post above and below the disc level, and distraction is applied. The disc annulus is incised in a rectangular fashion with a blade, and a pituitary rongeur is used to perform the initial discectomy. Angled curettes are then used to evacuate
the nucleus pulposus and remove the cartilaginous end plates. As the discectomy progresses, additional distraction is applied to maximize the restoration of lordosis and height of the disc space.

The end plates are flattened so that the later grafting can be done with a parallel-sided graft that will be in close apposition over its entire surface to achieve a “gapless” graft position. This involves shaping of vertebral end plates with a high-speed drill using magnified vision, with the operating microscope, as it provides superior visualization and illumination.

The superior end plate of the disc space is usually cup shaped (Figure 2.7, A). To flatten it, the anterior portion in front of the central depression is removed using repetitive side-to-side stroking movements of the drill to create a flat surface from one side of the vertebral body to the other. Once the anterior portion is flattened (Figure 2.7, C), we can often see residual cartilaginous end plate and we will remove it with a curette. The microscope is then positioned so that the field of view is coaxial with the end plate (Figure 2.7, H). This helps create the desired flat surface as protruding irregularities are easily seen and removed. The posterior part of the superior end plate of the disc space is then resected (Figure 2.7, D) as needed to flatten it down to the PLL. Again, gentle side-to-side sweeping movements of the drill are used.

The inferior surface of the disc space slopes cranially at its depth and have an upward curve at the lateral ends. Using the flattened superior end plate as a visual reference, the inferior end plate is shaped to be parallel to the superior from side to side, and then flattened to be parallel to the already flattened superior end plate. This involves resecting increasing amounts of bone as the resection proceeds into the depth of the interspace (Figure 2.7, E). Progress can be checked frequently with the fluoroscopy system, which aids in achieving perfectly flattened parallel end plates.

### 2.4.1.5 Decompression of the spinal canal and foramen

As the end plate recontouring is completed to the level of the PLL, a substantial portion of the osteophytic protrusion into the spinal canal will have been removed. The PLL provides protection for the neural elements. Light pressure with the drill will progressively thin down and remove the bone to the PLL. The end plates can then be undercut 1-2 mm with the drill to remove residual osteophytes behind the margins of the vertebrae (Figure 2.7, F).
Figure 2.7 Sequential steps in the multilevel discectomy and fusion procedure. (A) Initial view. (B) Anterior osteophyte removal. (C and D) Flattening of superior end plate of upper vertebra. (E) Contouring of inferior end plate to the superior vertebra. (F) Undercutting of marginal osteophyte. (G) Assessing end plates for parallelism with caliper and measuring dimensions for grafting. (H) View is obtained coaxial with the vertebra (*) rather than obliquely (#) to perfect end plate flattening. (I and J) Curetting residual osteophytes behind the vertebra. (K) Graft placement [18].
It is important that the vertebral bone removal be done to almost the full width of the interspace to resect the enlarged uncinate processes and uncinate spurs bilaterally. At the lateral margins of the interspace posteriorly, the drill is used to complete the removal of the disc and open the neural foramina laterally, in essence beginning an anterior foraminotomy, which will then be completed with curettage. We avoid downward pressure of the drill in this region to avoid additional pressure on the root that is exiting in an anterior oblique angulation through the foramen.

We then complete the removal of the osteophytes and the spinal canal decompression with curettage using a series of angled curettes. To complete the removal of the superior osteophytes (Figure 2.7, I) and for all of the inferior vertebral osteophyte removal (Figure 2.7, J), we use curettes with 90° angulation to minimize intrusion into the spinal canal. These curettes are available with three different “reaches” that is, increasing length from the shaft to the cup of the curette. These are used in sequence behind the inferior and superior vertebrae.

Once sufficient decompression has been achieved, hemostasis is obtained using Gelfoam slurry, which is placed in the disc space and tamponaded into the epidural space with a cottonoid patty. This is repeated as needed. This will usually stop bone bleeding as well, but any residual bony bleeding from the posterior vertebral body can be stopped using wax applied to the site with an angled Caspar periosteal elevator. Any excess wax is then removed. We try to avoid use of wax on the interbody surfaces because it may hinder fusion.

2.4.1.6 Graft selection and insertion

Many types of grafting material have been used in the interspace. Because the goal of grafting is to achieve a solid fusion to provide structural support, bone (allograft or autograft) is the ideal material. It is living bone that matches the strength and elasticity of the adjacent bone, responds to stress by becoming stronger, and is self-repairing [190]. Synthetic materials lack all of these properties. They may be a poor biomechanical match with the adjacent bone and, if too dense, may erode into the vertebral bodies. They may also stress-shield the adjacent graft and cannot repair themselves if damaged. Cages and similar devices by bone should be used. The use allografting avoids donor site problems and pain. Tricortical iliac crest allograft is an excellent biomechanical match that provides a cortical shell for support and a cancellous core for early incorporation. However, when used in a
two-level anterior cervical fusion without plating, had a significantly lower fusion rate of 37% as compared with 83% for autograft [191], and is more likely to collapse [192]. In addition, when used with anterior cervical plating, allograft results in a fusion rate equal to that of autograft [193] and superior to non-instrumented autograft fusions [194]. It is also important, to use allograft bone that has not been subjected to high-dose radiation, as this substantially weakens the graft [190]. Regardless of the material chosen, the graft should ideally fill most of the prepared interspace, which in the middle to lower cervical spine will typically be 18-22 mm wide and 14-18 mm deep.

The Caspar adjustable calipers are used to measure the height, width, and depth of the prepared disc space to determine the size of the graft. The graft depth is approximately 1-2 mm shorter than the measured depth of the interspace.

The tricortical graft is inserted with the cortical surface toward the anterior margin of the vertebral body and the noncorticated surface toward the dura mater and gently tapped into position. We pass a nerve hook bilaterally and palpate the back of the graft, checking with fluoroscopy to verify that it has not rotated and sits in good position. The distraction is then released. This process is repeated at each level. If the fusion involves more than two levels, we first complete the decompression and grafting of the upper levels and then remove the distraction pins at these levels and relocate the retractor to expose the lower levels. Once the decompression is completed at these levels, we complete our fusion with bone grafting placed first in the lowest disc space to allow a more generous graft at that level, which is exposed to the most stress. We then proceed with inserting the remaining bone grafts in a caudal to cranial direction.

2.4.1.7 Plating and screw placement

Many cervical plating systems are currently available. Dynamic plating systems do not restrict settling. They allow for true load sharing on the bone graft, because the forces working on the bone graft include the axial load from the weight of the head and the cervical muscle forces [195, 196]. These forces are maintained even when the grafts are partially absorbed as part of the normal bone-healing process. This axial loading seems to encourages faster and more complete bone incorporation and therefore a higher rate of fusion [197].

Before the start of plating, the distraction pins are removed and the pin holes are waxed for hemostasis. A plate that covers no more than half of the upper and lower vertebral bodies
to be fused is preferred. As settling occurs in the first month or two, this shorter plate will extend over a greater extent of these vertebral bodies but will be less likely to encroach over the adjoining disc spaces. The plate length and alignment are verified with fluoroscopy. Any residual anterior osteophytes are removed to allow the plate to sit flat on the anterior surface of the vertebrae. Any additional contouring of the plate that is needed is performed using the system’s benders to ensure that the plate lies flush against the anterior spine surface. The plate is then aligned using the previously placed midline markings, and temporary pins are placed at both ends to hold the plate in position.

The two most cranial screws are aimed upward and inward to increase holding strength and the most caudal screws are aimed downward and inward. A drill guide, which creates convergent trajectories for the screws, is used. The holes can be drilled or made with a starter awl, but in either case, it is best to use fluoroscopic control to optimize the position and angulation with the vertebrae. When unicortical screws are used, the drill or awl hole is usually placed to a 14-mm depth using the fixed-depth drill guide. The fluoroscopic image of the drill depth in the bone allows one to choose the best screw length, which typically ranges from 14 mm to 18 mm. These screws are self-tapping. When bone density is poor, bicortical screws are preferable for their greater pullout force. These are drilled with the adjustable-depth drill guide, which allows the depth to be increased in 0.5-mm increments. This allows the drilling to progress safely under fluoroscopic control until the posterior cortex is attained. The bicortical screws are blunt tipped and not self-tapping, so the pilot hole is also tapped under fluoroscopic control before they are placed. Rescue screws with a larger diameter are also available if the initial screw torque is suboptimal.

After all screws are in position, the locking mechanism of each screw is engaged to prevent back-out of the body or plate, while allowing axial settling to occur. The most recent version of this system uses self-locking screws. In the previous version, a locking tool engages the internal locking pin and pulls the pin up into the locked position. The temporary plating pins are then removed, and the holes are waxed for hemostasis as needed.

2.4.1.8 Closure

Before closure, the wound is irrigated copiously with antibiotic solution to clean out any debris, blood, or tissue fragments. The retractor system is removed one blade at a time. The longus colli is repositioned over the lateral edge of the plate. Using the handheld Cloward
retractor, each layer of tissue is inspected for bleeding or damage before closing with sutures. Once hemostasis is achieved, we close in several layers and usually do not use drains. The sternocleidomastoid muscle fascia is brought together with 2-0 Vicryl absorbable sutures and the platysma is reapproximated with 3-0 Vicryl sutures. The skin is closed with 4-0 Monocryl absorbable sutures using a subcuticular stitch and reinforced with benzoin and Steri-Strips.

2.4.2 Multilevel laminectomy and fusion

2.4.2.1 Indications for multilevel cervical laminectomy

For patients presenting cervical myelopathy, poor prognostic indicators and, therefore, absolute indications for surgery are: (1) progression of neurologic signs and symptoms; (2) presence of myelopathy for 6 months or longer; or (3) severe spinal cord compression, defined by a compression ratio approaching 0.4 or transverse spinal cord area of 40 square millimeters or less [180, 183, 198-204]. Under these circumstances, conservatively treated patients nearly always experience neurological deterioration [205], with surgical intervention being the most reliable method to prevent disease progression.

Factors that influence the surgical decision-making process include the extent of disease, location of compressive pathology, spinal alignment, and the presence of congenital canal stenosis (Table 2.2). For cases with anterior compression limited to one or two levels, fixed kyphotic deformity, and no significant developmental narrowing of the canal, an anterior or circumferential decompression and stabilization is preferred [201-203, 206-208]. On the other hand, patients with compression extending more than two levels, developmental narrowing of the canal, lordotic deformity, and primary posterior compressive pathology are candidates for the multilevel laminectomy [200, 209-215].

Table 2.2 Indications for anterior and posterior approaches for cervical myelopathy.
Among the aforementioned factors, appropriate assessment of the cervical alignment is the most important factor when determining if a multilevel laminectomy is appropriate. Benzel defines an “effective” cervical lordosis as the configuration where no dorsal component of C3 to C7 crosses a line from the posterior caudal corner of C2 to an identical point on C7. Associated with this line is a zone of uncertainty, where a surgeon’s bias and experience determine if the configuration is consistent with a lordosis or kyphosis. Others consider a configuration that falls into this “gray” zone as a “straightened” spine [216]. The decision to perform a multilevel laminectomy in the presence of a straight spine requires consideration of additional factors, such as the degree of canal encroachment. Dorsal migration of the spinal cord away from ventral pathology may be insufficient with a straight cervical spine. Limits of ventral encroachment have been suggested, but no definitive value exists. Hamanishi and Tanaka considered a minimum lordosis of 10° required for adequate dorsal migration of the spinal cord [217]. Yamazaki et al observed ventral compression after posterior decompression when the lordosis was less than 10 degrees and the extent of ventral canal encroachment exceeded 7 mm in patients presenting with ossification of the posterior longitudinal ligament [218]. Under these questionable circumstances, the decision often rests on the surgeon’s clinical experience and procedural bias as there are no defined standards of treatment. After the decision has been made to perform a multilevel laminectomy, the surgeon must then decide whether the addition of a posterior cervical fusion is indicated.

### 2.4.2.2 Indications for posterior cervical fusion

The primary surgical goals when performing a posterior cervical stabilization and fusion include restoring stability, maintaining alignment, providing stability until fusion has matured, and alleviation of pain. These constructs provide stability by reinforcing the posterior tension band that is compromised by the pathologic process or surgical decompression. Determining the presence and extent of instability rests on careful assessment of both static and dynamic imaging. There have been numerous models and definitions created in an attempt to identify and quantify spinal instability [219, 220]. Although these models provide a foundation for operative decision making, each has limitations and cannot be universally applied to all clinical situations. From a practical standpoint, the presence of instability must be determined on an individual basis. Findings on radiographs that are suggestive of instability include: subluxation of more than 3.5 mm
and 4 mm on static lateral radiographs and dynamic views respectively, as well as more than 11 degrees of angulation between adjacent segments [221]. Under these circumstances a posterior decompression without stabilization is likely to lead to a progressive deformity that will require intervention at a future date.

Although not an absolute indication for supplemental posterior stabilization, the presence of a straight cervical spine should alert the surgeon to an increased potential for a postlaminectomy kyphosis. The extent of decompression may prove more significant under these circumstances, and has been correlated to postoperative spinal instability, deformity progression, accelerated spondylotic changes, and constriction of the dura mater by formation of extradural scar tissue [199, 204, 209-211, 215, 222-224]. In vitro studies have demonstrated significant mobility and potential for postoperative instability with the resection of 50% of the facet complex [225, 226]. Age has also been correlated to the development of a postlaminectomy kyphosis, requiring the surgeon to consider a stabilization when performing a multilevel decompression in a younger patient [227-229].

2.4.2.3 Contraindications for the posterior approach

Specific to the posterior approach, the presence of a fixed kyphotic deformity is an absolute contraindication when considering a multilevel laminectomy, even with the inclusion of a posterior cervical arthrodesis. These patients often require a circumferential approach to adequately decompress the neural elements, stabilize the spine, and optimize sagittal balance. A similar approach may be considered for patients with severe osteoporosis, who require 360 degree stabilization to prevent construct failure. Chronic injury to the spinal cord, as demonstrated on preoperative magnetic resonance imaging, is also considered a contraindication. Imaging characteristics consistent with intramedullary cystic necrosis, syrinx formation, or myelomalacia indicate permanent cord injury that is unlikely to improve with operative intervention [230].

Relative contraindications, not specific to the posterior approach, include a history of significant medical comorbidity, such as older age (> 70 years), diabetes, coronary disease, obstructive pulmonary disease, peripheral vascular disease, stroke, and social history of tobacco use or alcoholism [231-233]. Under these circumstances the risks of operative intervention often outweigh the benefits, particularly if there is no chance of neurologic recovery.
2.4.2.4 Patient positioning - Operative set-up

During the induction of general anesthesia the natural protective mechanisms resisting neck motion are inhibited, allowing unrestricted cervical manipulation that could result in spinal cord injury. Accurate blood pressure monitoring is required to avoid hypotension that could result in spinal cord ischemia or myocardial infarction. Before patient positioning, basic electrophysiological monitoring, including somatosensory evoked potentials, motor evoked potentials, and electromyography, is obtained, particularly for patients with severe cord compression. Although the value of electrophysiological monitoring is debatable, it can provide useful information during reversible maneuvers, such as patient positioning [234-236].

The patient is positioned prone with the arms tucked at the sides and appropriate padding to prevent pressure neuropathies. A Mayfield head holder or tongs with traction are used to secure the head. A neutral position is preferred because prolonged periods in either a flexed or extended posture may not be tolerated, especially in the presence of severe spinal cord compression. A second traction line is set up to extend the neck and maximize lordosis once neurologic decompression is achieved. After final positioning, repeat electrophysiological monitoring is performed. If a change is identified, factors that may affect potentials such as anesthetics or alterations in blood pressure should be verified and corrected. Neck position should be rechecked and returned to a more neutral position. Intraoperative fluoroscopic imaging is useful to verify cervical alignment after final positioning and confirm spinal level during the operative procedure. Also alignment may be rechecked during the procedure to optimize sagittal balance before any stabilization is performed.

2.4.2.5 Multilevel laminectomy

Once the patient is positioned and skin localization confirmed, a midline incision in the spine performed. Maintaining a midline approach in the avascular fascial plane will help decrease blood loss and minimize postoperative pain. The paraspinal muscles are elevated in a subperiosteal fashion using monopolar cautery. Dissection of the facet joints is completed if an arthrodesis is intended. Care is taken not to disrupt the facet capsule of uninvolved adjacent segments or if only a laminectomy is intended. Localization can be performed with anatomic landmarks, such as the prominent C2 spinous process, but confirmation with intraoperative imaging is recommended.
Resection of the lamina en bloc is the preferred approach. If required, keyhole foraminotomies are performed before resection of the lamina so that the lamina can act as a protective barrier during drilling of the foramen. The en bloc resection tends to be less time-consuming and avoids the insertion of any instrument into the central canal before the decompression. Using a high-speed drill equipped with small round burr, troughs are drilled bilaterally at the lamina-facet junction. The drill is held perpendicular to the dorsal surface of the lamina to provide the shortest route to the canal and avoid drilling of the lateral mass (Figure 2.8). Drilling initially passes through the dorsal cortex followed by the soft cancellous core, and finally the dense ventral cortex of the lamina. Bleeding from the medial wall of the trough is easily controlled with wax. Although a diamond bit may be used, this tends to slow the process and generate more heat. Regardless of the drill bit used, continuous irrigation is recommended to avoid thermal injury. The rostral aspect of the lamina tends to dive deep and requires more extensive drilling to completely disarticulate the lamina. Entry into the epidural space is confirmed with gentle palpation with either the drill bit or nerve hook. The ventral cortex may also be resected by inserting a small footplated rongeur into the trough.

Figure 2.8 The en bloc laminectomy approach avoids placement of instruments into the central canal before the decompression. Bilateral troughs are drilled at the lamina-facet junction with the drill bit oriented perpendicular to the dorsal surface of the lamina to avoid violation of the lateral mass [237].
Once the bony troughs are completed, the spinous processes at the rostral and caudal extremes of the decompression are elevated with clamps and the ligamentous attachments of the ligamentum flavum within the troughs are stripped with rongeurs. Epidural bleeding encountered is easily controlled with bipolar cautery and gelfoam. Symmetric elevation of the lamina is required to avoid levering the bone into the spinal canal (Figure 2.9). Once all ligamentous attachments are resected, the entire complex is removed. The underlying dura is inspected and epidural bleeding controlled. If no fusion is intended, a hemovac drain is placed to prevent postoperative hematoma and a multilayer closure is performed. The hemovac drain is typically removed within 24 hours of the operation. Patients may be placed in a soft cervical collar for several weeks.

Figure 2.9 The lamina and spinous processes are resected en bloc making sure the rostral and caudal ends are simultaneously elevated to avoid levering into the spinal canal. Curettes or rongeurs are inserted into the troughs to release any ligamentous tissue tethering the lamina [237].

2.4.2.6 Posterior cervical stabilization and fusion

The earliest attempts at stabilizing the subaxial cervical spine involved the placement of autologous bone along the posterior elements; however, this approach lacked immediate stability and required prolonged periods of immobilization. Wiring techniques were first
described in 1891 by Hadra [238], and since that time a variety of posterior wiring techniques have been developed that have demonstrated acceptable fusion potential with relatively low complication rates [239-243]. Postlaminectomy wiring techniques required the wire to be passed between adjacent facets or tied to either bone grafts or metallic rods (Figure 2.10) [244, 245]. Although facet wiring techniques have largely been replaced by more rigid, newer generation constructs, wiring continues to be a viable option.

Over the last several decades the emergence of lateral mass fixation has become the stabilization technique of choice [246-250]. Lateral mass fixation has proven to be a safe and biomechanically superior technique when compared with wiring procedures. Gill et al. demonstrated the increased rigidity and fusion potential with lateral mass fixation compared with posterior wiring techniques [251]. The intrinsic strength of the lateral mass screw provides immediate stabilization, allowing early mobilization and possibly eliminating the need for external bracing. The placement of cervical pedicle screws has also been described, demonstrating superior fixation when compared with lateral mass and anterior plating techniques [252]. Despite the biomechanical rationale for inserting cervical pedicle screws, this technique is not routinely practiced because of the technical demands and the potential neurovascular complications [253].
2.4.2.7 Lateral mass fixation

Fixation to the lateral masses has evolved from early generation screw-plate constructs to more versatile multiaxial screw-rod constructs. Plating systems were generally unyielding because of the predetermined position of the screw hole within the plate. These constructs could not adapt well to variations in the patient’s anatomy, instead the patient’s anatomy was forced to conform to the construct. Because of the rigidity of the plate in the coronal plane, all screws had to be positioned in line. In addition, points of fixation were sacrificed if the plate hole did not match the entry site within the lateral mass (Figure 2.11). Due to the dynamic interface between the screw and plate, bicortical screw purchase is required to obtain maximal stability [254]. Surface area for fusion formation was compromised because the plate was positioned flush against the dorsal wall of the lateral mass. Finally, revision surgery required removal of all the screws in order to disengage the plate. These deficiencies have largely been overcome with the evolution of multi-axial screw rod constructs [249].

Figure 2.11 A radiograph demonstrating how plate constructs have a limited ability to conform to the surgical anatomy. The right sided screw hole second from the top is positioned over the facet joint, eliminating the possibility for screw placement [237].
Various lateral mass screw insertion techniques have been described in the literature (Figure 2.12). The Roy-Camille technique uses the midpoint of the lateral mass as the insertion site and directs the screw without any rostral or caudal angulation and 10° laterally [255]. Jeanneret and Magerl describe a starting point 1 to 2 mm medial and superior to the midpoint of the lateral mass with the trajectory aimed 30° superior and 15 to 25° lateral [256]. An et al recommended a starting point 1 mm medial to the lateral mass center and angled 15° cranial and 30° lateral [257]. Finally, Anderson et al. modified the Magerl technique with a starting point 1 mm medial to the lateral mass center and aimed 20 to 30° cranially and 10 to 20° laterally [258]. These trajectories are intended for placement of screws into the lateral masses of C3 to C6.

Figure 2.12 The entry site for the screw with the Roy-Camille method is the midpoint of the lateral mass, perpendicular to the dorsal cortex in the sagittal plane. The screw is directed laterally by 10°. Using the Magerl technique the screw entry site is located slightly medial and cranial to the midpoint of the lateral mass. The screw trajectory is parallel to the facet joint in the sagittal plane and directed 25° laterally in the transverse plane. The entry site for the Anderson technique is located approximately 1 mm medial to the lateral mass midpoint with a rostral angulation of 30-40° and a lateral angle of 10°. The An technique uses an entry site similar to the Anderson technique but only 15° of rostral angulation and a lateral angulation of 30° [237].
Several studies have investigated the biomechanical characteristics and anatomic relationships of the various lateral mass screw techniques [259-262]. Montesano et al demonstrated 40% greater pullout strength when screws were placed using the Magerl than with Roy-Camille technique [261]. From a clinical perspective, however, there has been no difference in the complication rate between the different techniques [260]. Bicortical purchase of the lateral mass is associated with greater complications without a clear biomechanical advantage [262, 263]. The measurement of exact angles for screw placement is impractical, and a trajectory with a bias in the medial to lateral direction with a rostral angulation starting close to the lateral mass midpoint will create an appropriate screw trajectory (Figure 2.13). The surgeon needs to develop a clear understanding of the anatomy, perform an appropriate exposure, and study preoperative imaging in order to obtain the optimal screw insertion.

Figure 2.13 The general trajectory required for safe lateral mass screw placement. A lateral trajectory directs the screw away from the transverse foramen and vertebral artery, while the rostral angle avoids the nerve root traversing deep to the superior facet of the caudal spinal segment. Bone volume is sufficient with this trajectory to enhance screw purchase [237].

Exposure for lateral mass fixation requires soft-tissue dissection to be extended until the far lateral margin of the facet is identified. To avoid compromise of uninvolved segments, care must be taken to maintain the facet capsule at the rostral and caudal extremes of the intended fusion. Lateral mass landmarks must be clearly identified for appropriate placement of screws. The medial border is defined by the valley at the lamina-lateral mass junction. The rostral and caudal boundaries are defined by the adjacent facet joints. Although the
relationship of the vertebral artery and nerve root to the subaxial lateral masses is generally consistent, appropriate screw placement requires a detailed understanding of these anatomical relationships. The vertebral artery lies anterior to the lamina-lateral mass junction whereas the nerve root passes anterolaterally, deep to the caudal superior facet.

Once the soft-tissue exposure is completed, entry sites for the lateral screws are marked by scoring the dorsal cortical wall with a high-speed drill. This site is typically in close proximity to the midpoint of the lateral mass. The drill bit is placed into the entry site, perpendicular to the dorsal cortex. Once the bit engages the bone, the trajectory is altered aiming from the infero-medial quadrant toward the supero-lateral quadrant, away from the nerve root and vertebral artery. Resection of the spinous processes may be necessary to obtain the optimal trajectory (Figure 2.14).

![Figure 2.14 Lamina are left intact during drilling of the lateral masses to act as a protective barrier. The prominent spinous processes can obstruct the trajectory for appropriate lateral mass drilling; therefore resection will allow the optimal screw trajectory. Once drilling of the lateral masses is completed, the lamina is resected](image)

Laminectomies are performed only after the holes are drilled to protect the dura and neural elements. Once completed, the screw holes may be tapped and filled with bone wax to prevent excessive bleeding. The lamina is then resected with the en bloc technique. If a fusion is performed, all bone resected is saved as autograft. Lateral mass screws are inserted into the predrilled holes aiming in a supero-lateral direction (Figure 2.15). Malleable rods are cut and contoured, and locking mechanisms are engaged. Rods should be contoured so that
significant force is not required to seat the rod within the screw. The posterolateral spine, including the facet joints, is decorticated and the grafting material is impacted across the spine and into the facet joints (Figure 2.16). Closure is performed in the same manner as for an isolated laminectomy.

Figure 2.15 Once the decompression is completed, the lateral mass screws are inserted with a rostral and lateral angulation with respect to the lateral mass. The computed tomographic image demonstrates appropriately placed screws and their relationship to the transverse foramen [237].

Figure 2.16 The final stabilization construct is depicted in the schematic and intraoperative photograph. The lateral masses and facet joints are decorticated and the bone graft impacted along these surfaces. To enhance stability, the newer generation screw-rod constructs allow insertion of cross-links to create a rectangular construct. Placing bone graft along the exposed dural surfaces, especially along a decompressed nerve root, should be avoided to prevent the possibility of recurrent stenosis [237].
2.4.2.8 Cervical pedicle screws

Specific indications for cervical pedicle screws have not been defined. With the exception of C7, the placement of subaxial cervical pedicle screws is not routinely performed due to the potential for catastrophic neurovascular injury, morphologic characteristics and variation of the cervical pedicles [264], the technical difficulty involved with insertion, and the lack of clinical data supporting the superiority of cervical pedicle screws over lateral mass screws. Despite the technical difficulties, placement of cervical pedicle screws may serve as a pragmatic solution under unusual circumstances where lateral mass fixation cannot be achieved. In animal and cadaveric biomechanical studies, the placement of cervical pedicle screws has demonstrated superior stability, fixation, and reduction potential when compared with lateral mass fixation [252, 265].

In vitro studies have demonstrated an unacceptable potential for injury when depending only on anatomic topography for the placement of cervical pedicle screws [266, 267]. The inability for accurate insertion based on visualized anatomic landmarks is primarily due to the inherent morphologic variability of the cervical pedicle trajectories and the minimal margin of error allowed for appropriate screw placement (Figure 2.17). Increased accuracy has been observed with direct exposure of the pedicle through a laminoforaminotomy and the addition of computer-assisted navigational techniques [266-268]. Even with a laminoforaminotomy, in vitro studies have demonstrated a 39.6% incidence of critical damage, with possible nerve root or vertebral artery injury [253].

Abumi et al have published extensively on the placement of cervical pedicle screws [253, 269-273]. They chose an entry site just lateral to the midpoint of the lateral mass in close proximity to the posterior edge of the superior articular surface. The cortical bone is drilled away to expose the dorsal cancellous bone of the pedicle. Trajectory through the pedicle is created with a hand-held probe with a lateral to medial inclination ranging from 25 to 45°. Cannulation of the pedicle is performed with realtime fluoroscopic imaging to supplement tactile feedback. Using this technique, Abumi and colleagues reported rates of pedicle violation ranging from 5.3% to 6.9%; however, no injury to the vertebral artery was observed. Using the same technique, Ludwig et al [274] reported a 12% rate of critical injury to the vertebral artery, nerve root, or spinal cord in a cadaveric model.
Figure 2.17 The trajectories required for appropriate cervical pedicle screw placement in both the sagittal and axial planes. A steep lateral to medial inclination and the significant variability of the pedicle trajectory make the insertion of cervical pedicle screws technically demanding. Potential for neurovascular injury exists because of the proximity of the vertebral artery, nerve root, and spinal cord [237].

Based on the available literature, it seems that successful placement of cervical pedicle screws not only requires a comprehensive understanding of the three-dimensional pedicle anatomy and the surrounding neurovascular tissues, but also requires supplementation with direct visualization of the pedicle or utilization of advanced navigational techniques. Despite these maneuvers, considerable risks remain and more conventional methods of posterior cervical stabilization should strongly be considered before the placement of these implants.
3.1 Introduction

Exposure of the human body to ionising radiation may lead in both acute (short term) and long term health effects. The estimation of radiation doses received by exposed persons is important for developing dose-response relationships for these effects, which constitute the baseline for risk assessment. By extrapolating such relationships may be used over broader dose ranges compared to those for which data are available, specifically in the low dose range, which is of significant importance for radiological protection during diagnostic or interventional radiology procedures. For assessing radiation doses from external exposures to ionising radiation as well as the associated risk, application specific quantities have been established by the International Commission on Radiological Protection (ICRP) [24, 153, 154] and by the International Commission on Radiation Units and Measurements (ICRU) [275-278]. The basic dosimetric quantities approved by the ICRP are based on the measurement of the energy imparted to organs and tissues of the human body. Radiological protection deals with managing exposures to ionising radiation so that acute damage is avoided and the risk of long term health effects is restricted to acceptable levels.

The development of health effects induced by ionising radiation begins with energy absorption in tissues, leading to ionizations with molecular changes that can occur in groups, for example, in the genetic material of the cells, the DNA in the cell nucleus. Other interactions that may also contribute in understanding the tissue response to ionising radiation include communication between cells, called “bystander effect” and may promote the transmission of genomic instability. However, there are insufficient data that such effect contributes to the carcinogenesis in humans at low doses [279]. At higher doses, short term effects to organs and tissues mainly arise as a result of cell killing and in extreme cases, such as accidental exposures, can cause death of the exposed individual. This type of effects is
called “tissue reactions” in ICRP 103 [24] having previously been termed non-stochastic effects in ICRP 26 [154] and deterministic effects in ICRP 60 [153]. At lower doses or dose rates these effects are usually not perceived, but damage to the genetic material may occur that can result in an increase of cancer risk many years later or hereditary disease in future generations. Such effects continue to be called stochastic since the probability of their occurrence, but not their severity, is increased with increasing dose [24].

In this chapter, health effects arising from exposures to ionising radiations, their evolution during the years in the light of new scientific data, as well as their place in assessing radiation-induced cancer risk, setting radiation safety standards and applying principles and systems of radiation protection are discussed.

3.2 Classification of radiation qualities in radiological protection

For radiation protection purposes, the physical quantity used to define the quality of a radiation beam is the linear energy transfer (LET). The LET focuses on the energy absorbed (with linear rate) inside the medium as the charged particle traverses the medium, while the stopping power focuses on the energy loss by a charged particle as moving through the absorbing medium.

LET is defined as follows [278]:

“LET of charged particles in a medium is the quotient dE/dl, where dE is the average energy locally imparted to the medium by a charged particle of specified energy in traversing a distance of dl.”

X-rays and gamma rays are low-LET radiations, while neutrons, protons and heavy charged particles are high-LET radiations.

3.3 Health effects

The biological effects of radiation can be classified in two categories: somatic (may occur in the exposed individuals) or genetic effects (may occur in their descendants) [280].
3.3.1 Somatic and genetic effects

The somatic effects are divided into deterministic effects and stochastic effects, while the genetic effects are of stochastic nature only.

- Somatic effects are the possible development of radiation induced cancer, sterility, cataracts and life shortening that occur in the exposed individuals.
- Genetic or hereditary effects are the detrimental effects that can occur in the descendants of the exposed individual due to the radiation induced mutations to the genes and DNA of the genetic cells.

Radiological protection in the dose range occurs in diagnostic and interventional radiology mainly deals with the protection against radiation-induced cancer and hereditary disease. These are exclusively late effects since may be expressed many years after radiation exposure [280].

3.3.2 Stochastic effects

Exposure of the human body to ionising radiation, even at low doses such that occur in diagnostic and interventional radiology, may result to damage of the genetic material in cells that can lead in radiation-induced carcinogenesis many years later, genetic disorders in future generations and some developmental effects under specific conditions [281]. These diseases are called stochastic effects, due to their probabilistic nature and may be epidemiologically detectable in a population. It is assumed that any exposure to ionising radiation is liable to cause such an effect, with no threshold in dose received. It is reported by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2000 [282] that "studies on DNA repair and the cellular/molecular processes of radiation tumorigenesis provide no good reason to assume that there will be a low-dose threshold for the induction of tumours in general". Hereditary disease due to exposure to ionising radiation has not been demonstrated in humans, but animal studies have showed significant evidence of heritable damage to germ cells. For both radiation-induced carcinogenesis and hereditary disease it is the probability of their occurrence, not the severity, that depends on the dose. They may ensue if irradiated cells are modified rather than killed. For radiological protection purposes, it is assumed that the risk for stochastic effects increases with dose, with no threshold. A linear non threshold (LNT) dose response model is used for the assessment of radiation-induced cancer and hereditary disease. Since it
is not possible to prevent them, exposure limits are set, in order reduce their occurrence to an acceptable frequency and avoid unacceptable levels of risk. There are also substantial differences in radiosensitivity among the organs and tissues of the body. Thyroid in children, the female breast, gonads and the red bone marrow have a relatively high sensitivity for the development of solid cancers and leukaemia whereas the muscle and connective tissue have a relatively low sensitivity.

The ICRP has defined the quantity effective dose [24, 153] in order to evaluate doses from external or internal exposures on a routine basis. In the estimation of effective dose, radiation weighting factors, \( w_R \), are used to reflect the variation in biological effectiveness of different radiations, as well as tissue weighting factors, \( w_T \), to reflect the variability in radiation sensitivity of different tissues for the induction of stochastic effects. However, other factors such as gender, age and individual sensitivity may influence the individual risk but are not taken into account in the dosimetric quantities.

The concept of radiation detriment, as recommended by the ICRP, consists of the following components: the fatal cancer risk attributable to radiation exposure, expected life lost, morbidity from non-fatal cancer, and severe hereditary effects [24, 153]. These aspects make undesirable to choose a single quantity in order to represent the radiation detriment following an exposure.

### 3.3.3 Tissue reactions

At doses above 0.5-1 Gy, related mainly with accidental situations, tissue reactions (previously called deterministic effects) (e.g. skin injuries or hair loss) may occur if exposures exceed the threshold doses for such effects within a relatively short period of time after exposure. Tissue reactions arise from the impairment of the integrity and function of organs and tissues and clinically perceptible damage occurs above the threshold dose. Most organs or tissues of the human body are not affected by the loss of a few cells, but, if the number of cells lost is considerably large, there is remarkable damage and, hence, loss of organ/tissue functions. The dose thresholds vary with the quality of the radiation and the extent as well as the severity of these effects increases proportional to the dose or dose rate above these values.

The radiation injury varies from one tissue or organ to another depending on cellular radiosensitivity, the function of differentiated cells, cellular composition and cell renewal capacity. However, the loss of reproductive capacity of the cells, development of fibrotic
changes and cell death are the main processes that determine the pathogenesis in most tissue reactions. The most sensitive tissues, with respect to early tissue reactions, include rapidly proliferating cell systems such as hematopoietic tissue, the cells covering the inside surface of the gastrointestinal tract, the basal cell layer in the skin, and the male germ cells. For example early skin reaction may occur a few hours or days after exposure. On the other hand, late tissue reactions depend partially on damage to the blood vessels or connective tissue elements that are essential for the proper functioning of all organs and tissues as well as of the lens of eye. Such effects can be expressed several months or even years after radiation exposure.

High-LET radiation (neutrons and alpha particles), causes more biological damage per unit of absorbed dose than low-LET radiation. Values of relative biological effectiveness (RBE) for tissue reactions for high-LET in comparison with low-LET radiations were provided in ICRP 58 [283]. Generally, the RBE values for tissue reactions were found to be lower than those for stochastic effects and to vary with the tissue damage described.

The implementation of the radiation weighting factor, $w_R$, developed from RBE values for stochastic effects after exposure to high-LET radiations would lead in an overestimation of the likely occurrence as well as the severity of any tissue reaction. When assessing the potential for these reactions, the average absorbed dose to the organ or tissue, weighted by a suitable RBE value with respect to the type of radiation, should therefore be used. These RBE values may vary for different biological endpoints and different tissues or organs.

**Table 3.1 Radiation induced skin reactions after a single exposure [284].**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Acute exposure threshold (Gy)</th>
<th>Onset</th>
<th>Peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary epilation</td>
<td>3</td>
<td>~3 weeks</td>
<td></td>
</tr>
<tr>
<td>Permanent epilation</td>
<td>7</td>
<td>~3 weeks</td>
<td></td>
</tr>
<tr>
<td>Early transient</td>
<td>2</td>
<td>~ hours</td>
<td>~24 h</td>
</tr>
<tr>
<td>Erythema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main erythema</td>
<td>6</td>
<td>~10 d</td>
<td>~2 weeks</td>
</tr>
<tr>
<td>Dry desquamation</td>
<td>10</td>
<td>~4 weeks</td>
<td>~5 weeks</td>
</tr>
<tr>
<td>Moist desquamation</td>
<td>15</td>
<td>~4 weeks</td>
<td>~5 weeks</td>
</tr>
<tr>
<td>Secondary ulceration</td>
<td>20</td>
<td>&gt;6 weeks</td>
<td></td>
</tr>
<tr>
<td>Late erythema</td>
<td>15</td>
<td>~6–10 weeks</td>
<td></td>
</tr>
<tr>
<td>Dermal necrosis</td>
<td>18</td>
<td>&gt;10 weeks</td>
<td></td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>12</td>
<td>&gt; 52 weeks</td>
<td></td>
</tr>
</tbody>
</table>
Tissue reactions should be considered apart from the stochastic effects without threshold doses. They cannot be addressed in the context of effective dose or kerma area product (KAP), but skin injury is directly linked to peak skin dose.

The expressions of radiation induced skin reactions are presented in Table 3.1. Early transient erythema, similar to sunburn, occurs a few hours after irradiation and reaches a peak value within 24 h. A second and more severe erythema develops after a latent period of 8-10 days. It is red in color, limited to the irradiated area, and is accompanied by a sensation of heat and itching. Acute skin reactions, such as moist desquamation and ulceration of the skin may occur 2-4 weeks after irradiation.

Transient erythema occurs after single doses greater than 2 Gy, main erythema occurs at doses greater than about 7 Gy, while moist desquamation (Figure 3.1) and ulceration (Figure 3.2) occur after single doses of 15-20 Gy (Table 3.1). In general, the level of doses occur in diagnostic radiology is not large enough to cause skin reactions, but these effects are not uncommon for dose intensive procedures of interventional radiology.

![Figure 3.1 Moist desquamation erythema after radiofrequency catheter ablation [285].](image-url)
3.3.4 Direct and indirect effects of radiation

The interactions of ionising radiation with matter result in loss of radiation energy through ionisation and free radicals are formatted due to the breakage of chemical bonds in molecules. Free radicals are known to play a major role in biological tissues. When radiation energy is received by a specific macromolecule with observable biological effects, such as DNA, it is then termed a direct effect of radiation. The photons absorbed in the water of an organism, may additionally causing excitation and ionisation in the molecules. The radicals formed are able to spread far enough to reach and damage the critical tissues. This is called as an indirect effect of ionising radiation. The absorption of energy depends on the abundance of material in the path of the radiation. As about 80% of the mass of a living cell is water, the greatest amount of the radiation energy deposited will be absorbed in cellular water. Thus, most the biological damage caused by low-LET radiations, such as X-rays or electrons, is due to indirect action [117].
3.4 Dose response curves

A plot of a biological effect (e.g. cancer induction or tissue response) as a function of the dose is termed dose response curve. Various dose response curves either for cancer induction (curves A, B, C and D) or tissue response (curve E) are presented in Figure 3.3.

Curve A, B, C and D represent a linear relationship with no threshold, a linear relationship with threshold $D_T$, a linear quadratic relationship with no threshold (assumed for stochastic effects), and a linear relationship with no threshold (the region below the dashed line represents the natural incidence of the effect), respectively. On the other hand, the curve E represents a sigmoid relationship with threshold $D_1$ (assumed for deterministic effects). The curves are schematic only and are presented separately for clarity (in practice the dashed line would be lower) [280].

![Figure 3.3 Typical dose response curves for cancer development (curves A, B, C and D) and for tissue response (curve E).](image)

3.5 Relative biological effectiveness (RBE)

It has been shown that equal doses of different types of radiation produce not equal biological effects. Comparison of these effects is defined as RBE. It is the ratio of the doses of reference radiation and the test radiation required to produce an equal amount of a specific biological effect. The reference radiation used was 250 kV X-rays, but recently, $^{60}$Co radiation has become the standard. RBE varies with cell system end point and dose and is
higher at low doses or low dose rates. For high doses with a single fraction, the RBE is lower than for multiple small fractions. For radiation protection purposes, the ICRP has described the effectiveness of radiations of different qualities by using a series of radiation weighting factors \(w_R\) [286].

### 3.6 International organizations on radiation effects

There are two scientific committees that collect and analyse data from the recent literature regarding biological effects of ionizing radiation. Biological Effects of Ionizing Radiation (BEIR) [287, 288] and UNSCEAR report periodically the most up-to-date and comprehensive data on important issues such as risk models, risk estimates for radiation induced cancer and hereditary effects from exposure to low-level ionising radiation. In addition, the ICRP is involved in recommendation and development of guidelines in the field of radiation protection [117].

### 3.7 Risk estimates from exposure to low level ionising radiation

Extrapolation of risk estimates based on epidemiological studies of exposed human populations at moderate to high doses continues to be the main basis for the estimation of radiation-related risk at low doses and dose rates. Current knowledge of damage response mechanisms and quantitative data on dose and time dose relationships support the LNT hypothesis. The risk from exposure to low-level ionising radiation is uncertain, and a simple extrapolation from high-dose effects may not be entirely justified in cases such as adaptive responses, genomic instability and bystander effects. However, although there are intrinsic uncertainties at low dose range, direct epidemiological measures of radiation cancer risk necessarily reflect all mechanistic contributions (from induced genomic instability, bystander effects, and adaptive responses) and therefore may provide insights about these contributions. Based on the mechanistic arguments, a linear response in the low-dose region is recommended. Quantitative analyses of dose responses for carcinogenesis and for life shortening in laboratory animals also support this response. These studies also support a dose and dose rate effectiveness factor (DDREF) in the range of approximately 2 when data are extrapolated to low doses from effects induced by doses in the range of 23 Gy.
The ICRP concludes that although the presence of a low-dose threshold does not seem to be improbable for radiation-related cancers of certain organ/tissues, the scientific data does not encourage the existence of a universal threshold [289]. The LNT hypothesis, in combination with an uncertain DDREF for extrapolation from high doses, continues to be the basis for radiological protection at low doses and low dose rates.

### 3.7.1 Risk models for cancer

In order to assess the health effects of radiation on the exposed individuals, the incidence (frequency) of a specific effect is studied in both exposed and non-exposed populations (same age, sex, etc.). Risk estimates are generally include determination of the relative risk (RR), excess relative risk (ERR) or excess absolute risk (EAR) per unit of radiation dose. For a specific effect, RR is defined as the ratio of the frequency of this effect (for example number of cancer cases) in the exposed group \(R_r\) and the frequency of the same effect \(R_o\) in the non-exposed group (RR = \(R_r/R_o\)). The ERR is defined as RR minus 1 (ERR = RR – 1). The EAR is defined as the difference between the frequencies remarked in the exposed and the non-exposed groups, respectively (EAR = \(R_r - R_o\)).

For evaluating the risk of radiation induced cancer in humans, two different models are implemented: (i) absolute risk models and (ii) RR models. The absolute risk model hypothesizes that radiation gives rise to a ‘crop’ of cancers over and above the natural incidence and not related to it. After the latency period has passed, the cancer risk returns to ‘spontaneous’ levels. The RR model hypothesizes that the radiation contributes to the increase of the natural incidence of cancer at all ages after the exposure by a given factor. Since the natural or spontaneous cancer incidence increases significantly as the age increases, the RR model predicts a larger number of radiation induced cancers in old age. The RR model is preferred by the BEIR committee for estimating risks after radiation exposure [117].

### 3.7.2 Time course and latency period

Epidemiological data derived from the lifespan study of the atomic bombs survivors in Japan and data from other studies constitute the main source of risk estimates currently used in radiological protection. The latency period is the time interval between the exposure to
ionising radiation and the incidence of cancer. Leukaemia has a minimum latency period of approximately 2 years after exposure; the pattern of risk over time peaks after 10 years (most cases occur in the first 15 years) and decreases thereafter. Solid tumors demonstrate a longer latency period compared to leukaemia, from 10 to 60 years or even more [117].

3.7.3 Dose-response relationship for cancer

The LNT hypothesis was introduced by the ICRP [289] as the best practical approach to estimating risk from exposure to low doses and low dose rates. It assumes that there is a linear relationship between radiation dose and associated risk, without a threshold at low doses/dose rates. This means that there is no level of radiation exposure associated with no health risk. The gradient of the linear dose - response curve provides the risk coefficient (cancer risk per unit radiation dose received) suitable for use at low level exposures.

3.7.4 Dose and dose rate effectiveness factor

The results obtained by comparing the Japanese data for atomic bomb survivors with those of other epidemiological studies, including studies of multiple medical and chronic exposures, have demonstrated a difference in the risk estimation with respect to the dose. The BEIR and UNSCEAR committees concluded that there is a dose rate effect for low-LET radiation, with fewer malignant tumors induced if a given dose were to be delivered at low dose rate over a period of time than if it were delivered in an acute exposure.

The DDREF is defined as the factor by which the radiation-related cancer risks resulted from high acute doses should be reduced in the cases that the radiation is delivered at low dose rate and/or with small dose fractions. In 2007, the ICRP concluded “that the adoption of the LNT model combined with a judged value of DDREF provides a prudent basis for practical purposes of radiological protection” [24]. For general purposes in radiological protection, the ICRP recommends a DDREF of 2 [24, 153] for doses ≤ 200 mSv at any dose rate and for higher doses if the dose rate is ≤ 100 mSv/h.
3.7.5 Cancer risk

The ICRP recommendations for radiation protection purposes are based on the Japanese study and other epidemiological studies. In the 1977 Recommendations, the ICRP [154] have introduced the concept of radiation detriment in order to quantify all deleterious effects from exposure to ionising radiation. This concept takes into account not only the probability of each type of effects, but also the severity of the effect. The whole body morality risk factor for radiation induced cancer was $10^{-2}$ Sv$^{-1}$ averaged over both sexes and all ages (whole population). The average risk factor for genetic effects was $0.4 \cdot 10^{-2}$ Sv$^{-1}$ as expressed in the first two generations. Despite the fact that these estimates may vary between workers and whole population, the Commission was not recommended the use of separate values for protection assuming that the differences was not large enough.

In the 1990 Recommendations [153], the concept of detriment was elaborated to include fatal cancer risk plus an estimate of the incidence of severe hereditary effects all weighted for non-fatal cancer, relative life years lost and life impairment for non-fatal cancer. The nominal probability coefficients for stochastic effects are presented in Table 3.2. The main reason for the differences observed in cancer risk estimates was that in ICRP 26 an additive model was used for risk calculations. This model assumed that the radiation induced risks are independent of the naturally incident cancers. On the other hand, ICRP 60 assumes that radiation induced cancers were consistent with a multiplicative model where the number of radiation-induced tumors arise as a percentage of those naturally occurring.

<table>
<thead>
<tr>
<th>Exposed Population</th>
<th>Fatal Cancer</th>
<th>Non Fatal Cancer</th>
<th>Hereditary Disorders</th>
<th>Total Detriment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working Population (20 to 64 yrs of age)</td>
<td>4.0</td>
<td>0.8</td>
<td>0.8</td>
<td>5.6</td>
</tr>
<tr>
<td>Whole Population (0 to 90 yrs of age)</td>
<td>5.0</td>
<td>1.0</td>
<td>1.3</td>
<td>7.3</td>
</tr>
</tbody>
</table>

Table 3.2 Nominal probability coefficients for stochastic effects in ICRP 60 ($10^{-2}$ Sv$^{-1}$).

In the 2007 Recommendations [24], the risk coefficients have not significantly changed since 1990. The values are presented in Table 3.3 along with those provided by the 1990 recommendations. It is important to notice that these values were based on data regarding cancer incidence weighted for mortality and life impairment. If the fatal cancer risk is taken
into account for the whole population of all ages, then the risk coefficient was $4 \times 10^{-2} \text{ Sv}^{-1}$ compared to $5 \times 10^{-2} \text{ Sv}^{-1}$ in 1990 Recommendations.

**Table 3.3** Detriment-adjusted risk coefficients for stochastic effects in ICRP 103 ($10^{-2} \text{ Sv}^{-1}$).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole</td>
<td>5.5</td>
<td>6.0</td>
<td>0.2</td>
<td>1.3</td>
<td>5.7</td>
<td>7.3</td>
</tr>
<tr>
<td>Adult</td>
<td>4.1</td>
<td>4.8</td>
<td>0.1</td>
<td>0.8</td>
<td>4.2</td>
<td>5.6</td>
</tr>
</tbody>
</table>

The total detriment risk coefficients are about 25% lower in the 2007 Recommendations than in 1990. This is mainly attributed to the fact that in 2007 estimates were based upon incidence data, while in 1990 were based on mortality data. The usage of incidence data has the advantage that such data are more certainly diagnosed, whereas in the case of mortality the cancer may be the underlying cause of death and some data may be missed in the reporting. In addition, the mortality fraction of cancers would be more reliable when obtained from initial incidence data. Secondly, as the total hereditary risk is 0.3-0.5% per Gy to the first generation, which is less than the one tenth of the fatal cancer risk, it is believed to take some hundreds of generations for defects to reach equilibrium and the risk to the first generations will be about 10% of the cancer risk to parents.

**Figure 3.4** The lifetime attributable risk from a single small dose as a function of age at the time of exposure [290].
Furthermore, there is sufficient evidence that cancer risk is also dependent on the age at exposure, sex and race of the exposed person. Younger people have much higher risk for stochastic effects than older, while females are slightly more radiosensitive than males (Figure 3.4). Tables 3.4 and 3.5 are available to calculate the age- and sex-specific lifetime attributable risks for cancer incidence and cancer mortality, following radiation exposure [288].

**Table 3.4 Lifetime attributable risk for cancer incidence [288].**

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Age at exposure (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Males</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>76</td>
</tr>
<tr>
<td>Colon</td>
<td>336</td>
</tr>
<tr>
<td>Liver</td>
<td>61</td>
</tr>
<tr>
<td>Lung</td>
<td>314</td>
</tr>
<tr>
<td>Prostate</td>
<td>93</td>
</tr>
<tr>
<td>Bladder</td>
<td>209</td>
</tr>
<tr>
<td>Other</td>
<td>1123</td>
</tr>
<tr>
<td>Thyroid</td>
<td>115</td>
</tr>
<tr>
<td>All solid</td>
<td>2326</td>
</tr>
<tr>
<td>Leukaemia</td>
<td>237</td>
</tr>
<tr>
<td>All cancers</td>
<td>2563</td>
</tr>
<tr>
<td>Females</td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>101</td>
</tr>
<tr>
<td>Colon</td>
<td>220</td>
</tr>
<tr>
<td>Liver</td>
<td>28</td>
</tr>
<tr>
<td>Lung</td>
<td>733</td>
</tr>
<tr>
<td>Breast</td>
<td>1171</td>
</tr>
<tr>
<td>Uterus</td>
<td>50</td>
</tr>
<tr>
<td>Ovary</td>
<td>104</td>
</tr>
<tr>
<td>Bladder</td>
<td>212</td>
</tr>
<tr>
<td>Other</td>
<td>1339</td>
</tr>
<tr>
<td>Thyroid</td>
<td>634</td>
</tr>
<tr>
<td>All solid</td>
<td>4592</td>
</tr>
<tr>
<td>Leukaemia</td>
<td>185</td>
</tr>
<tr>
<td>All cancers</td>
<td>4777</td>
</tr>
</tbody>
</table>

\(^a\) Number of cases per 100 000 persons exposed to a single dose of 0.1 Gy.

**Note:** These estimates are obtained as combined estimates based on relative and absolute risk transport and have been adjusted by a DDREF of 1.5, except for leukaemia, which is based on a linear quadratic model.
3.8 Radiation safety standards

Safety standards are developed by the International Atomic Energy Agency (IAEA) under a well established approach based on knowledge of radiation effects and on the principles of radiation protection. The basic safety standards published by IAEA are based on the recommendations of the ICRP, which also take account the scientific data provided by the UNSCEAR on the health effects and risk of ionising radiation as well as on levels of radiation exposure due to the different sources [282, 291].
The decisions for protection and safety should be based on purely scientific criteria and the safety standards implicitly encourage professionals to make their own judgments about the relative importance of different kinds of risks and balancing between risks and benefits. Due to the general consensus about of radiation risk, international safety standards should provide a desirable international framework for radiation protection. For these reasons, international consensus is basic to the IAEA standards [292, 293], which are prepared with the broad participation and authorization by its Member States and relevant international organizations (Food and Agriculture Organization of the United Nations, IAEA, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization and World Health Organization (WHO).
CHAPTER 4

DOSIMETRIC QUANTITIES AND UNITS

4.1 Introduction

In the field of radiation dosimetry there is a need to have understandable and precise dosimetric quantities and units that can be readily used in clinical practice in order to obtain quantitative measurements. In diagnostic and interventional radiology various quantities and terminologies have been used (sometimes incorrectly) for the specification of dose along the central beam axis at the point at which the X-ray beam enters the patient or a phantom representing the patient. These include exposure at skin entrance (ESE), input radiation exposure, entrance surface air kerma (ESAK), entrance air kerma (EAK), air kerma, entrance surface dose (ESD), entrance skin dose and integral skin dose. Different names are used for the same quantity, for example ESAK, air kerma and EAK. Furthermore, the same abbreviation, ESD, is used for both entrance surface dose (absorbed dose most likely expressed in air) and entrance skin dose (absorbed dose most likely expressed in skin). The absorbed dose to air is a quantity that has physical meaningful only in air. A problem that often occurs has been the use of this quantity in cases, which is not suitable or cannot be measured, due to the lack of secondary electron equilibrium (at or close to air-tissue interfaces).

Therefore, international standardization in dosimetry is of critical importance for the successful exploitation of radiation technology in medicine and radiation protection, as well as in industry and other applications. In addition, harmonized guidelines for clinical dose measurements are also needed. Three international organizations are active in relation to dosimetric quantities and units. The ICRU, which is mainly working with the physical aspects of dosimetry, including measurement methods, calibration of dosimeters, and methods for determining organ and tissue doses. The ICRP, which mainly works with assessments and quantification of biological effects of radiation and provides guidance and
recommendations on all aspects of radiation protection against ionising radiation. The IAEA, which disseminates international standards for safety and radiation measurement, conducts dose audits and comparisons, develops and transfers dosimetry techniques, and provides training and guidance on quality assurance and radiation measurements. The main objectives are to help to achieve and maintain a high level of quality in dosimetry and radiation protection, to improve the implementation of traceable standards at the national level and to ensure the control of radiation dose in medical X-ray imaging worldwide. Also national bodies like the Greek Atomic Energy Commission (GAEC), Health Protection Agency (HPA), National Council on Radiation Protection and Measurements (NCRP) have also proposed guidelines for radiation protection in their respective countries. In the literature are available several reviews of the evolution of the dosimetric quantities and units [294, 295].

The following text describes in detail the dosimetric quantities adopted to the system of international radiological protection, relating them and provides some background that must be addressed in using these quantities.

### 4.2 Basic dosimetric quantities

Basic quantities are fundamental quantities defined in ICRU 60 [276]. These quantities are briefly discussed below.

#### 4.2.1 Fluence

The fluence ($\Phi$) is defined as the quotient of the number of particles $dN$ incident on a sphere of cross-sectional area $da$, by $da$ (Figure 4.1):

$$\Phi = \frac{dN}{da} \quad (4.1)$$

Unit: $m^{-2}$.

The particles included in the radiation field may have any direction, but photons and electrons are counted separately, contributing to the photon fluence and the electron fluence, respectively.
4.2.2 Energy fluence

The energy fluence ($\Psi$) is defined as the quotient of the radiant energy $R$ incident on a sphere of cross-sectional area $da$, by $da$ (Figure 4.1):

$$\Psi = \frac{dR}{da}$$

(4.2)

Unit: J/m$^2$.

If the particles have the same energy $E$, then the energy fluence is given by the formula:

$$\Psi = E \cdot \Phi$$

(4.3)

![Figure 4.1 Definition of fluence and energy fluence utilizing a spherical surface, S.](image)

4.2.3 Kerma and kerma rate

The kerma (K) is defined as the quotient of the initial kinetic energies $dE_{tr}$ of all charged particles (electrons) transferred by uncharged particles (photons) at a certain position in a mass $dm$ of a given material, by $dm$:

$$K = \frac{dE_{tr}}{dm}$$

(4.4)

Unit: J/kg or gray (Gy).

The kerma rate ($\dot{K}$) is defined as the quotient $dK$ by $dt$, where $dK$ is the increment of kerma in the time interval $dt$:

$$\dot{K} = \frac{dK}{dt}$$

(4.5)

Unit: J·kg$^{-1}$·s$^{-1}$ or gray per second (Gy/s).
It is worthwhile noting that the kerma correspond to the kinetic energy received by the secondary charged particles at the moment of liberation. This energy does not necessarily spend in the mass dm (or volume dV) where they were liberated. For the case of photons in the diagnostic energy range, the energy transferred corresponds to the sum of the kinetic energies of electrons at the moment that they liberated in an incoherent scattering or photoelectric interaction in the mass dm.

If the energies of bremsstrahlung photons and annihilation photons emitted due to interaction of liberated charged particles with matter are subtracted from the energy transferred, the quantity net energy transferred is defined. For the case of photons in the diagnostic energy range that interact with low atomic number materials, the energy transferred equals the net energy transferred, since there is no pair production or bremsstrahlung emission by the released electrons [280].

4.2.4 Energy imparted

The mean energy imparted (\( \bar{\varepsilon} \)) in a given volume to the matter equals the radiant energy, \( R_{in} \), of all those charged and uncharged ionising particles which enter the volume minus the radiant energy, \( R_{out} \), of all those charged and uncharged ionising particles which leave the volume, plus the sum, \( \Sigma Q \), of all changes of the rest energy of nuclei and elementary particles which occur in the volume:

\[
\bar{\varepsilon} = R_{in} - R_{out} + \Sigma Q
\]  

(4.6)

Unit: J.

For the photon energies used in diagnostic radiology, \( \Sigma Q \) is zero.

4.2.5 Absorbed dose

The absorbed dose (D) at a point is the quotient \( d \bar{\varepsilon} \) by dm, where \( d \bar{\varepsilon} \) is the mean energy imparted to matter of mass dm:

\[
D = \frac{d \bar{\varepsilon}}{dm}
\]  

(4.7)

Unit: J/kg or gray (Gy).
In other words, the absorbed energy is defined as the statistical average of the energy imparted per unit mass \( dm \) at a point [278]. To illustrate this definition, energy absorption of 280 J in a 70-kg person gives a mean-whole body absorbed dose of 4 Gy.

### 4.2.6 Kerma and absorbed dose

Kerma measures the amount of energy that is transferred from photons to electrons per unit mass at a certain position, while the absorbed dose measures the energy deposited in a unit mass at a certain position. However, for kerma the volume of interest is the place where the energy is transferred from photons to electrons, while for absorbed dose is where the kinetic energy of charged particles is spent. Thus, the charged particles entering the volume contribute to the absorbed dose but not to kerma. Furthermore, the charged particles liberated by a photon may leave the volume, carrying away part of their kinetic energy. This energy included in kerma but not to absorbed dose [280]. At energies used in diagnostic and interventional radiology if the production of bremsstrahlung within low atomic number materials is negligible, the absorbed dose and kerma, for a given material and radiation field are numerically equal, when secondary electron equilibrium is established. For higher energy photons, kerma will be higher compared to the absorbed dose whenever secondary electron equilibrium is not established (close to an interface between different materials), since some highly energetic secondary electrons and X-ray photons escape the absorbing volume before depositing their energy [296].

### 4.3 Application specific dosimetric quantities

Application specific quantities are practical dosimetric quantities that are used for patient dose measurements in medical X-ray imaging. However, there has been ambiguity in the name of these quantities and their (sometimes incorrect) use [277]. Owing to the equivalence of numerical values of absorbed dose and kerma in the same material for the X-ray energies used in medical imaging and under conditions of secondary electron equilibrium, have often been alternatively referred to in terms of absorbed dose (usually abbreviated to dose) or in terms of kerma. Furthermore, because of the ambiguous nature of the absorbed dose (in the vicinity of interfaces), it is not possible to convert it, for a given exposure, to, for example, an organ dose via one single conversion coefficient, as is routinely done when using an air
kerma measurement. Thus, air kerma instead of the absorbed dose is used as a baseline of all directly measured application specific quantities [277]. In addition, due to the complex nature of the absorbed dose to air, the calibration of dosimeters for use in diagnostic and interventional radiology is standardized in terms of air kerma worldwide. However, there are some exceptional cases in which the absorbed dose to the tissue surrounding a metal implant is the quantity of interest.

It is necessary to specify the point of measurement or calculation (Figure 4.2) for these quantities with respect to the X-ray tube focus and the patient or phantom. Since diverging radiation beams are used in medical X-ray imaging, the kerma and dose will decrease with the distance from the X-ray tube focus in accordance with the inverse square law. Radiation backscattered from within the patient or phantom will make a significant contribution to the kerma or dose (backscatter factor (BSF) values ranging from 1.25 to 1.60 for general radiology [297]). A number of recommended names, symbols and fields of application specific quantities are presented in Table 4.1.

<table>
<thead>
<tr>
<th>Dosimetric Quantity</th>
<th>Symbol</th>
<th>Field of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident air kerma (rate)</td>
<td>$K_i$</td>
<td>Radiography, including mammography and fluoroscopy</td>
</tr>
<tr>
<td>Entrance surface air kerma (rate)</td>
<td>$K_e$</td>
<td>Radiography, including mammography and fluoroscopy</td>
</tr>
<tr>
<td>Air kerma area product (rate)</td>
<td>$P_{KA}$</td>
<td>Radiography and fluoroscopy</td>
</tr>
<tr>
<td>Air kerma length product</td>
<td>$P_{KL}$</td>
<td>CT</td>
</tr>
<tr>
<td>CT air kerma index</td>
<td>$C_K$</td>
<td>CT</td>
</tr>
</tbody>
</table>

Only application specific quantities that are relevant to radiography and fluoroscopy are outlined below [277].

### 4.3.1 Incident air kerma

The incident air kerma ($K_i$ or INAK) is the kerma to air from an incident X-ray beam measured on the central axis of the X-ray beam at the surface of the patient or phantom (in
the absence of patient or phantom) (Figure 4.2). Only the primary radiation incident on the patient or phantom and no scatter contribution is included.

Unit: J/kg or gray (Gy).

### 4.3.2 Entrance surface air kerma

The entrance surface air kerma ($K_e$ or ESAK) is the kerma to air measured on the central axis of the X-ray beam at the surface of the patient or phantom (in the presence of patient or phantom) (Figure 4.2). Includes the radiation incident on the patient or phantom and a contribution from photons backscattered from inner tissues, which is not included in free in air measurements. In this case, it is impractical to measure absorbed dose in air, since absorbed dose to air and air kerma are not numerically equal, due to the lack of secondary electron equilibrium at air-tissue (phantom) interface.

Unit: J/kg or gray (Gy).

The ESAK is related to the incident air kerma by the BSF:

$$K_e = K_i \cdot BSF$$

If measurements are made at distances different than the actual focus skin distances (FSDs), the inverse square law must be applied to these measurements, in order to correct the differences in doses.

For procedures involving prolonged fluoroscopic exposures, it is important to determine the ESAK rate because of the potential to give high skin doses that may exceed the threshold for deterministic effects.

---

**Figure 4.2** Diagram of the measuring geometry for the dosimetric quantities [296].
4.3.3 X-ray tube output

The X-ray tube output ($Y(d)$) is the quotient of the kerma in air at a specified distance, $d$, from the X-ray tube focus by the tube current-exposure time product (tube loading), $P_t$, (Figure 4.2) [277]:

$$Y(d) = \frac{K(d)}{P_t}$$  \hspace{1cm} (4.9)

Unit: J·kg$^{-1}$·C$^{-1}$ or Gy·C$^{-1}$ or Gy·A$^{-1}$·s$^{-1}$.

The $Y(d)$ may be implemented in conjunction with the inverse square law to estimate the air kerma incident on the patient or phantom if the tube loading is known. The magnitude of the $Y(d)$ will depend on the design of the tube, tube voltage and filtration, and may change as the tube ages.

4.3.4 Air kerma-area product

The air kerma-area product ($P_{KA}$ or KAP) is defined as the air kerma, $K(x, y)$, in a plane perpendicular to the incident beam axis integrated over the area, $A$, of interest (Figure 4.2):

$$P_{KA} = \int_A K(x, y) \, dx \, dy$$  \hspace{1cm} (4.10)

Unit: J·kg$^{-1}$·m$^{-2}$ or Gy·m$^{-2}$.

The KAP has the useful property that it is constant with the distance from the X-ray tube focus (when interactions in air and extrafocal radiation can be neglected), since the cross section of the beam is a quadratic function which cancels the inverse quadratic function of the dose. It is also invariant if it is measured not so close to the patient or phantom which introduces a significant contribution of backscattered radiation.

KAP is a measure of the total energy imparted to the patient. It can be converted to ED by using appropriate conversion factors [298, 299]. In the diagnostic energy range, the KAP is often termed erroneously dose area product (DAP) assuming that air kerma is approximately equal to the absorbed dose. For procedures involving fluoroscopy, where the tube voltage, tube current, field size and beam direction can vary during the procedures, the INAK is not a good measurement of the radiation detriment. In these cases, the KAP may be used instead.

The KAP rate is defined as the quotient of the increment in the KAP by the time interval $dt$. 
4.4 Quantities related to stochastic and deterministic effects

A point quantity such as absorbed dose is not very useful to assess radiation exposures and to describe the dose-response relationship for radiation effects. The dosimetric quantities related to stochastic and deterministic effects (or the protection quantities) are the mean dose absorbed in organs and tissues, equivalent dose and effective dose. Except the localized skin dose, it is not possible to measure directly such doses and are generally estimated from application specific quantities using conversion coefficients derived from Monte Carlo (MC) simulations or experimental measurements with phantoms. The goal of these quantities is to assess the biological effects resulting from exposure to ionising radiation and to have sufficient information to control these effects. Risk assessment is based on the linear dose-effect relationship as well as in the accumulation of dose in the low-dose range. Averaging the absorbed dose to organs and tissues over a long period would not be an acceptable procedure. In addition, special treatment is needed in the case of heterogeneous exposures.

4.4.1 Organ and tissue dose

The mean absorbed dose in a specified organ or tissue is given the symbol $D_T$ in ICRU 51 [275]. It is equal to the ratio of the mean energy imparted to the organ or tissue, $\bar{\varepsilon}_T$, to the mass, $m_T$, of the organ or tissue [277]:

$$D_T = \frac{\bar{\varepsilon}_T}{m_T}$$

Unit: J/kg or gray (Gy).

For stochastic effects, the ICRP 60 [153] recommends that the mean absorbed dose in an organ or tissue is the appropriate dosimetric indicator. For organs, such as uterus, gonads and lens of the eyes is recommended individual dose determination. Furthermore, as the dose distribution within the body is quite heterogeneous during diagnostic and interventional radiology examinations, some organs may be partly irradiated, while some others that are located inside the X-ray field receive dose considerably exceed the mean absorbed dose [280]. For deterministic effects, however, the dose to the most greatly irradiated area(s) of tissue is more relevant and mean absorbed dose in this localized area is the required quantity [277]. For example, knowledge of the skin dose, especially to the most exposed part of the body, during interventional procedures is necessary in order to avoid such effects or reduce their severity.
4.4.2 Equivalent dose

The equivalent dose ($H_T$), to an organ or tissue, $T$, is defined in ICRP 60 [153] and ICRU 51 [275]. For a single type of radiation, $R$, it is calculated by multiplying the radiation weighting factor, $w_R$, and the organ absorbed dose $D_T$:

$$H_T = w_R \cdot D_{T,R}$$

(4.12)

Unit: J/kg or sievert (Sv).

The concept of equivalent dose is applied only to radiation exposures of humans. The radiation weighting factor accounts for the differences in the RBE of the incident radiation in producing stochastic effects at low doses in organ or tissue, $T$. These factors are dependent both on type of particles and their energies. They are defined as a function of LET. LET is the radiation energy lost per unit length inside the material and is approximately equivalent to the stopping powers for charged particles (keV·μm$^{-1}$). For the X-ray energies used in diagnostic and interventional radiology, $w_R$ is taken to be unity for 200 keV photons. X-rays and electrons are low-LET radiations and can cause less biological damage compared to high-LET radiations (e.g. a particles) at the same dose.

The values of the radiation weighting factors reported in ICRP 60 [153] are presented in Table 4.2. These factors have been revised in ICRP 103 [24] (Table 4.3). Figure 4.3 shows that in the energy range below 1 MeV, $w_R$ values for neutrons are less than those reported in the ICRP 60 [153].

<table>
<thead>
<tr>
<th>Radiation type and energy range</th>
<th>Radiation weighting factors, $w_R$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photons, all energies</td>
<td>1</td>
</tr>
<tr>
<td>Electrons and muons, all energies</td>
<td>1</td>
</tr>
<tr>
<td>Protons, other than recoil protons, energy $&gt; 2$ MeV</td>
<td>5</td>
</tr>
<tr>
<td>Neutrons, energy $&lt; 10$ keV</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>10 keV to 100 keV</td>
</tr>
<tr>
<td></td>
<td>$&gt; 100$ keV to 2 MeV</td>
</tr>
<tr>
<td></td>
<td>$&gt; 2$ MeV to 20 MeV</td>
</tr>
<tr>
<td></td>
<td>$&gt; 20$ MeV</td>
</tr>
<tr>
<td>Alpha particles, fission fragments, heavy nuclei</td>
<td>20</td>
</tr>
</tbody>
</table>
**Table 4.3** Radiation weighting factors in the 2007 recommendations [24].

<table>
<thead>
<tr>
<th>Radiation type</th>
<th>Radiation weighting factors, $w_R$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photons,</td>
<td>1</td>
</tr>
<tr>
<td>Electrons and muons</td>
<td>1</td>
</tr>
<tr>
<td>Protons and charged pions</td>
<td>2</td>
</tr>
<tr>
<td>Alpha particles, fission fragments, heavy ions</td>
<td>20</td>
</tr>
<tr>
<td>Neutrons</td>
<td>A continuous curve as a function of neutron energy (see Figure 4.3)</td>
</tr>
</tbody>
</table>

**Figure 4.3** Radiation weighting factor, $w_R$, for neutrons. Step function and continuous function given in ICRP 60 [153] and function adopted in ICRP 103 [24] Recommendations.
4.4.3 Effective dose

The effective dose (E or ED) is defined in ICRP 60 [153] and ICRU 51 [275]. It is the sum over all organs and tissues of the body of the product of the equivalent dose, $H_T$, to the organ or tissue and the corresponding tissue weighting factor, $w_T$, for that organ or tissue:

$$ E = \sum_T w_T \cdot H_T $$  \hspace{1cm} (4.13)

Unit: J/kg or sievert (Sv).

In radiation protection, the tissue weighting factor for an organ or tissue, $T$, weighting the equivalent dose to that organ or tissue to the total deleterious (stochastic) effects resulted from uniform irradiation of the whole body. The sum of the tissue weighting factors over all the organs and tissues of the human body is unity.

The values of the tissue weighting factors recommended by the ICRP are presented in Table 4.4. The number of tissues and organs taken into account was increased, and the values for some tissue weighting factors were modified in ICRP 103 recommendations [24] (Table 4.4).

<table>
<thead>
<tr>
<th>Organ/Tissue</th>
<th>Tissue weighting factors, $w_T$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICRP 60</td>
</tr>
<tr>
<td>Red bone marrow</td>
<td>0.12</td>
</tr>
<tr>
<td>Colon</td>
<td>0.12</td>
</tr>
<tr>
<td>Lung</td>
<td>0.12</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.12</td>
</tr>
<tr>
<td>Breast</td>
<td>0.05</td>
</tr>
<tr>
<td>Remainder tissues</td>
<td>0.05$^a$</td>
</tr>
<tr>
<td>Gonads</td>
<td>0.20</td>
</tr>
<tr>
<td>Bladder</td>
<td>0.05</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>0.05</td>
</tr>
<tr>
<td>Liver</td>
<td>0.05</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.05</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.01</td>
</tr>
<tr>
<td>Brain</td>
<td>-</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>-</td>
</tr>
<tr>
<td>Skin</td>
<td>0.01</td>
</tr>
</tbody>
</table>

$^a$Remainder tissues (10 organs/tissues): Adrenals, upper large intestine, brain, small intestine, kidney, muscle, pancreas, spleen, thymus and uterus.

$^b$Remainder tissues (13 organs/tissues): Adrenals, Extrathoracic region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate, Small intestine, Spleen, Thymus, and Uterus/cervix.
The quantity ED was introduced to solve conceptual and practical problems with until then used limitation concept based on “critical organ” and “maximum permissible dose”, since enough knowledge became available to calculate a weighted whole-body dose. The weighting procedure was first described in ICRP 26 [154], but the new quantity (effective dose equivalent) was introduced by Wolfgang Jacobi [300]. There are a number of assumptions, simplifications and approximations included in the definition of ED. In general, it assumes validity of the LNT model in the low-dose range and validity of temporal additivity of dose in this dose range. In 1991 [153], ICRP replaced the quantity effective dose equivalent with the effective dose.

The organ doses that are needed for the calculation of ED could be calculated using a family of reference phantoms for male and female adults [301]. Using these phantoms, dose conversion coefficients are calculated for external exposures under standard irradiation geometries [302].

ED is not based on data from any individual and does not provide an individual-specific dose but rather that received by a reference person under given exposure conditions. Therefore, and because of the approximations and simplifications, it is not suitable for risk assessments of individuals. However, it is of practical value for comparing the relative doses related to stochastic effects from different X-ray examinations, the use of similar technologies and techniques in different hospitals and countries and the use of different imaging technologies for the same examination, provided that the representative patients or patient populations for which the effective doses are derived are similar with regard to age and gender.

4.5 Relationship between dosimetric quantities

The protection quantities (defined by the ICRP) are not directly measurable. To overcome this limitation, the ICRU has introduced a set of operational quantities which can be easily measured in routine practice (point doses at defined locations in specific phantoms) and intended to provide a reasonable estimate for the protection quantities, avoiding either underestimation or overestimation of the radiation risk. The relationship between the protection and operational quantities with the absorbed dose is illustrated in Figure 4.4 [303]. More detailed information are available in ICRU Publication 57 [304] and ICRP report 74.
which also provide coefficients for the conversion between protection and operational quantities that can be used in radiation protection against external exposures.

Figure 4.4 Relationship between physical protection and operational quantities [303].

### 4.6 Conversion coefficients for the evaluation of organ and tissue doses

A conversion coefficient (CC) affiliates the dose delivered to an organ or tissue to a readily measured or calculated dosimetric quantity:

\[
CC = \frac{\text{organ or tissue dose}}{\text{measured or calculated quantity}} \tag{4.14}
\]

Suffixes are added to CC to indicate the two quantities that are related; for example the coefficient:

\[
CC_{D_T, K_i} = \frac{D_T}{K_i} \tag{4.15}
\]

relates the organ dose, \( D_T \), to the incident air kerma, \( K_i \).
CHAPTER 5

INSTRUMENTATION FOR DOSIMETRY

5.1 Introduction

The doses delivered to patients in both diagnostic and interventional procedures should be accurately determined, even if usually small, in order to maintain a reasonable balance between image quality and patient exposure. There are also some situations where high doses to patient’s skin may occur, due to the prolonged fluoroscopic exposures [285, 306, 307]. Dose measurements are also essential in acceptance testing and quality control (QC) of the equipment, as well as in the optimization of examinations for image quality and dose. A radiation dosimeter is a device, instrument or system which measures or assesses, either directly or indirectly, the quantities exposure, exposure rate, air kerma, air kerma rate, absorbed dose or equivalent dose and their rates, or related dosimetric quantities of ionising radiation. It usually consists of a measuring assembly (electrometer) and one or more detectors. These instruments are also used to determine the half value layer (HVL). Measurement of a dosimetric quantity is the experimental process to quantify the value of the quantity utilizing dosimetry systems (dosimeters and readers). To be useful, radiation dosimeters should have various desirable characteristics such as accuracy and precision, sensitivity, intrinsic linearity, dose or dose rate dependence, energy dependence (intrinsic energy dependence, absorbed-dose energy dependence), directional dependence and spatial resolution/size effects), readout convenience, convenience of use. The choice of a radiation dosimeter and its electrometer must therefore be made prudently, taking into consideration the requirements of the measurement conditions. An accurate dose measurement requires correct calibration of the instrumentation in X-ray beams of known properties. Some dosimeters automatically perform conversion and/or correction in order to display the actual air kerma. In most cases the calibration coefficient is applied through the dosimeter’s software. The specification of radiation qualities is important, since the response of all
dosimeters strongly depends on the X-ray spectrum utilized. Radiation qualities are usually specified by means of the X-ray tube voltage and HVL. X-ray beams used in diagnostic radiology and fluoroscopy cover the range between 50-150 kV. Dosimetric techniques should be implemented so that ensure appropriate levels of accuracy and long term stability. Measurement of tube voltage and exposure time is performed with non-invasive, portable electronic devices called kV meters and timers.

This chapter summarizes the instrumentation required for measuring radiation dose, tube voltage and exposure time including a discussion of situations in which they are appropriate, as well as the special requirements for calibration of such instruments.

5.2 Selection of instrumentation for dosimetry

Ionisation chambers are the main devices used for dosimetry in diagnostic and interventional radiology [308]. Their primary advantage is that it is a precise instrument with low energy dependence and a few other complicating factors. An ionisation chamber should be calibrated over the energy range that will be used, since different chambers can show variations in energy dependence. The design and performance of ionisation chambers must be matched to the needs of the clinical measurement. Parallel-plate and cylindrical chambers are mainly used. KAP meters are special types of parallel-plate ionisation chambers used to measure the integral of the air kerma over the entire area of an X-ray field. The reading of the KAP meter can be converted into the energy imparted to the patient [309].

Other devices with special properties, for example thermoluminescent detectors (TLDs) and semiconductor detectors, are also used [308, 310]. Although ionisation chambers have been the standard instruments for dosimetry for many years, semiconductor detectors have found wide use for QC measurements due to their convenience of use. Real-time measurements may be conveniently accomplished with semiconductor dosimeters. The small size of TLDs allows their implementation for conducting measurements on patients. The main disadvantage of these devices has been the energy dependence of their response which differs considerably from that of ionisation chambers. Measurements involving scatter radiation, such as patient exit dose are also performed with ionisation chambers and special care need to be taken if attempting to use semiconductor detectors for this purpose. Film dosimeters (including radiochromic films) may be placed on patient’s skin or inside cavities to measure the skin or organ doses. Film dosimeters have been extensively used in dose
Chapter 5 Instrumentation for dosimetry

Audits or in radiation dose monitoring in clinical routine in hospitals, but they are not used for calibrations of other dosimeters in secondary standards dosimetry laboratories (SSDLs). Other instruments are needed to measure the X-ray tube voltage (kV meters) and exposure time (timers) that can be used without direct connection into the electrical circuits of the X-ray units.

5.2.1 Ionisation chambers

5.2.1.1 Free air chambers

The free air chamber is the fundamental standard for perceiving the unit gray for the quantity air kerma for a particular energy range [311]. Various primary standards dosimetry laboratories (PSDLs) and some SSDLs use free air chambers to calculate the air kerma (rate) in photon beams. Comparisons of measurements with free air chambers from different hospitals usually agree to ± 0.5%, which is within the limit of the uncertainty [312].

![Figure 5.1 Basic design of a parallel-plate ionisation chamber. 1: polarizing electrode, 2: measuring electrode, 3: guard ring, a: height (electrode separation) of the air cavity, d: diameter of the polarizing electrode, m: diameter of the collecting electrode, g: width of the guard ring [296].](image-url)
5.2.1.2 Cylindrical and parallel plate chambers

The most common type of ionisation chamber for the measurement of the air kerma is a parallel plate chamber. These chambers (also known as plane parallel chambers) use two parallel, flat electrodes, placed with a few millimetres interval. Their major disadvantage is the directional dependence of their response. They are calibrated with their plates oriented perpendicular to the beam axis, which is also the orientation in which they should be used. The entrance window should always face the focal spot and special caution is required in cases that some chambers have different entrance and exit windows. A schematic diagram of a parallel plate ionisation chamber is presented in Figure 5.1. The most common chambers have effective volumes from about 1 cm³ to several hundreds of cm³ and are suitable for application over a wide range of exposure rates. Owing to their shape and size, they can be safely placed in hollow spaces, such as on the X-ray table under a phantom, or in contact with the image intensifier [117].

On the other hand, a cylindrical ionisation chamber is a gas filled cavity surrounded by a conductive outer wall and a central collecting electrode (Figure 5.2). Their response is symmetrical with respect to their axis. They are usually oriented with the cylindrical axis perpendicular to the X-ray beam [296]. The cylindrical chambers are uniformly sensitive and have an effective volume of a few cubic centimeters (3-6 cm³). Irrespective of their geometrical design, ionisation chambers used in radiology should be of the vented type (their sensitive gas volume should communicate with the atmosphere). Humidity has an insignificant effect on air mass changes, but temperature and pressure significantly affect the air mass within the chamber and the air density correction factor, kTP, should be applied to the dosimeters’ readings. Requirements on performance of ionisation chambers are set in International Electrotechnical Commission (IEC) report 61674 [313].

![Basic design of a cylindrical ionisation chamber](296)
5.2.1.3 Transmission ionisation chambers

In examinations using fluoroscopy, irradiation geometry (field size, focus skin distance, projection) and exposure times may vary individually from patient to patient with respect to the clinical conditions. If the detector mounted on the tube housing is ‘transparent’ to the X-ray beam, then both focal and extrafocal radiation will pass through its sensitive volume. If attenuation in the air is neglected, the X-rays transmitted through the detector will pass every plane perpendicularly along the central axis of the X-ray beam. If the air kerma over beam area is integrated over the entire plane, the KAP will be invariant with the distance from the X-ray tube given that the beam is contained by the KAP meter. In this case, the KAP is a quantity suitable for monitoring patient exposure. A detector possessing such properties is called transmission ionisation chamber [314].

A transmission ionisation chamber is generally comprised of layers of polymethyl methacrylate (PMMA) coated with a conductive material. Graphite, is a commonly used coating material, which is close to air equivalent and introduces low energy dependence for measurement of air kerma. However, a limitation of graphite coating transmission chambers is that graphite coating is non-transparent to light. Therefore, light transparent materials are mostly used, since contain high atomic number elements such as indium and tin, giving rise to relatively strong energy dependence compared to graphite coated chambers [315, 316]. Transmission ionisation chambers are generally used as detectors to KAP meters. Requirements on performance of KAP meters are set in IEC report 60580 [317]. Depending in their use and calibration, the KAP meters measure either the incident radiation or the transmitted radiation. In the latter case, the attenuation of the radiation by the KAP meter is taken into account.

An alternative to transmission ionisation chamber based KAP meters is the mathematical (software) KAP meters. They are based on an integrated software program, which utilizes information about the X-ray tube output and the collimation area of the X-ray field to derive the KAP reading. KAP is a measure of the total energy imparted to the patient and can be converted to effective dose using appropriate conversion coefficients [298, 299]. KAP meters have the advantage that they can be used in fluoroscopy procedures which involve different angulations and patient positions. The main drawback is that their readings do not include backscatter component and thus do not indicate skin dose. Furthermore, they exhibit some energy dependence and thus correction factors should be derived. The configuration of the KAP meter introduces some bias to the KAP value. For example, if there is some
material between the KAP meter and patient, the patient will receive lower dose than the displayed KAP value. This is particularly true for under couch KAP meter installations and different calibration coefficients should therefore be derived for such exposure geometries. Owing to the presence of extrafocal and scatter radiation, they should be calibrated in situ.

### 5.2.2 Solid state dosimeters

Solid state dosimeters can be used for patient dosimetry external to the body or a phantom as the ionisation chambers, for measurements internal in a phantom, for occupational and public exposure monitoring.

#### 5.2.2.1 TLDs

Some materials, after absorption of ionising radiation, maintain part of the absorbed energy in metastable conditions. These trapped electrons or holes remain at the metastable condition until they are excited to recombine and dissipate the energy in the form of ultraviolet, visible or infrared light. If the method of excitation is heat, the process is called thermoluminescence. The amount of light emitted is proportional to the radiation received by the material. If the stimulating agent is light, the process is mentioned as optically stimulated luminescence [308].

Thermoluminescence has found extensive use in radiation dosimetry. TLDs are commercially available in various shapes (powder, chips, rods, ribbons), sizes and made of various materials. The dosimeters most frequently used in medical applications are based on lithium fluoride doped with magnesium and titanium (LiF:Mg,Ti) (TLD 100), lithium fluoride doped with magnesium, copper and phosphorus (LiF:Mg,Cu,P) (TLD 100H, 600H, 700H) and Mn-doped lithium tetraborate (Li₂B₄O₇:Mn) (TLD 800) because of their tissue equivalence. Other materials have also been used (CaSO₄:Dy and CaF₂:Mn) because of their high sensitivity [318, 319]. The relationship of dose to thermoluminescence signal is linear up to doses of < 1 Gy. However, for higher energy photons, correction factors for a non-linear response can be applied.

There are many processes that can influence the thermoluminescence measurement and great caution must be taken to be precise when used as dosimeter. Extensive descriptions of various thermoluminescent materials as well as information for their preparation, handling and evaluation are available in the literature [318, 320]. During the readout, the TLD emits
light the intensity of which is proportional to the energy deposited during irradiation. Approximately 1% of the energy deposited in the thermoluminescence material is emitted as light when the material is heated. A typical cycle in the TLD reader includes a preheat phase without light emission, a read out period with glow curve for dose measurement, an annealing period without light integration and a cooling-down period. During the preheat, the temperature of the dosimeter is maintained constant for some seconds to remove low temperature signals. The annealing cycle is the method used to prepare the dosimeters for reuse by eliminating, through a preheat phase, low temperature glow peaks without affecting higher temperature peak. An annealing cycle should be established depending on the type of material used. Their reproducibility is of critical importance in order to obtain accurate measurements. During the measurement (integration interval) we receive the glow curve, which is the graphical representation of the emitted light intensity that increases with the increasing temperature (Figure 5.3). The light emitted results to an electrical signal that can be converted to one of the dosimetric quantities of interest. For a specific X-ray beam, to overcome this problem the dosimeter should be calibrated in a beam of that type, itself already calibrated by some other means.

There are many factors that influence the final result of a dose measurement. These include factors related to the performance of the instrument and those related to procedures of TLDs preparation and handling. The trapped electrons are also slowly released at room temperature. This process is called fading and this effect must be corrected when evaluating the TLDs long period after irradiation. Special attention is needed to situations where the TLDs are stored at high temperatures. When calibrating the dosimeter, the whole system has to be considered [320].

![Figure 5.3 A typical TLD glow curve of LiF:Mg,Ti obtained at a low heating rate [280].](image-url)
5.2.2.2 Semiconductor dosimeters

The small size of TLDs makes them suitable to perform measurements on patients, but they do not provide real time indication of patient exposure. On the other hand, semiconductor detectors combining both advantages of solid state detectors since are also small in size and respond instantaneously to their irradiation. They produce strong signals from moderate amounts of radiation, they are inflexible and do not demand correction for pressure, which makes them appropriate for certain clinical applications.

The simplest of semiconducting devices is the diode, which based on a p-n junction between the p-type and n-type parts of a semiconductor (usually silicon or germanium) [308]. As ionising radiation strikes the semiconductor material, electron hole pairs are induced. This results the junction to become conductive and the current increases with the ion production rate. The size of the signal produced depends on the ionising properties of the radiation and on its ability to penetrate the junction. As the amount of energy required to produce an electron hole pair is known, and is independent of the energy of the incident radiation, counting the number of electron hole pairs permits the intensity of the incident radiation to be determined. However, the amount of ionisation reaching the junction may also depend on the cross sectional area of the junction in relation to the incidence of the beam. In addition, there may be some energy dependence and directional sensitivity to these devices. Metal filters are mainly used by manufacturers to compensate for the energy dependence of the signal of solid state detectors. Additionally, there is possibility to compensate for this effect electronically. Furthermore, semiconductors show a variation in dose response with temperature, dependence of signal on the dose rate as well as directional dependence and energy dependence even for small variations in spectral distribution of the X-ray beams. They are smaller in size and exhibit higher sensitivity compared to ionisation chambers. They can be used as relative dosimeters and but not for beam calibration, since their sensitivity significantly changes, due to the radiation damage in the structural properties of the junction, as a result of their repeated use. Therefore, it is recommended that the response of the dosimeter be checked regularly [296]. Diodes must be calibrated before they are used for in vivo dosimetry, and several correction factors have to be applied in order to calculate dose accurately. However, their calibration has to be repeated periodically since their sensitivity depends on their radiation history.
5.2.3 Film dosimetry

5.2.3.1 Radiographic film

Films perform various functions to the fields of diagnostic and interventional radiology, radiotherapy and radiation protection. It can be used as a radiation detector, a relative dosimeter, a display device and an archival medium \[117, 280\]. The provision, processing and analysis of these dosimeters are the tasks of specialized departments and companies and are not commonly within the responsibilities and duties of a medical physicist.

A radiographic film consists of an emulsion containing radiation sensitive silver halide grains, typically silver bromide (AgBr) grains, suspended in a gelatin matrix, coated uniformly on one or both sides of a flexible, transparent, blue-tinted base. When radiant energy strikes AgBr crystals, they become more susceptible to chemical change and form a latent (hidden) image in the film. This image becomes visible (film blackening) and permanent only after processing. When the film is developed, the crystals that have been altered by the radiation are reduced to small grains of metallic silver. The concentration of metallic silver (light transmission) is a function of the film opacity and can be measured in terms of optical density (OD) with devices called densitometers. The OD is defined as:

\[
OD = \log_{10} \frac{I_o}{I}
\]  

(5.1)

where \(I_o\) is the initial light intensity and \(I\) is the intensity transmitted through the film. Upon exposure to ambient background radiation a film would exhibit a background OD termed the fog density (OD_f).

![Figure 5.4 Typical H&D curve for a radiographic film. The OD is plotted against the log of the exposure.](image)
The relationship between the OD and dose should be linear, but this is only an ideal case. There are emulsions that are linear in response, some that are linear over a limited dose range and others that are non-linear. Thus, the sensitometric curve (also known as characteristic or H&D curve, named for developers Hurter and Driffield) should be established before using each film for dosimetry work. A typical characteristic curve for a radiographic film is presented in Figure 5.4. It has four regions: (1) fog, at low or zero exposures, (2) toe, (3) a linear portion at intermediate exposures, and (4) shoulder and saturation area at high exposures. The linear part is the region of optimum exposure conditions, the toe is the region of underexposure while the shoulder is the region of overexposure.

Important parameters describing the film response to radiation are the gamma, latitude and speed. The gamma is defined as slope of the straight line portion of the characteristic curve of the film. The exposure should be selected to make all parts of the radiograph lying on the linear portion of the characteristic curve, in order to ensure the same contrast for all ODs. The latitude is defined as the exposure range in which the ODs produce useful contrast (lie on the linear portion of the characteristic curve). The speed or sensitivity of a film is determined as the exposure required to reach an OD of 1.0 greater than the OD of. Generally, films are used for qualitative dosimetry, but with the appropriate calibration, careful handling, processing and analysis can also be implemented for dose evaluation. It provides excellent 2-D spatial resolution and, in a single exposure, gives information about the spatial distribution of radiation in the region of interest or the attenuation of the X-ray beam by interfering objects. The useful dose range of film is narrow and the energy dependence is pronounced for lower energy photons. However, above 200 keV the response is “flat” with energy, and films constitute good dosimeters in the range 200 keV to 1MeV. The response of the film also depends on several parameters, which are difficult to control. The OD depends not only to the exposure but also on the development and processing procedure. Therefore, a careful calibration over the exposure range of interest must be performed for each batch of film used and each development protocol. The need for a calibration over the exposure range of interest is also essential, since film is not a linear system except for very small exposures.

Typical applications of a radiographic film are qualitative and quantitative measurements in radiotherapy, including electron beam dosimetry, QC of radiotherapy machines (size and shape of radiation field, accuracy of light localizer, the size of penumbra around a field, leakage radiation around collimators and the positioning of special radiation shields),
confirmation of treatment planning in various phantoms and portal imaging [280]. Radiographic films can also be used for personal radiation monitoring using film badges.

5.2.3.2 Radiochromic film

Radiochromic film is a new type of film used for dosimetry in radiotherapy. The most frequently used is the GafChromic film. It is a colourless film with almost equivalent tissue composition (9.0% hydrogen (H), 60.6% carbon (C), 11.2% nitrogen (N) and 19.2% oxygen (O)) that develops a blue colour during radiation exposure.

Radiochromic film includes a special dye that is polymerized during exposure to ionising radiation. The polymer absorbs light, and a suitable densitometer can be used to measure the transmission of the light through the film. Radiochromic films are self-developing, and do not require developer or fixer. Additionally, it exhibits very high resolution since it is grainless and can be used for dosimetry in stereotactic radiotherapy, as well as for measurements of dose distributions in the vicinity of brachytherapy sources.

Dosimetry with radiochromic films has several advantages than with radiographic films, such as convenience of use, not need for darkrooms, film cassettes or film processing, independence on dose rate, better energy response characteristics (except for low energy X-rays of \( \leq 25 \text{ kV} \)), and insensitivity to ambient conditions (although excessive humidity should be avoided). They are generally less sensitive compared to radiographic films and are useful for dosimetry at higher doses, although the dose response non-linearity have to be corrected in the upper dose region.

Radiochromic film is a relative dosimeter. They are commonly used for the measurement and mapping of patient’s skin dose during diagnostic and interventional radiology procedures. If appropriate care is taken with calibration and the ambient conditions, a precision better than 3% is achievable [280].
## 5.3 Summary of properties of common dosimetric systems

The advantages and disadvantages of the most common dosimetric systems are summarized in Table 5.1.

**Table 5.1 Advantages and disadvantages of the four most common dosimetric systems [280].**

<table>
<thead>
<tr>
<th>System</th>
<th>Advantage</th>
<th>Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ionization chamber</td>
<td>Accurate and precise</td>
<td>Connecting cables required</td>
</tr>
<tr>
<td></td>
<td>Recommended for beam calibration</td>
<td>High voltage supply required</td>
</tr>
<tr>
<td></td>
<td>Necessary corrections well understood</td>
<td>Many corrections required for high energy beam dosimetry</td>
</tr>
<tr>
<td></td>
<td>Instant readout</td>
<td></td>
</tr>
<tr>
<td>Film</td>
<td>2-D spatial resolution</td>
<td>Darkroom and processing facilities required</td>
</tr>
<tr>
<td></td>
<td>Very thin; does not perturb the beam</td>
<td>Processing difficult to control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Variation between films and batches</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Needs proper calibration against ionization chamber measurements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy dependence problems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cannot be used for beam calibration</td>
</tr>
<tr>
<td>TLD</td>
<td>Small in size: point dose measurements possible</td>
<td>Signal erased during readout</td>
</tr>
<tr>
<td></td>
<td>Many TLDs can be exposed in a single exposure</td>
<td>Easy to lose reading</td>
</tr>
<tr>
<td></td>
<td>Available in various forms</td>
<td>No instant readout</td>
</tr>
<tr>
<td></td>
<td>Some are reasonably tissue equivalent</td>
<td>Accurate results require care</td>
</tr>
<tr>
<td></td>
<td>Not expensive</td>
<td>Readout and calibration time consuming</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not recommended for beam calibration</td>
</tr>
<tr>
<td>Diode</td>
<td>Small size</td>
<td>Requires connecting cables</td>
</tr>
<tr>
<td></td>
<td>High sensitivity</td>
<td>Variability of calibration with temperature</td>
</tr>
<tr>
<td></td>
<td>Instant readout</td>
<td>Change in sensitivity with accumulated dose</td>
</tr>
<tr>
<td></td>
<td>No external bias voltage</td>
<td>Special care needed to ensure constancy of response</td>
</tr>
<tr>
<td></td>
<td>Simple instrumentation</td>
<td>Cannot be used for beam calibration</td>
</tr>
</tbody>
</table>
5.4 Summary of characteristics of diagnostic dosimeters

The basic characteristics of diagnostic dosimeters with respect to their applications are summarized in Table 5.2.

Table 5.2 Basic characteristics of diagnostic dosimeters [117].

<table>
<thead>
<tr>
<th>Application</th>
<th>Type of detector</th>
<th>Range of X-ray tube voltage (kV)</th>
<th>Range of air kerma or air kerma rate</th>
<th>Intrinsic error (%)</th>
<th>Variation of energy response (%)</th>
<th>K rate dependence (%)</th>
<th>Angular dependence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General radiography</td>
<td>Cylindrical, spherical or plane parallel IC(^a)</td>
<td>60–150</td>
<td>10 μGy to 1 Gy</td>
<td>5</td>
<td>±5</td>
<td>±2</td>
<td>±3 @ ±5°</td>
</tr>
<tr>
<td></td>
<td>Solid state detectors</td>
<td></td>
<td>1 mGy/s to 500 mGy/s(^b)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 mGy/s to 5 mGy/s(^d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>Plane parallel IC(^a)</td>
<td>50–120</td>
<td>10 μGy/s to 10 mGy/s(^d)</td>
<td>5</td>
<td>±5</td>
<td>±2</td>
<td>±3 @ ±5°</td>
</tr>
<tr>
<td></td>
<td>Solid state detectors</td>
<td></td>
<td>0.1 μGy/s to 100 μGy/s(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy/interventional radiology</td>
<td>KAP meters</td>
<td>50–150</td>
<td>10(^a) to 10(^b) mGy m(^a)</td>
<td>10</td>
<td>±8</td>
<td>±5</td>
<td>--</td>
</tr>
<tr>
<td>Fluoroscopy/interventional radiology</td>
<td>KAP meters</td>
<td></td>
<td>10(^a) to 10(^b) mGy m(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mammography</td>
<td>Plane parallel IC(^a)</td>
<td>22–40</td>
<td>10 μGy to 1 Gy</td>
<td>5</td>
<td>±5</td>
<td>±2</td>
<td>±3 @ ±5°</td>
</tr>
<tr>
<td></td>
<td>Solid state detectors</td>
<td></td>
<td>10 μGy/s to 10 mGy/s(^b)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.1 μGy/s to 100 μGy/s(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>Cylindrical pencil type IC(^a) of 100 mm active length(^f)</td>
<td>100–150</td>
<td>0.1–50 mGy/s</td>
<td>5</td>
<td>±5</td>
<td>±2</td>
<td>±3 @ ±180°</td>
</tr>
<tr>
<td>Dental radiography</td>
<td>Cylindrical, spherical or plane parallel IC(^a)</td>
<td>50–100</td>
<td>1–10 mGy/s</td>
<td>5</td>
<td>±5</td>
<td>±2</td>
<td>±3 @ ±5°</td>
</tr>
<tr>
<td></td>
<td>Solid state detectors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>KAP meters</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cylindrical pencil type IC(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) IC: ionization chamber.
\(^b\) Unattenuated beam.
\(^c\) For air kerma rate measurements.
\(^d\) In the light of new CT technologies and the revision of CT dosimetry methodology, new types of detector may be proposed that will be suitable for measuring pulsed radiation as well.
\(^e\) For air kerma area product (rate) measurements.
\(^f\) Attenuated beam.
5.5 Calibration of instrumentation

5.5.1 Specification of the X-ray beams

A dosimeter should be calibrated at the appropriate radiation qualities. The quality of an X-ray beam can be characterized by the X-ray spectrum. It is recommended that the radiation quality of the X-ray beams used in medical imaging be characterized by a combination of parameters, including the first and second HVLs (HVL₁ and HVL₂), the ratio of HVL₁ and HVL₂ (referred as homogeneity coefficient), tube voltage and total filtration as well as their combinations. More specifically, in most cases the quality of an X-ray beam can be adequately characterized in terms of tube voltage, HVL₁ and HVL₂ or tube voltage, HVL₁ and total filtration. Additionally, the radiation intensity (including filtration) is an important characteristic of the X-ray tube and thus the X-ray tube output should also be defined.

The determination of the HVL is based on simple attenuation measurements, usually in aluminum. The HVL₁ is the thickness of the aluminum required to attenuate the radiation intensity of the X-ray beam to the half of its initial value. The air kerma or the air kerma rate is the quantity recommended for the characterization of X-ray beams used in medical imaging. If different quantities are used may result to different HVL₁ values. The HVL alone is not adequate to specify the X-ray beam quality, since markedly different spectra can sometimes result in the same value of HVL₁. Scattered radiation other than any that might initially be present in the X-ray beam should be excluded from the measurements. A narrow beam and a large distance between the aluminum and the ionisation chamber should be used in order to obtain the correct HVL value. The instrument used for attenuation measurements should exhibit weak energy dependence over the range concerned. The use of a monitor is advisable to facilitate correction for variations in the X-ray tube output. The monitor should be positioned such that its readings are independent of the thickness of the aluminum. By reducing the field diameter, the amount of scattered radiation recorded will be reduced, but the field dimensions must be larger than the sensitive volume of the ionisation chamber. The diaphragm must be of sufficient thickness to absorb the primary beam. A radiographic method may be used to check the alignment.
5.5.2 Calibration facilities

All instruments used for dosimetry in diagnostic and interventional radiology must be calibrated, possessing a valid calibration certificate from an accredited calibration laboratory, usually an SSDL. The SSDLs calibrate their reference class ionisation chambers at PSDLs and use them to calibrate the user’s dosimeters. Calibrations directly traceable to primary standards are available for most of the radiation qualities used in radiology. Comparisons between several PSDLs have demonstrated the mutual equivalence of the primary standards for radiation qualities developed in order to meet clinical requirements.

5.5.3 Radiation qualities for calibration

The qualities used for the calibration of dosimeters for different applications are shown in Table 5.3 [321]. The RQR series correspond to the primary beams incident on the patient, while the RQA series the attenuated beams transmitted through the patients. For the RQR and RQA quality series, an X-ray tube with tungsten anode and aluminum and/or cooper filtration is used.

The calibration coefficient, $N_K$, of a dosimeter is usually obtained at the RQR 5 (70 kV). For the other qualities, $Q$, a correction factor $k_Q$ is provided to take into account the energy dependence of the dosimeter response. The quality factor $k_Q$ is defined as the ratio of the calibration coefficients at radiation quality $Q$ that of RQR 5.

<table>
<thead>
<tr>
<th>Application</th>
<th>Range of HVL$_{1/2}$ (mm Al)</th>
<th>Reference code</th>
</tr>
</thead>
<tbody>
<tr>
<td>General radiography</td>
<td>Unattenuated</td>
<td>2.11–5.62</td>
</tr>
<tr>
<td></td>
<td>Attenuated</td>
<td>5.38–13.3</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>Unattenuated</td>
<td>1.78–5.62</td>
</tr>
<tr>
<td></td>
<td>Attenuated</td>
<td>3.78–13.3</td>
</tr>
<tr>
<td>CT</td>
<td></td>
<td>7.00–10.0</td>
</tr>
<tr>
<td>Mammography</td>
<td>Unattenuated</td>
<td>0.28–0.36</td>
</tr>
<tr>
<td></td>
<td>Attenuated</td>
<td>0.56–0.58</td>
</tr>
<tr>
<td>Dental radiography</td>
<td></td>
<td>1.78–3.20</td>
</tr>
</tbody>
</table>
5.5.4 Requirements for equipment used for calibration

All equipment used for calibration at an SSDL shall be of a reference class and be available in duplicate at the SSDL. This includes ionization chambers, electrometers, thermometers, barometers and a device to measure the relative humidity of air. For calibration purposes, the only detector that is considered to be a reference class dosimeter is an ionization chamber [296]. The primary advantage of ionisation chambers is that they exhibit small variation in energy response and good long term stability. Table 5.4 presents the recommendations on the upper limit of the variation in energy response for ionisation chambers, for different applications. The time interval between the periodic calibrations of the standard instrument should be within the acceptable period defined by national regulations. If such regulations do not exist, the time interval should not exceed three years. Monthly measurements are necessary to check the stability of the reference chambers.

Table 5.4 Maximum variation of energy response for ionisation chambers used at SSDLs.

<table>
<thead>
<tr>
<th>Application</th>
<th>Tube voltage range (kV)</th>
<th>Maximum variation of response (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General radiography</td>
<td>60–150</td>
<td>±3</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>50–100</td>
<td>±2</td>
</tr>
<tr>
<td>Mammography</td>
<td>22–35</td>
<td>±1</td>
</tr>
<tr>
<td>CT</td>
<td>100–150</td>
<td>±1</td>
</tr>
<tr>
<td>Dental radiography</td>
<td>50–90</td>
<td>±2</td>
</tr>
</tbody>
</table>

5.5.5 Calibration of the instrumentation

The SSDL shall provide a calibration coefficient in terms of air kerma. In the case of ionisation chambers it is also important to measure the temperature and pressure at the time and place of measurement. There are also some dosimeters that measure temperature and pressure automatically and apply a correction for their influence. In this case, periodical checks need to be made in order to ensure that it is being made correctly. Air kerma area product meters require great care in their calibration, as their performance depends on the actual set-up in the hospital [322]. They may be calibrated in situ. The calibration of dosimeters should be done by the substitution method, using a transmission monitor. The cross-sectional area of the reference radiation beam should be sufficient to irradiate the
standard chamber or the device to be calibrated. The variation of air kerma rate over the useful beam area shall be less than 5%, and the contribution of scattered radiation to the total air kerma rate shall be less than 5% [323].

An SSDL should determine its calibration uncertainty, which has to include the uncertainty stated by the PSDL for the transfer chamber calibration, although this may be itemized separately. The procedure of establishing the uncertainty budget is described in the IAEA code of practice for dosimetry [296]. The expanded uncertainty ($k = 2$) for different types of instruments shall fall within the values given in Table 5.5. The IEC 61674 [324] requires that the detector and measuring assembly need to be calibrated as a system, but in cases of their separate calibration a calibration coefficient obtained as the product of the detector and measuring assembly calibration coefficient should be used.

**Table 5.5 Uncertainty for different types of instruments for an SSDL.**

<table>
<thead>
<tr>
<th>Type of instrument</th>
<th>Expanded uncertainty ($k = 2$) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference class instruments suitable for the calibration of other instruments in general diagnostic applications</td>
<td>3.5</td>
</tr>
<tr>
<td>Reference class instruments suitable for the calibration of other instruments in the mammography category</td>
<td>2</td>
</tr>
<tr>
<td>Field class dosimeters (50–150 kV)</td>
<td>5</td>
</tr>
<tr>
<td>Field class mammography dosimeters (20–50 kV)</td>
<td>3</td>
</tr>
<tr>
<td>Electrometers</td>
<td>1</td>
</tr>
</tbody>
</table>

### 5.6 Instruments for measurement of tube voltage and time

Depending on the model, a kV meter measures the absolute peak voltage (the maximum value of tube voltage during the exposure), the average peak voltage (average of all peak values), the average voltage (average of all values), the effective peak voltage (the tube voltage that provide the same contrast with a constant potential generator) and the practical peak voltage (the equivalent value of tube voltage of a waveform provided by an ideal generator that provides constant voltage and the same image contrast), which is considered as the standard quantity for the tube voltage. The kV meter is positioned in the primary X-ray beam and measures the tube voltage in the basis of attenuation measurements to cooper filters of different thickness. The long axis of these devices should be positioned
perpendicular to the tube anode-cathode axis, in order to eliminate the influence of the heel effect to the measurements. The intrinsic error of the practical tube voltage measurements should not be greater than \( \pm 2\% \) over the effective tube voltage ranges. Additionally, it is recommended 1.5\% limit of variation in energy response as tube filtration ranges between 2.5-3.5 mm Al [324].

The exposure time is measured as the difference between two points (pulse width) defined by a preset triggering level. It is proposed to measure the pulse width at the height of 50\% of the waveform peak (full width half maximum) (Figure 5.5) [117].

![Figure 5.5 Typical waveform for a three phase six pulse generator operating at 80 kV and 165 ms exposure time.](image)

For carrying out calibrations of non-invasive tube voltage measuring devices, an SSDL should be equipped with appropriate equipment for calibrating the voltage delivered by the generator connected to the X-ray tube. This should be done under the exposure conditions used in clinical practice. The best method employs an appropriately calibrated and frequency compensated resistor chain connected parallel to the generator and the X-ray tube. The peak voltage [313] is calculated from the readings of this device.
CHAPTER 6

FUNDAMENTALS OF IMAGE QUALITY

6.1 Introduction

A medical image is a visual representation of the internal structures or function of some organs and tissues of the body. This information can be acquired in one to three spatial dimensions. Radiography produces static images, while fluoroscopy produces real-time (dynamic) images at a lower dose rate [325]. Fluoroscopic imaging should exhibit high signal to noise ratio (SNR) to ensure high temporal resolution, but simultaneously patient dose must be kept at an acceptable level. Two fundamental properties are associated with these data. Firstly, there is no image can that exactly represent an object or function because of an associated error that equals to the difference observed between the true object and the image. Secondly, even when two images of the same anatomic region acquired with the same imaging system, there will not be identical due to the presence of noise.

There are many different ways to acquire a medical image. The concept of image quality in practical terms includes the information obtained from the image. Irrespective, of image formation method, one must be able to judge the fidelity of the image in an attempt to answer the question “How accurately does the image represent the body or the body function?” The quality of an image is determined by the imaging method, the performance of the equipment and the imaging parameters selected by the operator. In some cases spatial resolution is of priority concern, while in other cases contrast is the priority. Variations in image quality can be caused due to the non-optimum performance of the equipment or improper choice of exposure parameters. If the image is not properly displayed or the environmental conditions for perception is not suitable may lead to misdiagnosis or compromise the efficacy of an interventional procedure. Acceptable X-ray image quality is maintained by using a periodic quality assurance (QA) program.
Knowledge of image quality allows the comparison of various imaging systems for a given modality as well as the comparison of the information included in images obtained from different imaging modalities. The effect of image quality on an imaging task can also be specified. Different levels of image quality are required with respect to various imaging tasks; an image may be of sufficient quality for one task, but inadequate for another task. Image quality cannot be completely quantified by a single metric. There are several metrics for evaluating image quality, either objective or subjective (observers’ performance). When image quality is judged by task based criteria, its evaluation is more relevant. However, it should be noticed that it is also dependent on the observers’ performance.

In this chapter, both quantitative and qualitative methods of quantifying image quality are described.

6.2 Primary image quality indices

The evaluation of image quality should be based on measurable physical quantities. The three primary image quality indices are contrast, unsharpness and noise [326]. A variation in any one of these indices may result to a substantial change in the perception of image quality. In addition, artefacts or image distortions must also be taken into account when considering fluoroscopic image quality [327]. These indices are influenced and limited by the design of the fluoroscopic system; they are also highly dependent on equipment configuration and implementation by the operator [328].

6.2.1 Contrast

Contrast is the quotient of the signal difference to the average signal. The logic behind this definition is that a small difference is minor if the average signal is large, while the same small difference is readily visible if the average signal is small. Generally, a high contrast should be achieved in order to visualize anatomic characteristics well [326].

Two definitions of contrast are generally used in medical X-ray imaging. The Weber (local) contrast [117] is defined as:

\[
C = \frac{S_o - S_b}{S_o}
\]  

(6.1)
where \( S_o \) and \( S_b \) are the signals of the object and the background, respectively. It is also acceptable to consider the contrast of the image (\( g \)) or the contrast measured at other points in imaging chain, such as the contrast of an object displayed on a monitor.

The Weber contrast is commonly used in cases where small objects are present on a uniform background. The Michelson (modulation) \([117]\) contrast is commonly used for patterns where both bright and dark features undertake similar portions of the image. The modulation contrast is defined as:

\[
C_M = \frac{S_{\text{max}} - S_{\text{min}}}{S_{\text{max}} + S_{\text{min}}}
\]

where \( S_{\text{max}} \) and \( S_{\text{min}} \) are the highest and lowest signals, respectively.

The choice of which definition of contrast being used is situation dependent. Generally, the local contrast is intended to be used in the case of a small object presented on a uniform background, such as in simple experiments involving observers (two alternative forced choice experiments).

In medical imaging, the subject contrast is defined as the contrast (local or modulation) of an object against its background. The subject contrast strongly depends on the X-ray spectrum and the attenuation between the object and its background. As the beam energy increases, the Compton scattering becomes more predominant, leading to increased scattered radiation which will reduce the contrast. In simple terms contrast is a measure of the difference between densities of the exposed material \([329]\).

\[\text{Figure 6.1} \quad \text{X-ray spectral shaping: Influence of tube loading and Cu filtration [117].}\]
The energy fluence of the X-ray beam is significantly decreased when using Cu filtration and the tube current should be increased to maintain acceptably short pulse widths. The usage of metal filters (such as Cu) remove only low energy X rays that have little chance of penetrating the patient and hence generating contrast (Figure 6.1). Simultaneously, the removal of many low energy photons that would contribute only to the patient dose results at a lower kV technique at the same INAK rate improving subject contrast. As patient thickness increases, the additional Cu filtration is gradually reduced to maintain the short pulse widths and acceptable tube loading [329]. This is achieved through the automatic exposure control (AEC). The AEC controls the INAK rate to the image intensifier, to avoid variation in image brightness [330] and SNR that would compromise diagnosis or guidance of the instruments.

It determines the fluoroscopic technique factors such as tube voltage and tube current through predetermined curves that are stored in the generator (Figure 6.2). In some cases, the AEC controls and other operational parameters such as pulse length, added filtration and variable aperture setting [331].

Subject contrast is inherently poor in fluoroscopic imaging, especially at the high tube voltage values used to maintain patient dose at an acceptable level. Contrast is improved by using radiopaque markers on catheters or contrast agents. Contrast agents for fluoroscopy are selected regarding their chemical properties, toxicities and X-ray attenuation properties [329].

The image contrast depends on the subject contrast and the characteristics of the imaging detector. In radiographic and fluoroscopic imaging, the image contrast is mainly affected by
the X-ray spectrum incident on the X-ray detector, the detector material composition and thickness, and the greyscale characteristics of the detector, whether analogue (such as film) or digital [329].

The display contrast is the contrast of the image as displayed for final viewing by an observer. The display contrast is dependent on the image contrast, the greyscale characteristics of the monitor and any image post-processing that occurs prior to or during display [329].

### 6.2.2 Unsharpness

In the previous definition of contrast, large objects in the absence of blurring are considered. However, either assumption cannot be ignored. From the point of view of spatial domain, blurring reduces the contrast of small objects. Due to the effect of blurring the signal is spread laterally, so that a focused point becomes a diffuse point. One fundamental property of blurring is that increasing the signal diffusion, the intensity of the point image decreases, and consequently the image contrast [117, 326].

The effect of blurring on Weber contrast is presented in Figure 6.3 for a point blurred by convolution with Gaussian kernels of diameters 16 pixels, 32 pixels and 64 pixels. It can be seen, that the intensity of the signal decreases, as the amount of blurring increases, because the signal of the object is being spread over a larger area. This also means that the peak signal is only degraded if the object size is smaller compared to the width of the blurring function. On the other hand the contrast of larger objects will not be affected.

![Figure 6.3 A point object is blurred with increasingly larger kernels. The larger the kernel, the greater the blurring and the lower the contrast of small objects [117].](image_url)
The sharpness of a fluoroscopic image is affected by several factors, including the display matrix, field of view (FOV), video camera matrix, focal spot size, geometric magnification, image noise and motion. The large number of signal conversions that occur in an image intensifier degrade the sharpness of the fluoroscopic image. The sharpness of a fluoroscopic image obtained with a flat panel detector is influenced by the size of the image matrix compared with the display matrix and the pixel size of the detector, which may vary if pixels are binned at specific FOVs.

### 6.2.2.1 Limiting spatial resolution

The spatial resolution is a metric to quantify the capability of an imaging system to distinguish between two closely adjacent objects in space. The limiting spatial resolution is the maximum spatial frequency for which modulation is preserved without aliasing.

In fluoroscopy, the limiting resolution can be measured by imaging bar patterns including high contrast, sharp edged objects. It is typically measured in line pairs (LP) per mm. The higher the number of LP per mm the superior the resolution of the system. For fluoroscopy systems equipped with an image intensifier the limiting spatial resolution varies with magnification mode. Spatial resolution is affected by a number of factors including focal spot size and motion unsharpness. The modulation transfer function (MTF) is specified in terms of sinusoids and thus is measured in terms of spatial frequencies in cycles per mm. It provides the most detailed information about the spatial resolution.

Electronic magnification improves the image MTF but also decreases minification gain and decreases the sampling pitch of the input phosphor, increasing noise. The increased noise is compensated by adjusting the exposure parameters to obtain a constant noise level in the magnified image. For this reason, in an image intensifier system, the INAK rate increases to compensate for the decreased photon fluence per image pixel, as well as for the decrease in minification gain, and therefore image brightness. In flat panel systems INAK rate increases, as the image is magnified in response to the changes in the image matrix size.

There is no rigorous relationship between the MTF value and limiting spatial resolution of an X-ray system. The Coltman transform can be used to correlate the square wave response measured with a bar pattern and the sinusoidal response measured by the MTF. However, the ability to identify an object (and thereby distinguish it from its neighbour) is related to the
SNR. As a general rule, the resolution limit for most X-ray systems for high contrast objects occurs at the spatial frequency where the MTF ≈ 0.05 (5%).

6.2.2.2 Modulation transfer function (MTF)

In the special case of an analogue image, such as a film that is digitized, the measured MTF is the product of the film MTF and digitizer MTF. It is important to avoid aliasing during digitization process. This can be accomplished by using either sampling frequencies satisfying the Nyquist-Shannon theorem or digitizers including optics designed to eliminate aliasing.

The principle of cascaded analysis can be extended to more complex imaging systems that included a series of individual components (Figure 6.4). An example is a video fluoroscopic detector containing an image intensifier. In this case, the MTF of the image is determined by the MTFs of the image intensifier, video camera and lenses coupling the intensified image to the camera. The image passes consecutively through each of these components, and each subsequent component ‘‘receive’’ a continuous increasingly blurred image. The principle of cascaded systems analysis is extremely important, as it allows determination of the impact of each component on spatial resolution, and provides a useful tool for optimizing a system design. By investigating the MTF of each individual component it is possible to determine the weakest link in the imaging chain and to analyze the effect of various imaging conditions on image quality.

In many systems, however, aliasing is unavoidable. For example, aliasing will occur in a digital detector with very high limiting spatial resolution, much higher than can be supported by the pixel pitch of the detector. As presented in Figure 6.5, the limiting spatial resolution is 3.4 LP/mm, while higher frequencies are aliased during sampling process (the reversal of the bands is shown highlighted in yellow).

Due to the aliasing, predicting the exact image recorded by a system requires knowledge of the location of the objects relative to the detector matrix with subpixel precision, as well as knowledge of the blurring of the system prior to sampling. The latter can be determined by measuring the ‘‘presampling’’ MTF. The presampling MTF is measured using a high sampling frequency, so that no aliasing is present in the measurement, although includes the blurring effects of the sampling aperture.
Chapter 6   Fundamentals of image quality

Figure 6.4 The overall MTF is the product of the MTFs of the three sub-components A, B and C [117].

Fourier analysis provides a mathematical method for relating the description of an object or image in real space to its description in frequency space. To obtain a “true” image of an object the imaging system should be able to transmit every spatial frequency with 100% efficiency.

Figure 6.5 (a) A radiograph of a bar pattern is presented, (b) In the magnified region of the pattern, the limiting resolution is 3.4 LP/mm [117].

6.2.3 Noise

There is no imaging system that can acquire the same image twice. This fact is attributed to the nature of image noise. Image noise arises as random variations in the recorded signal
(number of X-ray photons detected) from pixel to pixel. In addition, it is not related to anatomy, but it arises from the random nature of the interactions involved in the production and detection of X-ray photons [332]. X-ray quantum noise follows Poisson distribution. Since quantum noise is related to the number of X-ray photons, the highly attenuating structures (bones) will appear noisier than less attenuating structures. In general, the relative noise in X-ray images can be increased by lack of absorption of X-rays, as well as by fluctuations both in the response of the detector to the absorbed X-rays and the signal produced in the detection medium.

In X-ray imaging system, quantum noise is one of the most important factors limiting the detection of objects. The ability to detect the disc is degraded as the magnitude of the noise is increased (Figure 6.6). The optimum radiation dose is just sufficient to visualize the anatomy or disease of interest, thus minimizing the potential for health effects. The ability to detect an object is related to SNR. Image noise and sharpness can mask and blur small details that would normally be visible in the image at a higher INAK rate [117].

![Figure 6.6 The ability to detect an object depends on both the contrast of the object and the noise presented in the image [117].](image)

The noise level in fluoroscopic images is significantly high, especially when low INAK rate used in order to maintain the patient dose at an acceptable level. Fluoroscopic systems equipped with image intensifiers are also characterized by low additive electronic noise. Therefore, is quantum limited at low INAK rate values. On the other hand, fluoroscopic systems equipped with flat panel detectors exhibit high levels of electronic noise and their imaging performance is limited by this noise at low INAK rate values. As a result, flat panel based systems require a higher INAK rate compared to image intensifier based systems for fluoroscopic imaging. However, flat panels perform better at high INAK rates, such as those used during digital acquisition imaging.
The mean variance is useful experimentally to determine whether the images acquired by a X-ray system are limited by the quantum noise. Such systems are called X-ray quantum noise limited, and the principal determinant of the image noise is the number of X-ray photons detected. In the mean variance experiment, the mean and standard deviation of the X-ray photons are measured as a function of the dose. When plotted log-log, the slope of this curve should be $\frac{1}{2}$. For digital detectors, this procedure helps to determine the range of air kerma values over which the system is quantum noise limited.

### 6.2.3.1 Measures of variance and covariance

Image noise can be characterized as uncorrelated in space if the value in each pixel is independent of the values in the adjacent pixels. If the system processes are additionally stationary (independent on the position and dependent only on the displacement) and ergodic (such as the incident X-ray photons), the calculation of the variance (standard deviation) per pixel of the image is required, in order to characterize the system noise.

In X-ray imaging, noise starts as ‘white noise’ (all spatial frequencies are represented in equal amounts), since the production of X-ray photons is uncorrelated both in time, in space and in direction and the probability of creating an X-ray does not depend on the previous photons that were generated, nor any subsequent photons.

In fact, images acquired by an imaging system are correlated in space. This is attributed to the fact that each photon will create multiple secondary carriers which diffuse from the point of their creation. Thus, the signal detected from a single photon is spread among several adjacent pixels. As a result, the pixel variance is reduced and neighbouring pixel values are correlated. Noise can also be correlated to the spatial non-uniformity in the imaging system (non-stationarity). In real imaging systems, this condition is only partially met and it must be decided if it is sufficiently met as to allow treating the system as shift invariant. An image usually shows spatial dependencies of both the signal and noise properties due to the differences in the efficiency and the sensitivity of the detectors. Thus, complete linear analysis of signal and noise propagation in a detector should take into consideration the dependence of both the signal and the noise on spatial frequency [117].
6.2.3.2 Noise Power Spectrum (NPS) (Wiener Spectrum)

The correlation of noise can also be determined (except the spatial domain using autocorrelation) in the spatial frequency domain using the noise power spectrum (NPS), also known as the Wiener spectrum. There are a number of requirements such as linearity, shift invariance, ergodicity and wide stationarity that should be fulfilled in order the noise properties of an imaging system to be completely described by the NPS. However, typical detectors have finite size and consequently are not stationary. In spite of these limitations, it is generally possible to calculate the local NPS.

Ideally, the NPS should be calculated from multiple images over the same region of the detector. However, by assuming stationarity and ergodicity, we can use images from multiple regions of the detector. In this way, the number of images that need to be acquired for the calculations is significantly reduced.

NPS is commonly used to characterize the imaging performance of a X-ray system. Specifically, the NPS is important in the investigation of sources of the detector noise. It facilitates the identification line frequency noise (50 or 60 Hz). In such applications, normalized NPS is calculated, since the absolute noise power values are less important compared to the relative noise power. The absolute calculations of the NPS constitute an integral part of detective quantum efficiency (DQE) and noise equivalent quanta (NEQ) measurements [333], while the NPS measurements are required to calculate the SNR in the application of signal detection theory (see section 6.3.1).

In contrast to the MTF, there is no way to measure the ‘presampling NPS’. This results, high frequency quantum noise (frequencies higher compared to those supported by the sampling grid) to be aliased to lower frequencies, in the same manner which high frequency signals are aliased to lower frequencies. Radiation detectors with high spatial resolution such as those based on photoconductors will alias high frequency noise, while detectors based on phosphors blur both the signal and the noise prior to sampling. There is no consensus if the noise aliasing is beneficial or detrimental. This role of noise aliasing is determined by the imaging task [117].

6.2.3.3 Cascade of image noise

Noise power spectra of a cascaded imaging system are more complex compared to the composition of the MTF. A proper analysis of noise should take into account various sources
of noise such as the primary quantum noise, the noise resulting from the transduction of the primary quanta into secondary quanta (such as light photons in phosphor or carriers in semiconductor), and various additional sources of noise such as electronic noise from the readout circuit of digital detectors. A simple approach to estimate the dominant source of noise in a medical image is to determine the number of quanta during different stages of the imaging cascade. The stage with the minimum number of quanta will be the main source of noise [117].

6.2.3.4 Image subtraction

A common method is to add or subtract medical images. In digital subtraction angiography (DSA) [325], a projection image with contrast agent is subtracted from a precontrast mask image to obtain an image that presents the difference in attenuation that arises from the contrast agent. This image depicts the contrast enhanced vascularity. However, the effect of this technique is to increase the image noise. This is attributed to the fact that pixel values in the precontrast and the contrast enhanced images are uncorrelated. As a result, the subtraction incorporates the noise of both images. The noise in the subtracted image is $\sqrt{2}$ greater than the noise in the source image. To improve this increase in the subtraction image, it is common to acquire the mask image at significantly higher dose, therefore decreasing the contribution of the mask noise to the subtraction.

6.3 Overall performance

The high contrast resolution of an imaging system is limited by the intrinsic blurring of the imaging system. At some point, the system is unable to distinguish two objects that are separated by a short distance, rather than displaying them as a single object. On the other hand, low contrast objects, even they are large in size, may not be perceptible because the signal of the object is significantly lower compared to the noise in the region of interest.

6.3.1 Signal to noise ratio (SNR)

Generally, the quantum SNR is defined as:
\[
\text{SNR} = \frac{\langle S \rangle}{\sigma_S}
\]  
(6.3)

where \( \langle S \rangle \) is the mean value of the signal and \( \sigma_S \) its standard deviation [333].

In the above definition of the SNR, a single pixel (or region) should be measured repeatedly over a series of images, provided that each measurement is independent. The ensemble average can be replaced by an average over a region of interest for ergodic systems. This definition is of value for quantum noise, because in a uniform X-ray field, X-ray quanta are not spatially correlated. However, the imaging systems blurring the images, and introduce correlation in the noise. As a result, it is not recommended to calculate pixel noise by analyzing pixel values in a region for absolute noise calculations. It is also important to notice that imaging systems have some lag or ghosting in which some residual signal is present over time. Lag will introduce correlation over time and make absolute noise calculations more difficult.

The quantum SNR is related to the relative variation of pixel values in a uniform region. An alternative definition of the SNR is often necessary to compare the intensity of a particular signal to the noise of the background. It is defined as the difference in the means of two regions to the noise in those regions:

\[
\text{SNR} = \frac{\langle S_o \rangle - \langle S_b \rangle}{\sigma}
\]  
(6.4)

where \( \langle S_o \rangle \) and \( \langle S_b \rangle \) are the mean values in the region of the object and background respectively, and \( \sigma \) is the standard deviation (noise) of the background (Figure 6.7). The standard deviation should be estimated using the background region that provides a meaningful result. The SNR, as defined in Eq. (6.4), can be used with different names, including the signal difference to noise ratio and the contrast to noise ratio (CNR).

According to the Rose criterion an object is distinguishable against its background if the SNR \( \geq 5 \) [334]. This requirement is actually quite strict. Depending on the image task, it is possible to operate successfully at lower SNR values. The assumption of the Rose model is that the factor limiting the detection of an object is the amount of radiation dose used to acquire the image. However, the design of imaging systems is driven by the goal of being quantum noise limited.
There are four potential factors limiting the detection of objects: (i) quantum noise limited, (ii) artefact limited, (iii) anatomy limited and (iv) observer limited. Quantum noise limited performance is the preferred mode of operation, because the ability to detect or discriminate an object is determined by the amount of radiation dose. Ideally, this represents how all the detectors should operate. Artefact limitation may occur in the case which the imaging system introduces artefacts that limit detection. Anatomy limited detection occurs when the normal anatomy mask the detection of objects, thereby reducing observer performance. Finally, in some cases which the observers’ performance is the limiting factor. For example, a lesion may be readily visible, but the observer is distracted by an apparent benign or normal finding. As a result, detection was possible but did not occur.

### 6.3.2 Detective Quantum Efficiency (DQE)

The quality of an image acquired by an X-ray imaging system is determined by the number of quanta used to produce an image. The DQE is defined as the fraction of the quantum SNR of the incident quanta that is used to produce the image. In other words, the DQE represents the fidelity of an imaging system [333, 335]. It is defined as:

\[
DQE = \frac{\text{SNR}^2_{\text{out}}}{\text{SNR}^2_{\text{in}}} \tag{6.5}
\]

where the $\text{SNR}^2_{\text{out}}$ is the SNR of the image and $\text{SNR}^2_{\text{in}}$ the SNR of the incident X-ray quanta given by:

\[
\text{SNR}^2_{\text{in}} = \varphi \tag{6.6}
\]

where $\varphi$ is the average number of X-ray quanta incident on the detector.
6.3.3 Noise Equivalent Quanta (NEQ)

The term NEQ refers to the effective number of quanta needed to obtain a specific SNR in an ideal detector [333]:

\[ \text{NEQ} = \text{SNR}^2_{\text{out}} \]  \hspace{1cm} (6.7)

so that is related to the DQE by:

\[ \text{DQE} = \frac{\text{NEQ}}{\phi} \]  \hspace{1cm} (6.8)

The NEQ indicates the net worth of the image data in terms of X-ray quanta, while the DQE denotes the efficiency of an imaging system to convert X-ray quanta into image data. The zero spatial frequency value of the DQE refers to a detector that counts X-ray quanta but does not produce an image. Thus, \( \phi \) is a simple measure of the X-ray quanta incident on the detector. By this definition, an imaging system that perfectly absorbs each photon and that does not introduce any noise will perfectly preserve the SNR of the X-ray quanta, and hence \( \text{NEQ} = \phi \) and \( \text{DQE} = 1 \).

6.3.4 Figure of Merit (FOM)

The goal of radiation protection in X-ray imaging is to obtain a figure of merit (FOM) based on the maximum benefit to the patient that corresponds to the smallest detriment. The SNR is related to the detection of an object on a background. Other metrics can also be used, such as CNR or signal difference to noise ratio. This calculation is based on parameters of the detector, so that they can be compared or optimized. It can act as a useful surrogate of the benefit, since a disease once detected can be treated. It is necessary, therefore, to relate this benefit to some metric of risk (such as the dose). This can be accomplished by introducing the FOM.

A useful metric is the ratio:

\[ \text{FOM} = \frac{\text{SNR}^2}{\text{ED}} \]  \hspace{1cm} (6.9)

where ED is the effective dose, while the \( \text{SNR}^2 \) is based on the fact that in quantum noise limited imaging, \( \text{SNR} \approx \sqrt{\phi} \); thus, the ratio is invariant with dose. Other descriptors of patient dose may also be used; for example, optimization in terms of ESD. Using the FOM, it is possible to determine the optimal exposure parameters (tube voltage, tube current, filtration) or geometric parameters for a specific task.
6.4 Artefacts

Artefacts in fluoroscopy usually arise from image distortions caused during different steps of imaging chain. Image intensifiers suffer from various image distortions, including veiling glare, vignetting, blooming, pincushion distortion and S distortion. On the other hand flat panel detectors are generally free from these distortions.

Veiling glare is a contrast reducing ‘haze’, which results from the scattering inside the image intensifier, including electrons within the electron optical system and, mainly, light photons within the glass output window. To avoid light photons, the output window of the image intensifier incorporates dopants to absorb scattered light, and whose sides are coated with a light absorbing material. In some cases, the optical coupling system between the output phosphor and the video camera is replaced by a direct fibre optic connection, which also reduces veiling glare [327].

Vignetting is an optical distortion that reduces the light intensity at the periphery of an image. This may be caused due to the deterioration of the video camera, and is also inherent to multielement lenses. It is possible to reduce vignetting in some cases by restricting the aperture size [327].

![Figure 6.8](a) Pincushion distortion (b); S distortion [327].

Blooming is due to the input of large signals to the video camera that exceed its dynamic range. These signals cause lateral spreading of charge within the camera, resulting in a diffuse image that is larger than the original. This effect can be minimized by using strict collimation of the X-ray beam. It can also be reduced or eliminated by using charge coupled device cameras [336].
Pincushion distortion causes enlargement of the fluoroscopic image near the edges (Figure 6.8(a)) and results from the curvature of the input phosphor, which is required for proper electronic focusing and structural support. Pincushion distortion is more serious for larger FOVs [327].

S distortion causes straight objects to appear curved (Figure 6.8(b)) and results from the acceleration of electrons in the electron optical system of the image intensifier in the presence of an external magnetic field, such as magnetic fields of the Earth, fringe fields from nearby magnetic resonance imaging units. S distortion can be minimized by proper site planning and by encasing the image intensifier in a high susceptibility metal [327].

6.5 Methodologies for evaluation of observer performance

The quantities used for the subjective evaluation of image quality of an imaging system measure the performance of a human observer in a well defined task based upon a series of images [333, 337, 338]. The following methodologies describe the performance of an observer in the task of detecting a known signal against a noisy background. A major disadvantage of this type of assessment is that thresholds at which objects can be (a) detected, (b) recognized and (c) identified are not the same. This means that results cannot be extrapolated from experimental studies to clinical images.

6.5.1 Contrast detail experiments

Contrast detail tests can be performed to compare X-ray systems at a given dose or the same technique over a range of exposures. There is a variety of commercially available contrast detail phantoms each of them containing objects of varying diameter and varying levels of subject contrast. The different levels of subject contrast can be achieved by utilizing either holes of different depths or circular objects with different attenuation properties. The plot of observer’s threshold contrasts as a function of the object radius is called contrast detail curve.

Some of the most popular test objects are available by the Leeds Test Objects Limited in United Kingdom [339]. The concept of their design was introduced by Hay et al. [340]. These include TOR CDR, TO 10, TO 12, TO 16, TO 20 and TOR 18FG. It is also important
to notice that these test objects are modality specific and can be used for either fluoroscopy or radiography systems.

TOR 18FG (Figure 6.9) is a routine test object designed to be used quickly and easily on a regular basis (weekly or monthly) to provide an ongoing check of imaging performance during fluoroscopy or fluorography, especially those aspects which are most liable to deterioration. It consists of eighteen circular discs of 8 mm diameter corresponding to a contrast range between 0.009 and 0.167, as well as a resolution test pattern including twenty one groups corresponding to spatial resolution values between 0.5 and 5 LP/mm. After an initial grey-scale check using the highlight and lowlight details, image quality is simply measured by counting the number of low-contrast details detected and the number of bar patterns resolved in the image. An ongoing record of these numbers will track any trend towards deterioration in imaging performance [339].

![Figure 6.9 TOR 18FG test object [339].](image)

The most important advantage of a contrast detail test is that it is easy and quick to perform. However, its greatest drawback is its subjectivity, since it depends on the observer performance. Thus, inter- and intra-observer variability can be high enough. Furthermore, because of a memory effect, the observer anticipates and reports a signal that cannot yet be
perceived. This can be attributed to the fact, that over time the observer becomes familiar with the expected image, resulting the test to lose its objectivity.

### 6.5.2 Forced choice experiments

A different method of evaluating observer performance is through alternative forced choice (AFC) experiments. In an AFC experiment, M alternative images are shown to the observer, whose task is to indicate the image that contains the signal. The percentage of correct scores (PC) in an M-AFC experiment is defined as:

$$PC = \frac{\text{number of correctly scored images}}{\text{total number of images}}$$ \hspace{1cm} (6.10)

The PC value varies between 1/M and 1. In order to more obtain accurate results, the number of images scored by the observer should be more than 100 [341]. Generally, 2-AFC experiments are carried out, such that the observers score 90% of all images correctly. Depending on the signal, the corresponding thresholds need to be very low, which can strain the observers. By increasing the number of alternative locations, the experiment becomes more difficult and higher thresholds may be required. The alternative signal locations can be on the centre of individual regions of interest or fixed locations contained within one single test image [342].

The CDRAD phantom (Figure 6.10) is designed for testing the physical properties of the X-ray systems, as well as the observer’s perception. It has been adapted from the Burger phantom [343]. It quantifies both the contrast detail properties of the system and the observer’s perception of these contrasts and details. The CDRAD phantom [344] is manufactured by Artinis Medical Systems B.V. in Netherlands and is applicable within the entire range of the X-ray systems, such as radiography, fluoroscopy and DSA. It consists of a squared Plexiglas tablet (265 x 265 mm$^2$) with a thickness of 10 mm, comprising 15 rows and 15 columns each of them containing cylindrical holes of specific diameter and depth. The first three rows include only one hole in each square, while the other rows include two identical holes, one at the centre and one randomly placed at one of the four corners, to allow verification of the detection of each object. Within a row the diameter is constant with exponentially increasing depth (from 0.3 to 8 mm), while within a column the depth is constant with exponentially increasing diameter (from 0.3 to 8 mm). This means that in
horizontal direction the image shows increasing contrast, while in vertical direction the image shows increasing spatial resolution.

There are four different patterns available, in order to avoid memorizing of the position of the corner holes, as the observers become familiar and gain experience with the usage of the phantom. In addition, the arrangement of the details is irregular and thus the observer cannot intuitively predict the location of a detail.

**Figure 6.10** Schematic representation of CDRAD 2.0 contrast detail phantom [344].

The image quality can be expressed in terms of correct observation ratio (COR), which is defined as the ratio of the correctly identified hole positions to the total number of squares [344]:

$$\text{COR} = \frac{\text{correctly observations}}{\text{total number of squares}} \times 100\%$$

(6.11)

Another method to quantify image quality is the Image Quality Figure (IQF) [345, 346]:

$$IQF = \sum_{i=1}^{15} C_i \ast D_{i,\text{th}}$$

(6.12)

where $C_i$ is the contrast in column i and $D_{i,\text{th}}$ is the threshold diameter in contrast column i.
Image quality increases with increasing number of correctly identified holes. In this case, the IQF becomes lower because the values of diameter and depth of the threshold holes are relatively small. Thus, the inverse IQF (IQF$_{inv}$) [344]:

\[
IQF_{inv} = \frac{100}{\sum_{i=1}^{15} C_i \ast D_{i,th}}
\]

(6.13)
can be used, in order to provide an increasing index for increased image quality.

The results can also be presented in a graph, called contrast detail curve [344], in which the threshold hole depth is plotted as a function of the hole diameter. For the comparison of different systems, images are acquired under identical exposure conditions and evaluated by the same observer and at the same time under the same viewing conditions. The better system will produce an image in which smaller contrasts and details are visible. This results to a shift of the contrast detail curve to the lower left part of the image (Figure 6.11). Comparison of the performance of several observers is also possible. In this case, the better performing observer produces a contrast detail curve more to the lower left part of the image.

![Figure 6.11 Contrast detail curve obtained with the CDRAD 2.0 phantom [344].](image)
6.5.3 Receiver operating characteristic (ROC) analysis

Receiver operating characteristic (ROC) analysis is the most complete way of quantifying observers’ performance in detection tasks. The ICRU reports that the ROC analysis is the standard method that allows the assessment of the performance of an imaging system without observer bias [347]. According to ROC analysis image perception by an observer does not only depend on the physical characteristics of the imaging system or the pathology but also on the performance characteristics of the observer and its ‘critical confidence level’. There are usually four confidence levels:

1. = certainly present
2. = probably present
3. = probably not present
4. = certainly not present.

In ROC studies the correct status of the image must be known. Images of phantoms containing lesions or abnormalities or clinical images can be used. The simplest approach, includes images that contain either one or no lesion and the observer is asked to indicate whether an abnormality/lesion is present or absent, as well as his or her critical confidence that is present. Despite the fact that ROC analysis is widely accepted as the gold standard of image quality assessment, its use is limited for routine quality assurance, since it is time consuming. There are variants of the ROC methodology which aim to increase the statistical power of the assessment. A detailed review of the different variants of the ROC method is given elsewhere [348].

6.5.3.1 Statistical decision theory

The task of detecting a signal is a binary decision because there are two truth states: the ‘normal’ state or the absence of a signal (H₀), and the presence of a signal (H₁). The observer must decide whether to categorize an image as normal (D₀) or as containing a signal (D₁). There are four possible outcomes to this decision (Table 6.1). A ‘true positive’ (TP) outcome occurs when an image that contains a signal is assigned to H₁. A ‘false negative’ (FN) outcome occurs when an image that contains a signal is assigned to H₀. A ‘true negative’ (TN) outcome occurs when an image that does not contain a signal is assigned to H₀, while a ‘false positive’ (FP) outcome occurs when it is assigned to H₁ [349].
Table 6.1 Decision outcomes of a detection task.

<table>
<thead>
<tr>
<th>Decision</th>
<th>Actual condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>$H_0$: signal absent (negative)</td>
<td>$H_1$: signal present (positive)</td>
</tr>
<tr>
<td>$D_0$: signal absent (negative)</td>
<td>TN</td>
</tr>
<tr>
<td>$D_1$: signal present (positive)</td>
<td>FP: type I error</td>
</tr>
<tr>
<td></td>
<td>FN: type II error</td>
</tr>
<tr>
<td></td>
<td>TP</td>
</tr>
</tbody>
</table>

There are two types of decision error. A type I error occurs when the truth state $H_0$ is rejected by the observer, in cases that it is actually true (FP). A type II error occurs when the truth state $H_0$ is not rejected, in cases that it is not true (FN). In medical imaging, a type I error results in patient stress and societal costs because of additional examinations, while a type II error results to misdiagnosis.

The accuracy of a procedure is defined as [350]:

$$\text{accuracy} = \frac{TP + TN}{N}$$  \hfill (6.14)

More meaningful performance measures are sensitivity, specificity. The sensitivity or the true positive fraction (TPF), measures the proportion of positive cases that are correctly detected [350]:

$$TPF = \frac{TP}{TP + FN}$$  \hfill (6.15)

Specificity measures the percentage of negative cases that are correctly identified. It is estimated through the false positive fraction (FPF) as follows [350]:

$$\text{specificity} = 1 - FPF$$  \hfill (6.16)

where

$$FPF = \frac{FP}{FP + TN}$$  \hfill (6.17)

In some cases, positive predictive values (PPVs) and negative predictive values (NPVs) are also reported:

$$PPV = \frac{TP}{TP + FP}$$  \hfill (6.18)

$$NPV = \frac{TN}{TN + FN}$$  \hfill (6.19)
In ‘decision theory’, the observer derives a decision variable, \( \lambda \), from each image. The probability density functions of the variable \( \lambda \) under the truth states \( H_0 \) and \( H_1 \), \( p(\lambda|H_0) \) and \( p(\lambda|H_1) \), are illustrated in Figure 6.12.

\[ \lambda = \lambda_c \]

**Figure 6.12** Decision outcomes in statistical ‘decision theory’ [117].

The ‘operating point’ of the observer, \( \lambda_c \), is the decision threshold at which the observer will call an image ‘normal’ (negative) or ‘abnormal’ (positive). Both the sensitivity and specificity values depend on \( \lambda_c \). It is often assumed that the probability density functions are normally distributed so that a binormal model can be used.

**Figure 6.13** Decision thresholds for probability density functions [117].

Different \( \lambda_c \) values reflect the vigilance of the observer (Figure 6.13). A low decision threshold (\( \lambda_c = A \)) represents an ‘aggressive’ observer, characterized by high sensitivity but simultaneously low specificity. The choice of the decision threshold depends on the task and
the ‘costs’ related with decision errors. In a diagnostic task, the reader might be ‘aggressive’, while when screening for a condition with low prevalence a high specificity (FPF < 0.1) is required (points B or C), although it results decrease in sensitivity.

Figure 6.14 ROC curves are symmetrical since the underlying probability density functions have equal variance [117].

The ROC curve illustrates the balance between sensitivity and specificity. It is generated by plotting the TPF as a function of FPF for all values of $\lambda$ (Figure 6.14). The start and the end points of the ROC curve are (0, 0) and (1, 1), respectively. The ROC curve lies on or above the diagonal. In cases which the ROC curve is below the diagonal, then the truth states $H_0$ and $H_1$ have been alternated, due to the observer misreading instructions. If the probability density functions of the truth states have equal variance, the ROC curve is symmetrical about a line from (0, 1) to (1, 0).

The area under the ROC curve (AUC) quantifies the overall decision performance. The values of AUC vary between 1.0 and 0.5. A perfect observer achieves an AUC of 1.0, while random guessing results in an AUC of 0.5. However, the AUC does not provide any information about certain regions of the ROC curve, which may be important when selecting between two procedures that are going to be used in a given detection task.
6.5.3.2 Receiver operating characteristic (ROC) experiments

In an ROC experiment, a single image is shown to the observer whose task is to provide a likelihood rating. For example, in a detection experiment, this could be the ‘likelihood of signal present’. Continuous rating scales or categorical scales consisting of less than ten categories have been used. ROC experiments provide better statistical power because one single image is required per trial, while in a 2-AFC experiment two images are required per trial. The ROC curve generated from rating data provides more detailed information about the task performance in specific regions of interest. However, ROC experiments are more demanding for the observer. This results in an increase to the reading time and observer fatigue. Curve fitting problems (such as the presence of hooks) can be overcome utilizing curve fitting software [351], whose curve fitting model does not allow the ROC curve to fall below the diagonal.

The most important limitation of ROC or 2-AFC experiments is the absence of signal localization. In clinical practice, the radiologist is required to identify the locations of potential lesions and to provide an overall rating of the image. To allow for more clinically realistic experiments, several extensions to ROC methods have been developed.

In the location ROC (LROC) experiments, the observer is required to identify the location of a lesion and to provide a confidence score. In an LROC curve, the FPF is plotted along the x axis, while on the y axis the TPF with correct signal detection. The upper right end point of the LROC curve is determined by the proportion of correctly detected signals.

In free response ROC (FROC) experiments, the observer is required to indicate the location of a lesion, but no scoring is provided. The FROC curve is the percentage of correctly detected signals plotted versus the average number of FP detections per image. FROC experiments are often used in the performance evaluation of computer aided detection systems [352].

In alternative free response ROC (AFROC) analysis [348], the proportion of correctly identified signals is plotted versus the probability at least one FP per image is found. In the AFROC analysis, a summary figure of merit exists, $A_{1J}$, which is the probability that lesions are rated higher than FP values in normal images. JAFROC is a software package developed to calculate $A_{1J}$ and statistical significance from human observer FROC data [353].
6.5.4 Viewing conditions

Ambient conditions in a viewing room can significantly affect observer performance. Ambient lighting decreases observers’ performance and should be kept below 50 lx. It is also recommended that observers need to wait at least 5 min for dark adaptation of their eyes prior to any reading. Moreover, there are indications that fatigue deteriorates performance [354].

6.5.5 Limitations of observer performance studies

The most important limitation of observer performance studies is intra- and inter-observer variability. The decision of an observer is mainly affected by his/her experience, perceptions, expectations, preferences and viewing conditions. The lack of consistency in the perception of images has been shown in studies where the observers were asked to re-evaluate images after a specific time interval and their perceptions were shown a variation up to 20%. To reduce intra- and inter-observer variability, it is recommended the use of multiple observers, averaging observer scores, observers should be experienced with images to be perceived and a reasonable time period should be elapsed before the next reading session in order to reduce memory bias from the observers.
CHAPTER 7

PATIENT DOSIMETRY ISSUES

7.1 Introduction

Patient dose estimation and dose surveys are important tools for QA in radiology. In order the patient exposures to be documented, well-defined and easy to use methods of dose measurement are required. QC also requires methods to estimate image quality for optimization of the each procedure. The concept of reference levels (RLs) was introduced as a practical tool to achieve optimization [156]. It should be seen as a practical aid to increase the awareness about the significance of patient dose levels and hence to promote optimization of imaging procedures. The adoption of the third quartile values for the establishment of diagnostic reference levels (DRLs) is a purely realistic approach to help identify those departments in most urgent need for better QC. In order to achieve meaningful comparisons between hospitals, nationally and internationally, standardized methods of dose measurement are needed. Since the risk for stochastic effects is believed to be without a threshold, the detriment increases with increasing patient dose. Patient dose measurements are therefore becoming of critical importance.

Dose measurements can be made either on patients or using appropriate phantoms. The use of phantoms for dosimetry purposes is also particularly important for the assessment of equipment performance. Close co-operation between the ICRU [277] and the IAEA is considered essential towards standardization processes and traceability of medical dosimetry. The IAEA Code of Practice [296] places emphasis on the selection of the appropriate equipment for dosimetry in diagnostic and interventional radiology (see Chapter 5), recommendations for establishing calibration facilities and guidance for dosimetry in clinical practice. The recommended measurements and dosimetric quantities need to be measured for each modality are summarized in Table 7.1.
**Table 7.1 Dosimetry quantities and measurement methodology for different modalities [296].**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Measurement subject</th>
<th>Measured quantity</th>
<th>Methodology</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>General radiography</td>
<td>Phantom</td>
<td>Incident air kerna</td>
<td>Methodology for using chest and abdomen/lumbar spine phantoms is described.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>Incident air kerna</td>
<td>Calculated from exposure parameters and measured tube output.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Entrance surface air kerna</td>
<td>Measurements on patient’s skin.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Air kerna-area product</td>
<td>Methodology same as for fluoroscopy.</td>
<td></td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>Phantom</td>
<td>Entrance surface air kerna rate</td>
<td>Measured directly on a phantom or calculated from the incident air kerna rate using backscatter factors.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>Air kerna-area product</td>
<td>Maximum skin dose is also measured. As the methods are not standardized they are not included in this Code of Practice.</td>
<td></td>
</tr>
<tr>
<td>Mammography</td>
<td>Phantom</td>
<td>Incident air kerna</td>
<td>Mean glandular dose is the primary quantity of interest. It is calculated from measured incident air kerna.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>Incident air kerna</td>
<td>Mean glandular dose is the primary quantity of interest. It is calculated from the incident air kerna estimated from measurements of tube output by using the exposure parameters for the examination.</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>Phantom</td>
<td>CT air kerna indices</td>
<td>Measurements in air or in PMMA head and body phantoms.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient</td>
<td>CT air kerna–length product</td>
<td>Direct measurements on patients are not described in this Code of Practice. Instead, a CT air kerna–length product is calculated from patient exposure parameters and results of phantom measurements.</td>
<td></td>
</tr>
<tr>
<td>Dental radiography</td>
<td>Patient</td>
<td>Incident air kerna</td>
<td>Calculated from exposure parameters and measured tube output for bitewing projection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Air kerna–length product</td>
<td>Used for calculation of the air kerna–area product for a panoramic projection.</td>
<td></td>
</tr>
</tbody>
</table>

It is preferable to perform dose measurements using a phantom simulating the patient in order to control the technical parameters, to compare the same system at different times, to compare different systems and for optimization of the procedure. When a phantom is used, the measured dose values will depend on its shape and size and it is essential that it is standardized so that such variations are avoided.
Dose measurements performed using a phantom cannot provide a direct estimation of the average dose for a given patient population and cannot indicate the dose variations occur in clinical practice because of the differences in patient size and composition and in radiographic technique. Thus, it is important that any measurements made using phantoms to be supplemented by measurements made on patients.

The IAEA Code of Practice [296] does not always determine the number of readings that should be taken for measurements with phantoms or on patients. In the case of patient dose measurements, only a single reading is possible unless multiple dosimeters are used (for example TLDs). It is important that TLDs are of high sensitivity and capable of detecting an air kerma of 0.1 mGy. It is a good practice to use a TLD dosimeter consisting of at least three TLD chips. For measurements with phantoms, it is possible to obtain only a single reading. When performing measurements as part of a QC programme only limited time may be available for a series measurements. This will introduce additional uncertainties mainly because of the uncertainty of exposure reproducibility and the uncertainty resulting from the accuracy of the measuring equipment.

The X-ray equipment for which the dose is measured should be properly maintained as part of regular QC and performs according to its specifications. The tube output should exhibit linear response with respect to the tube loading. Otherwise, additional measurements will be required.

This chapter provides information regarding the procedures followed for performing both phantom measurements and clinical measurements on patients. In each case, the description of the methodology is accompanied by a discussion describing the dosimetric quantities and the equipment used.

7.2 Dosimetric quantities in fluoroscopy

The ESAK rate is the primary quantity to be measured in fluoroscopy when using phantoms. On the other hand, for measurements on patients the KAP is the recommended dosimetric quantity [296]. It is a readily measured quantity closely related to the energy imparted to the patient and to the ED. Estimation of the maximum ESAK is particularly important for patients undergoing fluoroscopically guided procedures. Since the beam position on the entrance surface of the patient is not fixed, during such procedures, special methods are required to locate the maximum value.
7.3. Uncertainties in dosimetric quantities

The measurement uncertainty desirable in the application of specific quantities depends on the use of the measurement to be made [117].

- For estimation of absolute stochastic risk: 10%.
- For estimation of relative risks (comparative dose measurements): 7%.
- For estimation of the dose to the embryo/fetus: 7%.
- For quality assurance: 7%.

These uncertainties correspond to an expanded uncertainty (k = 2), and are in addition to any uncertainties occur in conversion coefficients used for the calculation of the risk related quantities. It is essential to estimate uncertainties for each measurement, but it is dubious whether these uncertainties can be achieved in all cases [118]. Background information is given in the following sections for both directly measured quantities, as well as quantities derived from directly measured quantities.

7.3.1 Uncertainties in quantities directly measured with dosimeters

The uncertainty associated with dose measurements depends on the type of dosimeter, a priori information about the radiation quality, the use of such information for determining the value of quality factor for the prevailing radiation quality, the accuracy with which the dosimeter is located at the measurement point, etc. In practice, it is recommended to select the desired level of uncertainty for a given task and then perform the appropriate measurements to achieve it. Information about the uncertainty levels are given in Table 7.2.

Scenario 1 refers to the case where an instrument in compliance with IEC standards is employed [313] (see second column in Table 7.2). It should be noted that these requirements represent a minimum level of performance, which may be exceeded significantly by ‘good’ instruments. In this scenario, the value of the measured quantity is obtained by multiplying the dosimeter reading by its calibration coefficient. An air density correction need to be applied based on the normal pressure at the altitude above the sea level at the location where the measurement is performed and on the average temperature in the room of measurement. No additional corrections are applied. This is acceptable as there is an upper limit on the range over which the dosimeters’ response can be varied when an influence quantity deviates from its respective reference value.
Scenario 2 (see third column in Table 7.2) refers to the case where a reference dosimeter the performance of which exceeds the requirements introduced by the IEC 61674 is used [313]. In this scenario, the air density correction needs to be based on the actual pressure and temperature values taken at the time of measurement. Except that, all the procedures in scenario 2 correspond to those of scenario 1. The decrease in uncertainty from scenario 1 to scenario 2 is achieved by decreasing the intrinsic error through calibration by a SSDL and by using a detector with a small energy dependence of response.

Scenario 3 (see fourth column in Table 7.2) describes the case where the conditions of exposure are tightly controlled (radiation quality, direction of radiation, air density, etc.) and where corrections for all relevant influence quantities are performed. A reference class dosimeter is used for measurements in this scenario.
7.3.2 Uncertainties in quantities derived from directly measured quantities

In many cases, it is important to determine quantities other than those directly measured by the dosimeter. Thus, additional contributions to the uncertainty of these quantities need to be taken into account [296].

For example, the ESAK can be determined by measuring air kerma on the surface of a phantom or the patient. In this case, the contributions of both INAK and backscattered radiation need to be taken into account. Alternatively, the INAK can be multiplied by the BSF corresponding to the exposure conditions prevailing (tube voltage, filtration, field size, anode material and angle).

Regardless of which of the two methods is employed, contributions other than those given in Table 7.2 need to be taken into account. The radiation backscattered from the patient has a spectral and angular distribution different compared to that of the incident radiation. As a consequence the response of the dosimeter to the backscattered radiation may be different than that of the incident. In the second alternative, the BSF is also associated with some uncertainty.

7.4 Dosimetry in fluoroscopy

Fluoroscopy is frequently used to assist a variety of medical procedures. More complex procedures also involve the generation of radiographs of specific anatomical areas. There are many factors that influence the patient dose during fluoroscopically guided procedures, such as fluoroscopy dose mode, frame rate (for fluorography and pulsed fluoroscopy), the number of radiographs generated, field size, magnification, fluoroscopy time (FT) and the complexity of the procedure. The fluoroscopy equipment is capable of producing very high dose rates and FT is normally measured in minutes. As a result, examinations involving fluoroscopy have radiation doses that may be significantly higher than those encountered in conventional radiography.

In interventional procedures, the local skin dose may become very high due to the long periods of fluoroscopy and the high number of frames and this may lead to skin erythema. Estimation of the ESAK on patients undergoing fluoroscopically guided procedures is therefore of critical importance. In such procedures, the position of the X-ray beam on the entrance surface of the patient is not fixed and special methods are required to identify the
maximum ESAK value. Knowledge of the skin dose during the procedure is necessary in order to avoid deterministic effects or to reduce their severity. Knowledge of the skin dose after the procedure is necessary, in order to resolve which patients require follow-up for potential deterministic effects.

The total KAP for the examination and the total FT are displayed on the console. The KAP is measured with a KAP meter, but can also be calculated. In the case of undercouch installations, the measured KAP overestimates the KAP delivered to the patient, because of the attenuation of the X-ray beam by the patient couch. Accurate correction for patient couch and table top attenuation is usually not practical as it is affected by the X-ray beam quality and projection.

Modern interventional fluoroscopy systems report the INAK at a reference point calculated from the KAP, the collimator settings and the exposure geometry. The reported INAK can be used to estimate the maximum value of the ESAK. This is considered as the maximum value since changes in the projection during the examination have been ignored. Despite its limitations, it may be a useful quantity for monitoring skin dose, but must be completely understood, calibrated and implemented with caution in patient dose surveys.

Measurements of ESAK rates on phantoms for selected clinical protocols and typical projections can be combined with FTs, exposure parameters and field size to estimate of the total ESAK for examinations.

There are two general approaches for the measurements:

i. Direct measurement on patients or phantoms.

ii. Indirect measurements on patients or phantoms. Free-in-air measurements to characterize the X-ray tube output can also be performed, which are then scaled for geometry and exposure parameters using actual patient or phantom exposures.

7.4.1 Measurements using phantoms

Dosimetry measurements with phantoms are very useful for QC, to evaluate equipment performance and to perform an intercentre comparison of a ‘standard patient’, but they cannot provide a direct estimate of the average dose for a given patient population. They cannot indicate the dose variations observed in practice because of the differences in patient size, in technique and experience of the operators performing the examination complexity, as well as differences in the exposure parameters that may be selected manually or
automatically. Such information can be obtained by measuring the patient dose for a sample of actual patients, or estimating its value using patient exposure parameters.

The measured dose will depend on shape and size of the phantom, and it is required that the phantom be standardized so that such variations are avoided. Phantoms must provide the same primary attenuation and scatter production as a typical patient over the whole range of energies used in clinical practice. Scatter may be important in terms of the spectrum of scattered radiation leaving the exit surface of the phantom and/or in terms of the spectrum of backscattered radiation. It is also desirable that such phantoms be inexpensive and constructed from readily available materials of stable and homogeneous composition and be stable dimensionally.

Slab phantoms made of PMMA or polystyrene containers (wall thickness of about 6 mm) filled with water are recommended by the ICRU [355, 356]. Simple phantoms constructed completely from PMMA or using PMMA (or polystyrene) as the wall of a box which is filled with water or a suitable solid substitute for water are described elsewhere [357]. They also include acrylic resins that can be varied in composition to match the properties of specific types of tissue [358, 359]. ICRU 48 [355] describes a wide range phantoms which are suitable for various imaging and dosimetric measurements in radiology. Some phantoms are designed for specific procedures while others are of general usage. These include and anthropomorphic phantoms, constructed from tissue substitute materials sometimes with embedded human bones. Such phantoms usually have cavities for the insertion of TLDs and are very useful for elaborate studies of the dose distribution within the body.

Sandborg et al. investigated the equivalency of 10 different materials with respect to several quantities [360]. The thickness of the phantom material corresponding to a specific thickness of soft tissue was determined at tube voltage 100 kV and was found to depend upon the thickness of soft tissue and the particular dosimetric quantity studied. Tissue substitutes ‘Mix-D’, ‘M3’ and water showed the closest equivalence to soft tissue, while materials without elements of atomic number > 6 (polystyrene and paraffin wax) were less good. PMMA showed intermediate performance between these two groups.

The IAEA has taken a similar approach in recommending an appropriate phantom for radiography and fluoroscopy. It recommends using a rectangular phantom of tissue equivalent material with a cross-sectional area of $30 \times 30$ cm$^2$ and thickness of 20 cm to simulate the trunk in anteroposterior - posteroanterior views (see Figure 7.1). Two polycarbonate containers, each one 10 cm thick filled with water, are recommended. A third
similar container may be added to simulate a heavier patient. It can also be noticed that in order to have a standardized geometry with flexible use of different phantom thicknesses, the 20 cm phantom provides an air gap between it and the image intensifier. Alternatively, a phantom of 18.5 cm of PMMA can be used. The water phantom is recommended because the backscatter from the two component CDRH phantoms (PMMA and aluminum) [361-363] may not give a good measure of the backscatter from the patient. Jennings describes a method for designing two component phantoms which can accurately simulate the attenuation and scattering properties of a given body section [364].

![Water phantom for measurements of ESAK in fluoroscopy](image)

**Figure 7.1** Water phantom for measurements of ESAK in fluoroscopy [296].

### 7.4.1.1 Equipment for measurements using phantoms

The ESAK rate can be measured using a water or a PMMA phantom. It is important that the detector responds to both direct and backscattered radiation. Alternatively, for detectors that do not respond to backscattered radiation, the ESAK rate can be calculated from the measured INAK rate and an appropriate BSF. Semiconductor detectors often possess this property.

The equipment consists of a:

(a) Dosimeter calibrated for beam qualities used in fluoroscopy.

(b) Chamber support stand.

(c) Water phantom of 20 cm thickness and cross-section of $30 \times 30$ cm$^2$. 

125
(d) Additional water phantom of 10 cm thickness and cross-section of $30 \times 30 \text{ cm}^2$ to simulate larger patients.

(e) Rig to support the phantom above the detector.

(f) Ruler.

(g) Thermometer and barometer (for measurements with an ionization chamber).

7.4.1.2 Aspects for measurements using phantoms

The 20 cm thick water phantom represents a standard adult patient [365]. Larger patients are simulated by adding another 10 cm of water. The walls of the container can also be made of PMMA. Suleiman et al. [366] modified the CDRH abdomen/lumbar spine phantom for fluoroscopy applications, in order to obtain a laterally homogeneous phantom with a smaller cross-sectional area compared to those of radiographic fields. Martin et al. [357] recommend the usage of a rectangular phantom of tissue equivalent material with cross-sectional area of $30 \times 30 \text{ cm}^2$ and thickness of 20 cm in accordance with the phantom recommended in the UK [367]. They provide a correction factor of 1.22 with which to correct the measurements of the ESAK made with a 20 cm PMMA phantom to correspond to those made using a 20 cm water phantom. The use of this single correction factor will introduce an uncertainty of 10%. They also found that a thickness of 185 mm could be used for the simulation of 200 mm of water for tube voltages in the range 60-110 kV with an uncertainty of less than 2%. While this is true for the radiation transmitted through the phantom, which controls the operation of the automatic brightness control (ABC), the backscattering properties of the phantom are also important and need to be taken into account when the ESAK rates are measured. A correction for different BSFs will be needed.

The fluoroscopy system should be operated under ABC. Care should be taken to ensure that the ABC system has stabilized before each measurement. Additionally, since fluoroscopy systems employ ABC, laterally homogeneous phantoms are preferred due to the difficulty of positioning an inhomogeneous phantom so as to achieve reproducibility of the measurements. If the dose rate does not stabilize, an investigation is recommended. Measurements should be carried out for all image intensifier field sizes, dose rates and ABC options representing routine clinical practice. The focus to image intensifier and focus to chamber distances, tube voltage, tube current, as well as any filtration selected should be recorded for each measurement.
A phantom with a smaller cross-sectional area may be used for measurements on systems with smaller image intensifiers, but the area must be large enough in order to cover the entire X-ray beam at its exit surface with the collimators completely open. The CDRH fluoroscopy phantom [366] has a cross-sectional area of $178 \times 178 \text{ mm}^2$. It consists of PMMA and aluminum sheets, positioned on the side of the phantom facing the X-ray tube. As the backscatter from the aluminum is likely to be significantly different from that of water, this choice is less satisfactory for measurements of the ESAK.

The measurements are highly dependent on the relative positions between the X-ray tube, patient entrance surface and image intensifier. Figure 7.2 presents the measurement geometry of patient ESAK rate for four different equipment configurations: (a) an under couch installation, (b) an over couch installation, (c) a C-arm fluoroscopy system, (d) C-arm fluoroscopy system, lateral exposures [357]). Instructions for these measurements are given in the IAEA Code of Practice [296].

**Figure 7.2** Configurations for measurement of patient ESAK (a) an under couch installation, (b) an over couch installation, (c) a C-arm unit, (d) C-arm unit, lateral exposures [296].
The uncertainty in the measurement of the ESAK rate can be estimated using the values of the relative uncertainties as given in Table 7.2 and adding additional contributions arising from factors specific to the procedure employed. The main source of the additional uncertainty arises from the effect of the radiation backscattered from the phantom on the energy response of the detector. The backscattered radiation has a spectral and angular distribution differing from that of the incident radiation. In addition, the effective measuring point of the dosimeter is not on the surface. No data are available but it is estimated that for ionization chambers these effects may introduce an additional uncertainty of 5%, at most, corresponding to a standard deviation of about 3%. This may be slightly less for a semiconductor detector but as no data are generally available, the above value for the ionization chambers will also be a good upper limit of the uncertainty for the semiconductor detectors. The contribution of these factors to the uncertainty in the determination of the ESAK rate is given in Table 7.3. The relative expanded uncertainty lies between about 8% and 14% depending on the scenario selected.

<table>
<thead>
<tr>
<th>Source of uncertainty</th>
<th>Uncertainty ((k = 1)) (%)</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement scenario (see Table 7.2)</td>
<td></td>
<td>6.3</td>
<td>3.5</td>
<td>2.7</td>
</tr>
<tr>
<td>Precision of reading</td>
<td></td>
<td>1.0(^a)</td>
<td>0.6(^b)</td>
<td>0.6(^b)</td>
</tr>
<tr>
<td>Uncertainty in measurement position(^c)</td>
<td></td>
<td>0.6</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Uncertainty in detector response to backscattered radiation</td>
<td></td>
<td>3.0</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Relative combined standard uncertainty ((k = 1))</td>
<td></td>
<td>7.1</td>
<td>4.7</td>
<td>4.1</td>
</tr>
</tbody>
</table>

\(^{a}\) One single reading taken.  
\(^{b}\) Standard deviation of the mean of three readings.  
\(^{c}\) Corresponding to 2 mm in the positioning of detector at a distance 500 mm from the X ray focus.

### 7.4.1.3 Measurement of the tube output

In situations where the exposure parameters are known, the INAK can be calculated directly from knowledge of these parameters and measurements of the X-ray tube output \((Y(d))\), using the equation:
\[ I_{NAK} = Y(d) P_h \left| \frac{d}{d_{FSD}} \right|^2 \]  

(7.1)

where

\( d_{FSD} \) is the focus skin (or phantom surface) distance,
\( d \) is the distance from the focus to the point of the tube output measurement,
\( P_h \) is the tube loading (mAs).

For the tube output measurement, the dosimeter is placed free-in-air on the central axis of the X-ray beam and high enough above the table to reduce the effects of backscatter to a low level. A solid state dosimeter with shielding for backscatter may be placed on the patient table (Figure 7.3). Tube output should be measured at a range of tube voltages and for the filters used in clinical practice. For the purposes of interpolation, the tube output for each filter can be fitted to:

\[ Y(d) = a(kV)^n \]  

(7.2)

where

\( Y(d) \) is the X-ray tube output,
\( kV \) is the tube voltage,
and \( a \) and \( n \) are constants, which are specific to the filter and target, respectively.

**Figure 7.3** Geometry for measurement of the tube output using a solid state dosimeter [117].
7.4.2 Patient dose measurements

The objective of patient dosimetry is generally to obtain an indication of the typical dose being delivered to an average-sized patient by the procedures and equipment used in a particular facility. For example, such measurements may be used for the establishment of DRLs.

Direct dose measurements during examinations provide the best indication of actual clinical practice. Patients, however, vary in size and hence in the thickness and density of the part of the body being examined. In order to be representative of the routine clinical practice in a particular facility and to be comparable with those from another facility, a careful selection of the measurement sample is required. A single measurement will not represent the clinical practice. The dosimetric data will need to be recorded from a patient cohort so that a median and/or average value can be estimated. Such values can be used for comparative studies at local, regional, national and international levels, always provided that the median values of the patient samples are similar. It is also evident that the patient cohort selected should be sufficiently large to reduce statistical variations in the median or the average dose to an acceptable level. Care has to be taken in the selection of patients according to their anatomical characteristics (body weight, height, thickness, body mass index (BMI)). A sample size in the range of 10-50 patients have been reported in the literature [368]. The patient sample should be selected so that the mean value of the patient weight lies within ± 5 kg of the 70 kg [369] or within ± 5 kg of the 60 kg in some geographical regions [370], in order the average value of the doses to be a good indication of the typical dose to an average patient. The use of the sample median rather than the sample mean has the advantage that it is little influenced by outlying values arising from very large or very small patients. If the sample average is to be used, patient selection based on weight can be helpful if the sample size is small. In any case, the recording of patient weight and height is recommended, to assist the interpretation of the results. Finally, it is noted that the relationship between risk related quantities and measured application specific quantities will depend on the field size and beam quality. Information concerning these parameters should be recorded as appropriate.

The IAEA Code of Practice [296] does not provide specific values for the number of patients or their size to be involved for a particular study. The sample should be selected so that best represents the patient population studied. It should be large enough to avoid statistical variations caused by a small number of patients and large variations in recorded
doses. If the number of patients involved in the procedures is not sufficient to provide a sufficiently large sample within given anatomical limitations, deviations from these limitations can be performed and the dose for a representative patient can be estimated by interpolation from doses to patients within an appropriate range of the anatomical characteristics. It would be advisable, at least for frequent examinations, to exclude those patients whose weights lie outside the 20 kg limit on the mean weight.

Generally, TLDs attached to the skin of the patient are recommended for the direct measurement of the ESAK in examinations with fixed projections. Alternatively, the INAK can be calculated with knowledge of the tube output and exposure factors. In examinations using fluoroscopy, the irradiation geometry and irradiation times vary individually. In this case, a KAP meter is recommended for the measurement of the KAP value. In interventional procedures carried out under fluoroscopic guidance, high absorbed doses may occur, due to long FTs. TLDs placed on the skin may underestimate the maximum absorbed doses if they are not placed at the right position. KAP measurements may be used to give an indication of the maximum skin dose by dividing the KAP value by the entrance area of the field on the patient. Alternatively, devices may be employed that allow the simultaneous measurement of the KAP and the ESAK. In such a combination the risk for stochastic effects may be assessed by means of the KAP and that for deterministic effects by means of the ESAK.

7.4.2.1 Equipment for patient dosimetry

The equipment consists of a:

(a) Dosimeter calibrated for beam qualities used in fluoroscopy.
(b) Chamber support stand.

7.4.2.2 Aspects for patient dosimetry

In examinations using fluoroscopy, exposure geometry and time vary from patient to patient. Effects of these variations on patient exposures are captured by the KAP value, which is easily measured using a flat transmission ionization chamber (KAP meter) mounted on the collimator housing. An important advantage of the KAP meter is that does not disturb the examination and provides real time information [371]. Thus, the measurement of the KAP using a KAP meter, either transmission chamber or built-in (software) meter, is recommended by IAEA Code of Practice for monitoring patient exposures in examinations.
involving fluoroscopy [296]. It is closely related to the energy imparted to the patient and ED and is thus suitable for comparisons of patient exposures.

The KAP meters should be calibrated for each condition where they are used. In principle, calibrations both in situ and at a SSDL are possible. However, it is unrealistic to calibrate each instrument at a SSDL and for built-in KAP meters this is not even possible. In this case, in-situ calibration is the only method available. In situ calibration is needed, in order to manage suitably the heterogeneous distribution of air kerma in the beam caused by the heel effect and extrafocal radiation [314, 316, 372, 373]. Procedures for in situ calibration of the KAP meter are described in Appendix C.

For use in interventional radiology, it has been recommended an extra copper filter to be added to the conventional aluminum filter. A separate calibration have to be performed for this set-up since the copper filtration introduces a beam hardening effect that may affect the calibration coefficient by as much as 6% at the same tube voltage. In some practices, this has been accomplished by placing the extra filter on top of the KAP meter [374]. The signal from the KAP meter will increase more than that from the reference chamber, due to the effect of scattered radiation produced in the filter.

IEC 60580 [317] specifies the acceptable limits of uncertainty in the response of KAP meters when the exposure parameters vary to the maximum likely extent. According to the IEC standard, the estimated expanded uncertainty of a KAP measurement is 25% at the 95% confidence interval (k = 2). This corresponds to the application of a single calibration coefficient representing an average over all influence factors. If the tube voltage is recorded and calibration coefficients for undercouch and overcouch installations are separately determined and applied, this uncertainty can be reduced. However, if the calibration coefficient has only been established for an overcouch installation, it is noted that the interference of a table with a mattress in the beam reduces the air kerma incident on the patient depending on the HVL, beam angulations and table construction [371, 375, 376]. The attenuation by the table top can be estimated as 15-30% for beam qualities with a HVL of 2-7 mm Al [371, 376]. This has to be considered when using the KAP values to estimate energy imparted to the patient or the ED). The uncertainty in the calibration coefficient when the tube voltage and filtration are known can be reduced to about 6% at the 95% confidence level. In fluoroscopy systems operating with ABC, the tube voltage is likely to vary during the examination. In this case, it may be useful to obtain information about the range of actual tube voltages and to adjust the applied calibration coefficient to limit the uncertainty to less
than 25%. In the future, the X-ray systems may be capable to automatically apply the correct calibration coefficient to the reading of the KAP meter. In addition, some X-ray systems use built-in KAP meters, which determine the KAP value based on calculations using exposure and collimation settings.

In fluoroscopically guided interventional procedures, the KAP offers a suitable quantity for monitoring patient radiation exposure. However, these procedures may also give rise to high skin doses and monitoring of these doses is crucial because of the potential to reach the threshold for deterministic effects. The estimation of the dose to the most exposed area of the skin is not straightforward, since the exposure parameters and projection angle change during the procedure and this area cannot always be anticipated. In order to estimate the maximum skin dose, it is therefore necessary to have a detector that measures the skin dose at many points simultaneously. Such distributions can be obtained using a rectangular array of TLD chips attached to the patient’s skin with a maximum distance between them of about 10 mm, which makes difficult its practical application. Another way is to use a low sensitivity film (commonly used in radiotherapy), properly calibrated, positioned close to the patient. The optical density of this type of film saturates at a dose of about 1-2 Gy and thus it is not capable of determining the maximum dose in some cases [120, 377]. This can be overcome by using radiochromic film, the sensitivity of which is adequate even for high dose interventional procedures [121].

A major disadvantage of the skin dose mapping procedures is that they do not provide information in real time, so as to allow possible adjustments of the technique (for example changing the projection) during the procedure. Real time measurements are possible to perform using real time dosimeters positioned on or near the skin but these cannot provide dose mapping since the number of real time detectors that can be used is limited. A priori knowledge of the location of the maximum skin absorbed dose would therefore be needed. Since this cannot be known in advance, the reading from the detector may underestimate the maximum skin dose. Real time detectors currently available are MOSFET detectors [378, 379] and scintillation detectors [380-382], that can be measure both the instantaneous dose rate and the cumulative absorbed dose.
Two alternative approaches to estimate the maximum possible INAK are available. The first method uses measurements at a reference point on the central ray of the X-ray beam, the interventional reference point (IRP) [116], which is 15 cm from the isocentre towards the X-ray focus (Figure 7.4). The value of the air-kerma at the IRP is derived from measurements obtained by a detector placed at the beam port [383, 384]. This method does not take into account changes in the projection during the procedure and the cumulative air kerma at the IRP may overestimate the maximum INAK at any point on the patient. The second method uses the measurements of the KAP to provide an indication of the maximum possible INAK if the FSD and field area are recorded during the procedure. As changes of the projection are not noted, this method overestimates the maximum INAK on the patient in a way similar to the method using the IRP.

Several studies investigating the correlation of maximum skin dose to KAP values in interventional cardiology procedures have been previously published [385-389]. A large variation was observed in the conversion coefficients, while in some cases no correlation was found between entrance skin dose and KAP for cardiac procedures. They also advocate the use of KAP values for specific examinations to alert staff about the potential for skin injury or to give an approximate indication of the skin dose, which however, requires direct measurements.

A system named CareGraph determines the skin dose distribution in real time using a mathematical model, which uses KAP values, combined with information on changes in the irradiation geometry and exposure parameters during the procedure [390]. A review of the methods used for skin dose assessment can be found in Balter et al. [391].

Figure 7.4 A schematic of the IRP [117].
Chapter 7   Patient dosimetry issues

7.5 Estimation of organ doses

7.5.1 Monte Carlo simulation

In most situations, it is not possible or practicable to measure organ dose directly. Instead, tabulated conversion coefficients are used that relate organ dose to easily measurable quantities, such as ESAK, INAK, and KAP. Such conversion coefficients are generally generated using MC based computer models, which offer a greater possibility for the simulation of a wide range of X-ray examinations and spectra compared to measurements with anthropomorphic phantoms.

The basic features of a MC model are the simulation of the X-ray field incident on the patient (including field size, direction and X-ray spectrum), the simulation of photon transport through the patient and the simulation of the patient body. For the diagnostic energy range, it is sufficient to assume that the energy deposited after a photon interaction is locally absorbed so that organ doses may be estimated by recording the energy depositions that take place when many photon histories are followed. An important exception to this is the energy deposition in the red bone marrow where the range of secondary electrons is comparable to the size of the marrow cavities. A correction may be applied for this effect [392].

Two approaches have been adopted for the simulation of the human body. The first is to use a mathematical (geometrical) phantom in which the body and the organs are constructed using combinations of various geometrical solids [393-395]. The Cristy phantoms are hermaphrodite. However, the adult phantom may be used to simulate an adult male while the 15-year old phantom an adult female. The group at the GSF-National Research Center for Environment and Health has developed male and female adult mathematical phantoms, Adam and Eva [396]. However, the mathematical phantoms are criticised as being unrealistic both in terms of the organ position and shape.

A second approach is to use voxel phantoms based on the anatomy of actual individuals. Such phantoms may be obtained from whole body CT or magnetic resonance images, which have been segmented, voxel by voxel, into different organs and tissues. The most comprehensive series of voxel phantoms has been developed at GSF. Other voxel phantoms have also been developed [397-400]. All of the phantoms represent European individuals except for Otoko (Japan) and the Visible Human (United States of America).
The statistical nature of the MC simulations results the organ dose conversion coefficients
to have statistical errors. In general, the statistical uncertainties in the doses to organs lying
within the radiation field will be less than those for organs located outside the radiation field.
In the latter case, the relative uncertainty will increase with the distance from the edge of the
field.

Organ dose conversion coefficients calculated using MC techniques have been published
by various authors. The most extensive data are those of the CDRH in the USA, the GSF in
Germany and the National Radiological Protection Board (NRPB) in UK. In addition, PC
based MC computer programs are available from the Radiation and Nuclear Safety Authority
(STUK) in Finland (PCXMC) [401], as well as from the radiation dosimetry group of the
Department of Nuclear Energy at the Federal University of Pernambuco in Recife/Brazil
(CALDoseX 5.0), which can compute organ doses for user specified radiation fields (see
Appendix A), with the added feature of adjusting the size of the phantom, including sizes
suitable for paediatric dosimetry. CALDoseX online is a dosimetric service available on the
internet (www.caldose.org) as a web server that provides the ability for real time MC
calculation of organ and tissue absorbed doses. Four handbooks are available from the
CDRH, which provide conversion coefficients for the determination of organ doses in
projections common in diagnostic radiology (adults) [402], in paediatric radiology [403],
upper gastrointestinal fluoroscopic examinations [404], fluoroscopic and cineangiographic
examination of the coronary arteries [405]. The GSF calculated conversion coefficients for
the estimation of organ doses normalized to INAK values for a wide range of exposure
conditions for projections common in diagnostic radiology (adults) [406] and paediatric
radiology [407-410]. Two reports are available from the NRPB which provide
comprehensive tabulation of conversion coefficients for the determination of organ doses for
adults [392, 411, 412] and children [413, 414], in terms of both ESAK and KAP values. The
choice between conversion coefficients that can be used to estimate organ dose from ESAK
or KAP will depend on the particular situation. The total energy imparted to the patient
(phantom) will increase with increasing field size, but the dose to an organ entirely inside the
X-ray field will show a much smaller fractional change. Coefficients normalized to KAP
values may be of specific utility for fluoroscopic examinations where the field size and
direction are changed during the procedure. Two computer programs has also been
developed, which can which can estimate organ doses using the NRPB data tabulation and
exposure parameters entered by the user [415, 416].
The choice of conversion coefficients for a particular situation will depend on data availability and how well the situation modeled matches the situation for which the organ doses are required. All conversion coefficients are dependent on beam quality and it will be adequate to interpolate linearly between values at different beam qualities [411]. A potential source of error is the use of the KAP in situations where the X-ray field extends beyond the patient body. A useful check on the precision of the estimation is to calculate the INAK from the KAP with knowledge of the X-ray field area and repeat the calculation of organ or ED using the former.

It is also important to notice that the size of the modeled patient, the position and size of the modeled organs and the position and size of the radiation field will not match those of the real situation. Significant errors may arise when the field size used in practice is different from that modeled, or when the beam centre deviates from the one calculated. Whole organs may lie entirely or partly within the field for one case and entirely outside the field for another and their depth within the body can be quite different. In general, the differences observed between the conversion coefficients obtained with different phantoms even with similar external dimensions are due to differences in the size, shape, and position of the internal structures of the phantoms. In addition, the conversion coefficients decrease with increasing patient size, due to the increased shielding provided to most organs as the body size increases. Petoussi-Henss et al. [417], demonstrate the differences in organ dose conversion coefficients when three different GSF phantoms which simulate an adult male are used. Detailed information about the differences between the organ dose conversion coefficients for different phantoms are provided by Zankl et al. [418]. They also note that the GSF voxel phantoms are based on patients examined in the supine position, whereas some X-ray examinations are performed with the patient in standing position. The position of some organs is quite different for the two positions.

7.5.2 Anthropomorphic phantom measurements

For situations where no appropriate MC calculated conversion coefficients are available, it may be necessary to take measurements of organ dose using a suitable anthropomorphic phantom. The measurement of skin dose for a fixed radiation field is quite straightforward, provided that the INAK varies slowly across the field. For the measurement of dose received by internal organs, TLDs are often used. This presents more difficulty, especially for large
organisms (such as lungs) or broadly distributed tissues (such as red bone marrow) because of the difficulty of obtaining adequate spatial sampling. This difficulty may arise from either or both of two effects: the rapid reduction of dose with depth in tissue and the partial irradiation of some organs by the primary beam.

### 7.6 Estimation of effective dose utilizing Monte Carlo simulation

Calculation of ED requires knowledge of the organ doses that can be derived from the tabulations discussed in previous section and the appropriate tissue weighting factors (see Chapter 4). Extensive tables of KAP to ED conversion coefficients, for adult and paediatric patients are available for radiography [412, 414, 419] and INAK to ED conversion coefficients for male and female adult phantoms [406]. Values of the ED can also be calculated using the PCXMC [401] or CALDoseX computer program [see Appendix A].

The UNSCEAR [282] has strongly emphasized that the ED should not be used directly to estimate the detriment from medical exposures, for example, by application of the nominal probability coefficients for cancer incidence and mortality provided by the ICRP [24, 153]. Such estimation would be improper, since there are differences in health status, age and gender between the population of patients undergoing examinations and the population for which these coefficients were derived.

Despite this drawback, the ED can be used for comparison purposes, for example, between procedures performed with different exposure parameters, or carried out in different hospitals or countries, or even for comparing different procedures. Additionally, it has increasingly been used to estimate the detriment from all medical imaging procedures [152]. While the tissue weighting factors are not different, the detriment per unit of ED for a patient population has been adjusted in order to take into account the age distribution. In the UK, correction factors have been estimated and are 0.15 (geriatric patients > 70 years), 0.85 (adult patients 16-69 years) and 1.8 (paediatric patients 0-15 years) of that for the whole population [420].

The conversion coefficients have been derived for fixed irradiation geometries (field size and field position). Limited information is available about the sensitivity of the conversion coefficients to a number of variations occur in clinical practice. Wise et al. investigated the effect on conversion coefficients of tube voltage, field size, field position, phantom size and sex [298]. While KAP was strongly correlated to the energy imparted to the patient, the
correlation to ED was considerably weaker. Large uncertainties in ED are caused by organs partly irradiated and sensitive to the exact positioning of the radiation field [421]. Organ doses and consequently ED are in addition strongly dependent on the patient model used in the MC simulations [417].

The ED is a quantity which allows the comparison of different types of procedures, use of different equipment and exposure protocols from a risk point of view and for this reason is a useful tool for optimizing the procedure methodology. For this application there is no need to quantify the risk coefficients. Estimates of risk may be valuable for cost-benefit analysis (for example justification of the purchase of dose saving equipment), where the cost may be expressed in terms of lives or money saved per unit of dose averted [422]. It must be kept in mind that the cancer risk coefficients are associated with large uncertainties and that risk estimates need to be handled with caution. Because of the dependence of the ED on the anthropomorphic model used for calculating organ doses, the energy imparted to the patient or the mean absorbed dose in the patient may serve as an alternative risk related quantity for optimization.

7.7 Radiation safety considerations

7.7.1 Patient protection

Fluoroscopically guided procedures may result in high doses to both patients and staff, and radiation protection is a critical component of a QA programme. In general, the use of good practice by the operator will result in the minimum patient dose required to complete a procedure safely. Good practice refers to the use of commonly known techniques, in order to obtain the best image quality at the lowest radiation dose. These actions include, but are not limited to [117]:

- Moving the patient as far from the X-ray source as practical.
- Placing the detector as close as possible to the patient (no air gap).
- Using the lowest electronic magnification required to perform the procedure (largest FOV).
- Collimating the X-ray field tightly to the anatomic area of interest.

In addition to good practice, all dose reduction tools available on the fluoroscopy system should be used. Spacers provided by the manufacturer are used to maintain a minimum
distance between the focal spot and the patient. Operators often find them inconvenient and as a consequence spacers are frequently removed and left off the equipment. The reduction in source to skin distance allowed when the spacer is removed can increase the maximum possible patient ESAK rate by 100%. Antiscatter grids should be removed when imaging small patients or thin body parts.

Most fluoroscopy systems provide additional tools that can be used to reduce the patient and operator doses. Last image hold is a feature that maintains the last fluoroscopic image on the viewing monitor pending fluoroscopy or acquisition being resumed. It allows the operator to view a static image without the use of additional radiation. Many systems allow the operator to archive the last image hold image to permanent storage instead of acquiring a digital acquisition image. Some systems extend this further by providing the capability to archive the entire previous sequence of fluoroscopic images instead of acquiring a digital acquisition series.

### 7.7.2 Operator protection

Occupational radiation safety considerations are often variations on the three cardinal rules of radiation protection: time, distance and shielding. Operators and other medical personnel remaining in the operating theatre during fluoroscopically guided procedures are exposed to scattered radiation and are at risk of developing both stochastic effects, including cancer, and deterministic effects, namely cataracts.

Non-essential personnel should exit the room while the X-ray tube is energized, and those persons remaining in the room should wear protective garments made of lead or an acceptable lead free material. Mobile barriers are useful for reducing the radiation dose to persons who remain stationary during procedures, and suspended shields can be used to reduce the dose to the face, eyes and neck of operators, while they are near the patient. It should be noted that the highest scatter radiation fields occur near the patient entrance field. Therefore, standing closer to the image detector is generally consistent with lower occupational dose levels [117].
CHAPTER 8

OPTIMIZATION OF PROTECTION IN CLINICAL PRACTICE

8.1 Introduction

Radiation safety is an important element of quality in medical imaging and interventional radiology. Radiologists, referrers and other professionals involved in the use of radiation must be properly trained in radiation protection in order to ensure quality care and patient safety. Selection of the right procedure by justification, usage of the right dose and choice of adequate imaging data by optimisation and errors prevention must be considered and applied in clinical practice.

The primary aim of radiological protection, as stated in the Publication 60 of the ICRP [153], is “to provide an appropriate standard of protection for mankind without unduly limiting the beneficial practices giving rise to radiation exposure”. Radiological protection approaches during medical practices is slightly different from that in other practices (for example, in industry). The medical exposure of patients is intentional. Except in radiotherapy, the aim is not to deliver a radiation dose to the patient, but to use the radiation in order to provide diagnostic information or to perform an interventional procedure. Nevertheless, the dose is given on purpose and cannot be decreased indefinitely without compromising the intended clinical outcome. Hospital and radiology facilities have to be reasonably accessible to the public, whose exposure is therefore more difficult to control compared to the industrial premises.

The growth in medical imaging and interventional radiology over the last two decades has yielded undisputable benefits to patients in terms of better quality of life and longer life expectancy. This growth mirrors new imaging technologies and applications, but a part of this growth can be attributed to the radiation overutilization occurs. In 2009, the American Board of Radiology Foundation organised a summit to discuss the causes and effects of the overutilization of medical imaging [423]. A number of actions to reduce overutilization was
proposed including national co-operation to develop evidence-based appropriateness criteria; broader use of practice guidelines in the request and delivery of procedures; decision support at the point of care; education and training of referring physicians, patients, and the public; accreditation of facilities; administration of self-referral, defensive medicine and payment reformation. Several strategies have been proposed in order to improve the quality of medical imaging by conducting research, raising awareness, providing education and training, strengthening infrastructure, and implementing policies procedures. In practice, these actions will result in choosing the correct procedure (justification), using the correct dose (optimization), and preventing errors along the patient journey [424].

A quality program for medical imaging and interventional radiology should maximize the benefits and minimize the risks associated with radiation exposure. Radiation risk should be considered and quantified through systematic radiation dose monitoring. The increased use of high dose interventional procedures, the repetition of these procedures in certain clinical conditions and the age of some patients (paediatric and young adults), could substantially increase the radiation risk.

This chapter describes the influence of radiation protection on the quality of medical imaging and intervention through justification and optimization actions, including referral guidelines, the use of DRLs and patient dose recording and tracking. The relevant ICRP recommendations and European Commission (EC) actions as well as their impact are also discussed. A number of actions to improve radiation protection in quality programs for medical imaging and interventional radiology is suggested. It is concluded that radiation protection and radiation dose management are integral parts of QA in medical imaging and intervention. Radiation safety issues should be included in education and training programs and research projects. While an individual action addresses a certain topic of radiation protection, collectively these actions will improve quality in medical imaging and interventional radiology. Leadership and on-going co-operation by developing and implementing innovative actions will ensure that radiation protection and quality objectives are succeeded.

8.2 Quality and patient safety in medical imaging

Quality in medical imaging has been defined as ‘a timely access to and delivery of integrated and appropriate procedures, in a safe and responsive practice, and a prompt
delivery of an accurately interpreted report by capable personnel in an efficient, effective, and sustainable manner’ [425]. Radiation safety is a key quality element when ionizing radiation is used in medical imaging and intervention. Radiologists and other eligible operators of X-ray systems, simple or sophisticated, must be properly trained in radiation safety and radiation protection to ensure quality and patient safety. Budget constraint is an important issue that may affect the level of quality and basic radiation safety. Sometimes, new medical imaging technology is introduced without the consideration for the economic and human resources required to ensure adequate staff training, including radiation protection or to implement a QC program, including patient dosimetry.

The driving principles of a quality system for medical imaging and interventional radiology are justification and optimization of each procedure. When ionizing radiation is used in imaging and intervention, the proper management of radiation exposure for both patients and staff has to be considered. Optimization should also include error prevention, covering unintended or over-exposures.

In relation to the monitoring of radiation exposure, the new imaging modalities can combine several acquisition modes (continuous or pulsed fluoroscopy, cine, digital subtraction, rotational acquisition) and can result in differences in radiation exposure and the corresponding image quality. Sometimes, ‘noisy images’ may be acceptable and diagnostic, while radiation dose saving is significant. The objective is to obtain the required ‘image quality’ for the clinical task, rather than ‘best image quality’ especially if the latter could involve much higher radiation exposure. Sometimes quality medical imaging is judged only by the accuracy and timeliness of a report, without radiation risk being taken into account [426]. With digital imaging, it is possible to obtain good or even excellent image quality resulting at times to too much diagnostic information while the patient could be inadvertently over-irradiated.

The successful development and implementation of a QA system in medical imaging and interventional radiology requires leadership and collaboration between radiologists, other clinicians, radiographers, medical physicists, and nursing professionals. Active participation and good communication between the referrers and other professionals involved are essential to ensure coordinated and continuity of care and the requested procedures are justified and not duplicated. Patient information on the benefits and risks of procedures should be available to facilitate informed decision-making and patient satisfaction.
Interventional radiology is an area in which a QA program, including radiation safety, has been developed including considerations for the pre-procedural, procedural and post-procedural steps [30, 112, 427]. The aim is to prevent radiation-induced injuries relating to complex procedures and to address the deficiencies due to the absence of a proper radiation management program.

**8.2.1 Improve quality by radiation protection**

Radiation protection and radiation safety are key elements for a quality program for medical imaging and interventional radiology. Radiation protection must be considered in:

(a) the design of the facility (X-ray room, waiting area, patients and staff flow, shielding, equipment selection, informatics infrastructure, and personnel training),
(b) equipment installation and commissioning (acceptance testing, connectivity between modalities with radiology information system (RIS) and picture archiving and communication system (PACS), staff training), and
(c) equipment use (routine daily practice, QA program, clinical audits including patient and staff doses, image quality, on-going training in quality and safety).

Good management in a medical imaging and interventional radiology facility includes leadership in radiation safety and radiation protection by advocating the importance of radiation protection to the health professionals and ensuring radiation protection is a substantial part of a quality management system in practice [428].

Scientific and professional societies and organizations, agencies, competent authorities, and standard organizations have contributed to improvements in radiation safety in medical imaging and intervention. The best outcome will be achieved when all the stakeholders (medical doctors, radiographers, medical physicists, other health professionals, regulators, health authorities and industry) are working together.

**8.2.1.1 Impact of ICRP recommendations**

The ICRP revised the risk factors for stochastic effects in 2007 [24] and there are no substantial changes to the overall cancer risk coefficient since the 1990 [153]. However, relevant changes were proposed for some organs such as breast and lung. The ICRP emphasized the higher radiation risk for children and the need for caution when applying
effective dose in medical exposure. Some refinements were made to the medical use of radiation by recommending the use of DRLs for interventional radiology and the use of staff doses as part of justification and optimization [155].

For tissue reactions (deterministic effects), the most relevant changes proposed in 2011 are new threshold doses for radiation cataracts in the lens of the eyes and for circulatory disease to the heart and brain. These changes, especially that on lens opacities, should have significant impact on the radiation safety of professionals involved in fluoroscopically guided interventional procedures and on the requirements in QA programs. The ICRP released its statement in April 2011 and included an update on the dose limit for the lens of the eye for occupationally exposed persons [429]. The immediate consequence was the adoption and incorporation of this change in the International Basic Safety Standards (BSS) [293] and European BSS [172].

The ICRP has recently published three documents detailing the recommendations for diagnostic and interventional radiology: Publication 117 on ‘Radiological protection in fluoroscopically guided procedures performed outside the imaging department’ [35], Publication 120 on ‘Radiological protection in cardiology’ [430] and Publication 121 on ‘Radiological protection in paediatric diagnostic and interventional radiology’ [431].

8.2.1.2 European Commission actions

The European regulations are quite strict on quality programs for medical imaging procedures. In fact, many requirements are included as part on the current Medical Exposure Directive (MED) [432], which will be further improved in the upcoming Directive on BSS [172]. QA programs, clinical audits and inspections by competent authorities are required. These quality programs include the QC of the X-ray equipment, patient dosimetry and involvement of medical physics experts (MPE). Training of the professionals involved in medical exposures, including radiation protection training, is another aspect of the European MED.

QA is defined in the European MED [432], as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component, or procedure will perform satisfactorily and comply with the agreed standards. QC is part of QA. The set of operations (programming, coordinating, implementing) intended to maintain or to
improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of equipment performance that can be defined, measured, and controlled.

In the new European BSS [172] optimization includes the selection of the equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, QA, and the assessment of patient and staff doses. Accidental and unintended exposures shall be part of the QA program. Member States of the European Union ‘shall implement a system for the registration and analysis of events involving or potentially involving accidental or unintended exposures’.

8.2.2 Radiation protection actions in quality programs

A list of radiation protection actions, which could form part of a quality program in medical imaging [428, 433]:

- To improve the radiation protection skills of medical doctors, medical physicists, engineers, radiographers, technicians, nurses, by education and training.
- To promote a closer working relationship between medical physicists and other health professionals (for example, collaboration between medical physicists and neurosurgeons is still uncommon).
- To promote a closer working relationship between radiologists, radiographers and medical physicists to improve justification and optimization and to reduce errors.
- To provide adequate infrastructure in a medical imaging facility, including radiation dose management and radiation safety for patients and staff [434].
- To improve interdisciplinary co-operation in research projects in the field of radiation health effects and health risks, especially with epidemiologists and radiobiologists.
- To define staffing requirements for radiation protection and radiation safety (for example, may be compromised by inadequate or unqualified staff).
- To integrate patient and staff radiation protection into medical practice (e.g. interventional radiology).
- To improve the integration of radiation protection into clinical quality programs.
- To address radiation safety issues and to prevent radiation injuries when introducing new technologies and techniques, especially in interventional radiology.
- To improve radiation protection in paediatric imaging, CT and interventional radiology.
• To improve the measurement, recording, analysis and archival of individual patient dose, which will impact on procedure justification and optimization [435].
• To refine criteria for the justification of radiological procedures in asymptomatic individuals after taking into account the amount of the radiation dose.
• To optimize the use of new imaging technology (flat detectors, PET/CT).
• To collaborate with equipment designers and manufacturers in radiation protection, image quality improvement and dose reduction.
• To improve the automated collection of patient and staff doses and data transfer to exposure databases.
• To promote the proper use of DRLs in diagnostic and interventional procedures.
• To improve the communication to patients on radiological risks and to minimize self-referral for certain procedures.
• To increase the support to medical physics in medical imaging facilities.

8.3 Dose recording and monitoring

In the past, patient dosimetry in interventional procedures was made over a small sample of patients to calculate the mean or median values as part of clinical audits and in the use of DRLs. With the introduction of digital systems, it is possible to easily collect and archive dosimetric and demographic data for these procedures together with images, as part of the digital imaging and communication in medicine (DICOM) header or other DICOM services, for example radiation dose structured reports (RDSR), and to manage an individual patient’s dose data [436, 437].

The analysis of this data is subjected to QC and should include: (a) a periodic calibration of the dose quantities as reported by the X-ray system, (b) an automatic detection and identification of high dose values, (c) a periodic statistical analysis of the local DRLs and comparison with national or regional DRLs, and (d) corrective actions when indicated to meet the requirements of QA and clinical audit programs.

The North American Society of Interventional Radiology (SIR) Standards of Practice Committee has recently published a document on ‘Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures’ [112]. This document stated that all available patient radiation dose data should be recorded. The society also recognizes that this may become mandatory in the future, as
the Food and Drug Administration (FDA) has already expressed an intention to establish requirements for CT and fluoroscopy systems to provide radiation dose data for incorporation into the medical record or a radiation dose database. The guidelines suggested an adequate recording of the different dose metrics, including skin dose mapping, for all fluoroscopically guided procedures is needed. The establishment of threshold levels to enable prompt analysis was also suggested.

Reiner proposed the elements for consideration when quantifying radiation safety and quality in medical imaging [438]. These included an automated recording, tracking, and analysis of the quality data. Very few data on radiation dose are being prospectively collected, tracked, or analyzed. These data can be used for the education and training, certification, research, practice guidelines development, and new technology development.

In 2012, an international collaboration on patient radiation safety has led to the publication of a ‘Joint position statement on the IAEA patient radiation exposure tracking’ [439], supported by the Conference of Radiation Control Program Directors USA (CRCPD), European Society of Radiology (ESR), FDA USA, IAEA, International Organization for Medical Physics (IOMP), International Society of Radiographers and Radiological Technologists (ISRRT) and WHO. The scope includes the recording, reporting and tracking of radiation doses of all imaging and interventional procedures employing ionizing radiation, including radiography, fluoroscopy, CT and nuclear medicine procedures.

### 8.3.1 Population based dose surveys

The ICRP states in Publication 105 [155] that it is not appropriate to set dose limits or dose constraints for patient exposures because the medical condition is invariably more significant than the potential for radiation harm arising from any justified exposure. Instead, the ICRP recommends that justification of each procedure and dose optimization be used as the primary tools for radiation protection of the patient. Dose monitoring is implicit in the optimization task. Patient doses can only be successfully monitored if information is available on the magnitude and range of doses occurred in clinical practice, and DRLs are based on these data. Local practice can then be improved by comparison with the appropriate DRLs.

A number of countries have rolling programmes of patient dose surveys, such as the Nationwide Evaluation of X ray Trends programme in the USA, and the five-yearly reviews
of the UK national patient dose database. Their findings are published on their web sites and as scientific papers. Several other countries conduct ad hoc patient dose surveys, the results of which can be found in the literature. A variety of methodologies (patient measurements, phantom measurements) and dose quantities (ESAK, INAK) are reported, so caution must be exercised when making comparisons [117].

8.3.2 Local dose audit

The dosimetric techniques described in Chapter 4 constitute the basis of the dose audit. Patient dose data can be recorded every 3-5 years for each examination, and a few months after a new installation. In many situations, a sample can be selected to best represent the patient population being studied and large enough in order to reduce the statistical error to an acceptable value. If patient’ flow is not sufficient to provide such a sample, constraints may be placed on the range of anatomical parameters that are accepted for the survey (patient weight or breast thickness). The dose for a ‘typical’ patient may then be found from the median value of this distribution or by interpolation of the sampled data to a standard patient size [117].

8.3.3 Role of the medical physicist

In collaboration with the other professionals, the medical physicist has a critical role in the planning, preparation and conduct of clinical audits of radiological practices. Medical physics expertise is inevitably required for judging the adequacy and quality of equipment, and assessing patient dose and image quality, as well as establishing and running the QA and QC programmes for equipment. Medical physicists often play a key role in the arrangements and provisions for radiation safety of patients and staff, which are among the major areas for clinical audits of radiological practices.

When the audit involves specific measurements or tests, the medical physicist usually takes care of these tests. Further, physicists are usually well practiced in making use of different mathematical and statistical tools, which can be of great value in organizing and analysing the audit data. For all these reasons, the audit team should include a medical physicist [117].
8.4 The three principles of radiological protection

8.4.1 Justification of a practice

No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed persons or to society to offset the detriment caused by the radiation. The decision to adopt or continue an activity involves a consideration of the benefits and risks. In medical imaging and interventional radiology, this consideration usually leads to a number of alternatives that will do more good than harm. The decision process could be complex, but is necessary. The harm is not only confined to radiation, but includes also economic and societal costs. Often, radiation risk is only a small part of the total consideration. Most of the assessments needed for the justification of a practice are performed on the basis of experience, professional judgment and common sense, but quantitative decision aiding techniques are also available and if the necessary data are accessible should be considered. Justification of medical exposures is the responsibility of both the radiological and the referring medical practitioner. Imaging methods with lower patient effective dose should be considered if the same diagnostic information can be obtained. This is true for all patients, but is especially important for younger patients. No new imaging modality should be established unless the exposed individual or society receives a net benefit to offset the detriment.

According to the ICRP [155], justification of a practice in medicine should be applied at three levels:

i. At the first and most general level, the use of radiation in medicine is accepted as doing more good than harm to the society. This general level of justification is now established.

ii. At the second level, a specified procedure with a specified objective is defined and justified. The aim of this second level of justification is to judge whether the radiological procedure will improve the diagnosis or treatment or will provide the necessary information about the exposed persons. The justification of the procedure at this level is a matter for national professional bodies, sometimes in combination with national health and radiological protection authorities and the corresponding international organizations. The total benefits from a radiological procedure include not only the direct health benefits to the patient, but also the benefits to the patient’s family and to society. Although in medicine, the main exposure is to patients, the
exposures to staff and to member of the public who are not connected with the procedures should be taken into account. Additionally, the possibility of accidental or unintended exposures should also be investigated. The justification of diagnostic investigations for which the benefit to the patient is of the primary objective needs special consideration. The decisions should be reviewed from time to time as new data become available about the risks and effectiveness of the existing procedure and about new procedures.

iii. At the third level, the application of a particular procedure to an individual patient should be justified to do more good than harm. Beyond checking that the required information is not already available, no additional justification is needed for the application of a generally justified simple diagnostic procedure to an individual with the symptoms or indications for which the procedure has already been justified. For complex diagnostic and interventional procedures, individual justification by the radiological practitioner and the referring physician may not be sufficient and should take account all the available information. This includes the detailed information about the proposed procedure and of any alternatives, the characteristics of the individual patient, the expected dose to the patient, and the availability of information on previous or expected examinations or treatments.

Although the principal aim of medical exposures is to do more good than harm to an individual patient, the ICRP recommends consideration of radiation exposure to staff and other individuals should be part of this justification process.

8.4.1.1 Referral guidelines and radiation protection

Some international organizations and national professional societies have published referral guidelines [440-443]. For these guidelines to remain relevant and to reflect rapid technological advances and changing practice, timely updates are needed, requiring both human and financial resources. In Europe, the MED stated in one of its articles: ‘Member States of the European Union shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure’ [432]. In addition to the existing national guidelines, the European Commission published ‘Radiation Protection 118. Referral guidelines for imaging’ in 2000 [441]. However, the majority of the content was not related to radiation protection. Due to
limited resources these European guidelines have not been updated regularly, but it is important to recognize the initial radiation protection recommendations are still currently valid. Further, updates of the typical radiation doses for several radiological procedures have been published as part of the DOSE DATAMED, DOSE DATAMED 2 and SENTINEL projects [444-446]. The American College of Radiology (ACR) has published appropriateness criteria [440], which are evidence based guidelines to assist referring clinicians in making the most appropriate imaging decision.

Guidelines are important, since not all imaging examinations give results that change the management of the patient or add confidence to diagnosis, and, hence, may add unnecessary radiation dose. There are several causes of unnecessary examinations, including:

- A repeated examination when relevant information was available but not obtained.
- Performing an irrelevant examination.
- Too frequent use of a particular examination.
- Inadequate clinical information preventing important clinical questions from being answered.

The recommendations in the referral guidelines [441] are classified as indicated when the examination is likely to contribute to clinical diagnosis and management of the patient. Other recommendations are specialized for examinations that are complex, expensive and require individual discussion with an expert radiologist. In total, the recommendations can be not indicated initially, routinely or not recommended at all. The guidelines further classify the typical effective doses into five groups from 0 to IV, where group 0 are examinations without ionizing radiation (ultrasound and magnetic resonance imaging) and group I are examinations where the effective dose is less than 1 mSv (limb and chest radiography). In groups II–IV, the effective doses are 1-5 mSv (intravenous urogram), 5-10 mSv (CT chest) and higher than 10 mSv (positron emission tomography/abdominal CT), respectively.

8.4.1.2 Sensitive populations

It is realized that the cancer excess mortality by age of exposure is approximately two to three times higher for children than for the average population. It is, therefore, important to optimize the imaging conditions for children. European guidelines with image and criteria for radiation dose are available for common paediatric examinations, but surveys show that the dose to the child can, in some cases, be reduced further.
Contrast media are sometimes necessary to visualize different soft tissues and vessels, since the subject contrast is inherently too low. The ideal contrast media will attenuate the X-ray beam more than the surrounding tissue but will leave body organs unaffected. However, this is not always possible. Some patients react adversely to injected iodine contrast media, with acute or late side effects, which may be severe. Special caution needs to be taken with patients suffering from kidney problems or diabetes. The use of contrast media must be evaluated prior to imaging such patients [117].

### 8.4.1.3 High skin dose examinations

Some interventional procedures may result not only to high equivalent doses to internal organs, but also to the local skin or eye lens where there potential is deterministic (acute) radiation damage (see Chapter 3). Examples of deterministic effects include skin erythema and temporary epilation, or lens cataract with visual impairment. The ICRP gives guidance on how to identify and manage patients with potential to high skin doses. In these situations, it is important that staff document the measures of absorbed dose that the imaging equipment provides after the procedure, so that any subsequent radiation injury can be managed properly [117].

### 8.4.1.4 Informed consent

Before the examination, patients undergoing imaging procedures should be informed of the potential risk associated with the examination. This includes the risk of allergic reactions to intravenous injected contrast media and potentially high skin doses following sometimes lengthy interventions. Healthy volunteers or patients undergoing alternative or experimental imaging procedures must also be properly informed of the risks. The scientist managing such research must seek and obtain approval from the ethics committee, in accordance with the national legislation [117].

### 8.4.2 Optimization of protection

In relation to any particular source of radiation within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposure
where these are not certain to be received should all be kept as low as reasonable achievable, economic and social factors being taken into account. The optimisation of protection is the most powerful of the components of the system of radiological protection. It should pervade all stages of the use of radiation in medicine. The underlying idea of the optimisation can be expressed by the question: *Are There Any Reasonable Steps That I Can Take To Improve Protection?*

The basic aim of optimisation of protection is to adjust the protection measures relating to the application of a source of radiation within a practice in such a way that the net benefit is maximized. As with justification, experience, professional judgment, and common sense play important roles in the optimisation procedures, all of which are consistent with the good practice of medicine.

### 8.4.2.1 Aspects to optimize quality and minimize exposure

The European Guidelines [441] highlighting the scenarios where inappropriate use could be avoided and radiation protection enhanced:

1. Repetition of investigations which have already been performed, for example, at another hospital, in an outpatient department, or in the accident and emergency department. *HAS IT BEEN DONE ALREADY?* Attempt should be done to get the previous images.
2. Investigation when results are unlikely to affect patient management, for example, when the anticipated *positive* finding is usually irrelevant, or because a *positive* finding is so unlikely. *DO I NEED IT?*
3. Investigating too often, before the disease could have progressed or resolved or before the results could influence the treatment. *DO I NEED IT NOW?*
4. Doing the wrong investigation. Imaging techniques are developing rapidly. It is often helpful to discuss an investigation with a specialist in clinical radiology or nuclear medicine before it is requested. *IS THIS THE BEST INVESTIGATION?*
5. Failing to provide appropriate clinical information and questions that the imaging investigation should answer. Deficiencies here may lead to the wrong technique being used. *HAVE I EXPLAINED THE PROBLEM?*
6. Over-investigation. Some clinicians tend to rely on investigations more than others. Some patients take comfort in being investigated. ARE TOO MANY INVESTIGATIONS BEING PERFORMED?

These six basic advices on radiation protection published in the 2000 EC guidelines are still valid today and probably will be in the next years. A regular update of referral criteria should be made by the professional organizations after taking into account radiation protection issues and having radiation protection specialists participating in the working groups. Amongst other updates, this process enables the incorporation of radiation dose for the various procedures as reported in the most recent literature. It is important to recognize that while a certain procedure is generally justified for a particular condition, its use for a certain patient requires a careful consideration of the individual’s specific circumstances.

8.4.2.2 How optimization affects justification

Justification and optimization are closely related and these two principles should be considered jointly in some cases. For example, due to technological advance but limited by resources, between and within countries, a procedure such as paediatric CT could not be justified in a facility without a paediatric radiologist or experience in low dose protocols, but could be the first option in other facilities where these conditions are met. The availability of better infrastructure such as experienced paediatric radiologist, CT scanner with dose reduction technology, and good quality program enables a facility to offer CT as the first choice for some conditions. Therefore, if and when radiation protection is fully optimized, certain procedures could be justified and appropriate even though these are usually not when such provisions are not met.

8.4.2.3 Strategies for ALARA in Fluoroscopy: dose reduction and image quality

Working as a medical physicist with the responsibility to optimize the procedures, it is necessary to use a strategy to perform the optimization in an efficient way. Different approaches exist. The examinations that result in the high patient doses should be optimized first. An alternative strategy is to focus on examinations that have questionable image quality, as such run the risk of not providing the necessary diagnostic information. It is important to consider carefully what methods to use for the optimization. As the
optimization involves both radiation dose and image quality, it is necessary to decide what relevant measures to use. Since, for the most imaging procedures, it is the stochastic risk that is of interest, a dose measure that can be used to estimate this risk should be used. Effective dose is, therefore, often the best choice. Although the use of effective dose for individual patients is not appropriate, it is suitable for groups of patients and for the comparison of the relative risk between different radiological examinations or for the comparison of doses before and after a change in imaging conditions (see Chapter 4). The age and sex of the patients need to be taken into account for a proper risk assessment. It could be argued that for interventional procedures for which there is a risk of deterministic injury, additional dose measurements, such as skin dose, are also relevant. However, such injuries are rare and can, in most situations, be avoided if the personnel are adequately trained and the imaging system is not malfunctioning.

Regarding the image quality, as described in Chapter 6, there is a large variety of methods intended for evaluation of this somewhat diffuse measure. No matter what method is chosen, it is important to keep in mind that the validity of the results is limited by the validity of the method. Thus, the method used should preferably incorporate the entire imaging chain. As the current gold standard for determining image quality is ROC methods (see Chapter 6), the use of such methods may be advocated for optimization. However, ROC studies may be a cumbersome task and they may not be best suited for daily optimization work.

For some common radiographic examinations, the EC has published guidelines that provide requirements, criteria for radiation dose and examples of good practice. The requirements include both image criteria and important image details and apply to ‘standard sized’ patients with the usual symptoms for that type of examination. The image criteria relate to important anatomical structures that should be visible in the images.

The criteria given in the EC guidelines for radiation doses to the patient are expressed in terms of ESAK. However, the IAEA code of practice recommends the use of KAP, as the dosimetric quantity in fluoroscopy. The advantage of KAP over the ESAK is that the X-ray field size is directly included in the measurement and that KAP values for different projections can be added together with reasonable validity. Adding the ESAK values from different projections is not meaningful. Internationally, the concept of DRLs has been implemented in many countries and standard doses are periodically measured locally in the hospitals and compared with the reference levels. If the reference level is exceeded in a particular X-ray room, the hospital needs to review their imaging conditions and to consider,
and possibly implement, corrective actions to reduce the dose if the clinical image quality requirements can still be met. The implementation of DRLs has led to a reduction in patient doses and must be considered as a successful radiological protection action and a first step towards achieving optimal imaging conditions.

8.4.2.4 Aspects of good practice

Listed below are some aspects associated with good practice. These include:

- **Continuous vs pulsed fluoroscopy**
  Historically, the fluoroscopy was performed in continuous mode. Whenever the fluoroscopy was activated, a continuous X-ray beam was produced. Since 30 fluoroscopic images were generated per second, the duration of each image frame was 33 ms \((1000/30 = 33)\). However, significant motion and loss of sharpness in the clinical images can occur due to the patient or organ motion. Most state-of-the-art fluoroscopy equipment offers an improved alternative to continuous fluoroscopy. When is activated, the X-ray beam is pulsed (turned ‘on’ and ‘off’ at a selected pulse rate). If the proper parameter settings are selected with respect to the size of the patient examined, the image quality can be significantly improved and the radiation dose to the patient significantly lowered.

- **Pulse width**
  The pulse width determines the duration that the patient is exposed to radiation during the production of a fluoroscopic image. This duration affects the system’s ability to ‘freeze’ any motion that occurs in the patient. Shorter pulse widths improve the sharpness in the fluoroscopic images, but also limit the number of photons used to form the image that increases the quantum mottle. The need for a sharp image must be balanced against the need for more photons to penetrate larger patients and properly manage the quantum mottle in the fluoroscopic image. Pulse widths for children should ideally not exceed 5 ms, while for adult patients should not exceed 10 ms. Continuous fluoroscopy with an effective pulse width of 33 ms, will tend to blur rapidly moving objects.
- **Pulse rate**
  The pulse rate determines the number of image frames that are generated per second. Depending on the application, the available pulse rates range from 30 pulses per second (interventional equipment) to as low as 1 or 0.5 pulses per second. When an object is moving, the distance it travels between successive pulses is inversely proportional to the pulse rate. This is called *temporal resolution* that increases as the pulse rate increases [447]. Adjustable frame rates can be used to suit the temporal resolution needed for each part of the examination. Carefully manipulated frame rates offers optimal image quality and potential reduction of radiation dose. Boland *et al* [448] studied the temporal resolution and its effect on the image and its perception, by changing the pulse rate during common fluoroscopic procedures. No difference was found on image quality in parts performed with 30 frames per second than that of 7.5 and 3.75 frames per second, although they detect a non-significant trend towards greater satisfaction with higher pulse widths especially in examinations involving moving objects. The authors concluded that some initial training may be required to gain acceptance of lower pulse rates by some users.

- **Tube voltage, tube current, and tube current/pulse width product**
  Since the penetration of the X-ray photons increases as the tube voltage increases, fewer photons are needed, in order to obtain the proper information at the image detector. This results in lower patient dose. However, higher tube voltage values decrease the contrast in the fluoroscopic image. On the other hand, the tube current determines the number of X-ray photons that are generated per unit time, while the pulse width determines how long X-rays are produced to create each fluoroscopic image. The product of the pulse width and tube current determines the number of X-ray photons, and consequently the quantum mottle in the images. If the pulse width is decreased to improve sharpness in the image, this must be offset by an increase in the tube current to keep the total number of X-ray photons used for each image (same quantum mottle in image) the same. The maximum value of the tube current is determined by the focal spot size and design of the X-ray tube. If the mAs product at the preferred pulse width and maximum mA is too limited to produce the required quantum mottle in the image, either the pulse width or the tube voltage should be
increased. This choice depends upon whether the overall image quality is limited by motion unsharpness or contrast, respectively.

- **Adapting the exposure settings to patient size**
  As the relationship between the exposure setting used and the resultant image quality and patient dose is dependent on the size of the patient, it is important to adjust the exposure setting to the size of the patient. Tube current is automatically adjusted according to patient size and density. However, it is still necessary to find the optimal dose level, as different tube current modulation techniques behave in different ways. Also, the relationship between image quality and noise level is dependent on patient size. This is mainly because the internal structures of thin patients are smaller, but because they have less intra-abdominal fat, which requires that the image noise be lower (and dose higher) to delineate the organs.

- **Beam Filtration**
  Beam filtration refers to the removal of low-energy photons. Since these photons cannot penetrate the patient and reach the image detector, they cannot contribute to image formation. All their energy would deposited in the patient’s body increasing the radiation dose. With added filtration, the energy of these photons is effectively removed. State-of-the-art fluoroscopy systems contain filters of multiple thicknesses that may automatically inserted, depending on the imaging task [447]. The use of thicker filters to reduce the patient dose requires production of more X-ray photons for each image which consequently require an increase in the pulse width. This causes manufacturers to set their machines to use pulse widths greater than 5 ms.

- **Managing high local skin doses**
  The patient should be placed close to the image detector, with the tube as far as possible from the patient in order to minimize local skin dose and to reduce the effect of geometrical unsharpness. This is of critical importance in interventional procedures, as long fluoroscopy times and multiple exposures can be anticipated. The local skin dose can be high if the same projection is maintained throughout the whole procedure. Changing the projection slightly may reduce the local skin dose below the threshold for deterministic skin injuries, but will not necessarily reduce the dose to
internal organs or the stochastic risk. To further reduce local skin dose, additional copper filtration can be dynamically inserted into the X-ray beam, provided the generator power is sufficient. Additional copper filtration increases the mean energy of the primary X-ray beam and increases the relative transmission through the part being imaged, and hence, for fixed image detector dose, decreases the dose to the skin of the patient. The documentation of high skin dose is facilitated by use of the cumulative dose at the ‘interventional reference point’ (IRP). For C-arm fluoroscopy systems, this point is located 15 cm from the isocentre, towards the X-ray tube.

- **Positioning of the patient - Focus to skin distance (FSD)**
  The patient should be positioned as far as possible from the X-ray source. The inverse square law states that the intensity of the X-ray beam is inversely proportional to the square of the FSD. Thus, if the FSD is increased during the procedure, the patient’s radiation dose will decrease. This also requires that the tube output per unit time must increase to maintain the same quantum mottle in the fluoroscopic image. Typically, the SSD on standard fluoroscopic tilt table is ~ 50 cm. The heaviest patients may need to be examined at the shorter SSD to prevent photon starvation at the image detector.

- **Protective shielding**
  Protective shielding should not typically be used on patients, with a few exceptions, for example, male gonad shields whenever the testicles are in, or close to the primary radiation beam. In such situations, their use is recommended when the protective shield does not obscure any important radiological structure or result in image artefacts.

- **Low attenuating materials**
  Any material between the patient and the image detector will reduce the radiation rate at the image detector and result to a loss of image information. If an AEC system is used, the exposure time will automatically increase with increasing amounts of absorbing material leading to an increase in patient dose. Consequently, efforts should be made to reduce this absorption. Such materials are the image detector protective coating, AEC chambers, couch, cushion and antiscatter grid. Most of these
are made from low atomic number, low density materials such as plastic or carbon fiber, with the exception of the lead strips in the antiscatter grid. It should be noted that if the X-ray tube is situated below the patient (as is common in interventional radiology), the couch and cushion add extra beam filtration, but do not necessarily increase patient exposure.

- **Scatter rejection methods**
  The majority of the photons exiting the patient have been scattered in the patient and have changed direction before reaching the image detector. These photons will not convey diagnostic information about the patient and will reduce the contrast and add noise to the image if they are not removed. Three methods are used to minimize the contribution of scattered photons to image formation. The most dose efficient method is a scanning fan beam. Here, only a small fraction of the patient is irradiated at a time, with one or several narrow moving collimators in front of and behind the patient, allowing all primary photons, but only a small fraction of the scattered photons, to reach the image detector. The second method is to increase the separation between the patient and image detector to 20-40 cm, to allow the scattered photons to miss the image detector to some extent. In these situations, this air gap technique is also more dose efficient than the third and most common method, the antiscatter grid technique. The grid consists of thin lead strips separated by a low density material, to allow a large fraction of the primary photons to pass through but selectively absorb the scatter. With increasing grid ratio, the solid angle that allows scattered photons to pass decreases and the efficiency of the grid increases, provided the interspace material between the lead strips is made of low atomic number and low density material such as fibre material, but not aluminum. In large patients, removal of scatter is essential to maintain object contrast in the image and reasonable overall image quality. However, the removed scatter did contribute to the brightness of the fluoroscopic image on the monitor. When it is removed, it must be replaced by primary radiation at the image detector which increases the radiation dose to the patient by a factor of 2 or more [448].
• **AEC setting**
  The setting of the AEC is important for both patient dose and image quality and should be evaluated for each type of examination. The AEC system usually consists of ionization chambers located behind the grid and before the image detector. During the exposure, the signal is read from the chamber and when the required air kerma is reached, a signal is sent to the X-ray generator to terminate the exposure. Digital image detectors have a wide useful dynamic range and can, to some extent, manage over- or under-exposure. Similar exposure correction systems exist in fluoroscopy systems and are known as ABC. The area used to monitor the signal level in the image intensifier is outlined in the monitor and can, to some extent, be changed in size and location to adapt to different projection and FOVs required.

• **Field of View**
  Most fluoroscopy systems allow the operator to select from three or more FOVs. The ‘normal’ mode provides the largest FOV and irradiates the entire surface of the image intensifier. Additional modes use smaller areas at the image detector. Since these smaller areas are expanded to fill the entire display monitor, the image of the anatomy on the monitor is electronically magnified. Typically, the image sharpness is improved in this case. The operator, however, should be aware that as the desired FOV becomes smaller, the radiation dose rate increases.

• **Limiting the radiation field (collimation)**
  Limiting the radiation field to the area of interest will both reduce the radiation risk and improve image quality (for a smaller irradiated volume, less scattered radiation will reach the image detector). The X-ray beam is automatically collimated to the size of the displayed FOV. The FOV should be limited to include only the anatomic area to be examined by manually adjusting the position of the collimator blades. Some state-of-the-art fluoroscopy systems provide a graphical display of the collimator blade position on the monitor. This allows the operator to adjust the blades and limit the FOV, without additional exposure to position the collimator blades. For example, reducing the radius of the X-ray field from 12 to 9 cm will almost halve the KAP value. The primary radiation field should not extend beyond the active area of the image detector.
• **Dose rate to image detector**
Most fluoroscopy systems allow the operator to adjust the dose rate to the image detector during the procedure to the level commensurate with the necessary detail. Low contrast image quality (soft tissue differentiation) is primarily determined by the amount of quantum mottle in the image [447]. The level of quantum mottle is inversely proportional to the square of the dose rate. This means that a relatively large increase in dose rate by a factor of 4 is required to reduce the quantum mottle in by a factor of 2. On the other hand, the image quality of high contrast images is primarily dependent on the sharpness of the images. In fact, elevated dose rates to the image detector may actually degrade the overall image quality in this case. Decreased quantum mottle does not improve the overall image quality, while the fluoroscopy system may be forced to select a longer pulse width (less sharpness) to deliver the elevated dose rate to the image detector [447].

• **Last image hold**
The last image hold feature allows the retention of the last fluoroscopic image on the monitor after the operator has stopped the exposure. Prior to the introduction of this feature, fluoroscopic images only appeared on the monitor while the patient was irradiated. The last image hold allows the operator to study the last image of the previous fluoroscopy sequence as long as necessary without further irradiation.

• **Fluoroscopy Store**
The fluoroscopy store feature, also known as “fluoro-save” or “fluoro-grab”, allows the operator to ‘grab’ a single fluoroscopic image during live fluoroscopy or to record the last image hold displayed on the monitor. Prior to the development of the fluoroscopy store, a radiographic image had to be created to record the clinical findings during fluoroscopy. Fluoroscopy store allows the ‘ad hoc’ acquisition of the necessary fluoroscopic images without the penalty of increased radiation dose per image.

• **Intermittent Fluoroscopy**
Reduced rate pulsed fluoroscopy, last image hold, and fluoroscopy store are all features that can be used to limit the number of recorded images during a procedure.
However, these features in no way eliminate the need the operator to activate the fluoroscopic exposure intermittently. Momentary activation allows last image hold, and fluoroscopy store to be used more effectively to reduce the number of created images even if reduced pulse rates (1-6 pulses per second), are used. Common sense maneuvers, such as placing the tower over the region of interest before turning on the fluoroscopy system are also important.

Table 8.1 Annual dose limits in according to the Greek radiation protection regulations.

<table>
<thead>
<tr>
<th>Organs</th>
<th>Dose Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Occupational</td>
</tr>
<tr>
<td>Whole body</td>
<td>20mSv in any calendar year</td>
</tr>
<tr>
<td>Abdomen of a woman with reproductive capacity</td>
<td>5 mSv in any consecutive 3 months interval</td>
</tr>
<tr>
<td>Abdomen of a pregnant woman</td>
<td>1mSv from declaration to delivery and intake radionuclides is limited to 1/20 ALI</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>150mSv</td>
</tr>
<tr>
<td>Skin, average over 1 cm²</td>
<td>500mSv</td>
</tr>
<tr>
<td>Other individual organs</td>
<td>500mSv</td>
</tr>
<tr>
<td></td>
<td>Public</td>
</tr>
<tr>
<td></td>
<td>1mSv</td>
</tr>
</tbody>
</table>

8.4.3 Dose limits

The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits as stipulated in the Greek radiation protection regulations. Individual dose limits have been set for occupational and public exposure so that a continued exposure just above the dose limits would result in additional risks from the relevant practices that could reasonably be described as ‘unacceptable’ in normal circumstances. Provided that the dose to patients has been properly justified, it is not appropriate to apply dose limits to medical exposures, because such limits would often do more harms than good. Furthermore, the benefits and detriments from medical exposures apply to the patient; there is no inequity. The annual dose limits stipulated in the Greek radiation protection regulations are given in Table 8.1.
8.5 Diagnostic Reference Levels (DRLs)

To improve the optimization of patient radiation protection in radiological procedures, the ICRP recommends the use of DRLs to compare procedures, which is applicable to groups of similar patients rather than individuals. DRLs are used to ensure that doses do not deviate significantly from those achieved at peer departments unless there is a known, relevant, and acceptable reason for this deviation [155].

However, the concept of DRLs is not well understood by many practitioners and referrers. The following provides some helpful hints relating to the use of DRLs [449]:

- DRLs are not dose limits, they should be used as investigation levels.
- DRLs are not applicable to individual patients.
- Comparison with DRLs shall be made using mean or median values of a sample of patient doses.
- Quantities used as DRLs should be easily measured.
- The use of DRLs should be made in conjunction with the evaluation of image quality.
- DRLs should be applied with certain flexibility allowing tolerances for patient size, and condition.
- DRLs are not differentiators for good or bad practice.
- Values that are under the DRLs may not necessarily be optimised values.
- Values that are over the DRLs should require an investigation and optimization of the X-ray system or operational protocols.
- DRLs should be used in a dynamic and continuous process of optimization.
- The goal in using DRLs is not to reduce patient doses if image quality or diagnostic information is compromised.
- Compliance or faults with DRLs should be discussed with the staff of the imaging department.

8.5.1 Definition

The DRLs were first mentioned by the ICRP in 1990 [153] and subsequently recommended in greater detail in 1996 [152]. From the 1996 report:

"The Commission now recommends the use of diagnostic reference levels for patients. These levels, which are a form of investigation level, apply to an easily measured quantity,
usually the absorbed dose in air, or in a tissue equivalent material at the surface of a simple standard phantom or representative patient. . . . The diagnostic reference level will be intended for use as a simple test for identifying situations where the level of patient dose or administered activity is unusually high. If it is found that procedures are consistently causing the relevant diagnostic reference level to be exceeded, there should be a local review of procedures and the equipment in order to determine whether the protection has been adequately optimized. If not, measures aimed at reduction of doses should be taken.

Diagnostic reference levels are supplements to professional judgment and do not provide a dividing line between good and bad medicine. It is inappropriate to use them for regulatory or commercial purposes. Diagnostic reference levels apply to medical exposure, not to occupational and public exposure. Thus, they have no link to dose limits or constraints. Ideally, they should be the result of a generic optimization of protection. In practice, this is unrealistically difficult and it is simpler to choose the initial values as a percentile point on the observed distribution of doses to patients. The values should be selected by professional medical bodies and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in the observed dose distributions. The selected values will be specific to a country or region.''}.

The DRLs does not represent a suggested or ideal dose or an upper limit for dose for a particular procedure. They represent the dose level at which an investigation of the appropriateness of the dose of the procedure should be initiated. In combination with an image quality evaluation, a qualified MPE should collaborate with the radiologist and radiation technologist to determine whether or not the required level of image quality could be obtained at lower dose levels. Thus, the reference levels implement as “trigger levels” to initiate quality improvement. Their purpose is to identify dose levels that may be unnecessarily high, to identify those situations where it may be possible to reduce dose without compromising the required level of image quality.

8.5.2 Use of diagnostic reference levels to reduce patient dose

The use of DRLs for dose optimization is endorsed by many professional and regulatory organizations, including the ICRP, ACR, American Association of Physicists in Medicine (AAPM), United Kingdom Health Protection Agency, IAEA, and EC. Reference levels are typically set at the 75th percentile of the dose distribution obtained from a patient survey
carried out across large and small, public and private, hospital and out-patient facilities using a specified dose measurement protocol and phantom. They are established locally, regionally and nationally, and internationally and significant variations have been reported both in different regions and countries [450]. Patient dose surveys should be repeated periodically to establish new reference levels, which can demonstrate changes in both the mean values and standard deviation of the dose distribution.

The use of DRLs has been shown to reduce the overall dose and the range of doses observed in clinical practice. For example, UK national dose surveys demonstrated a 30% reduction in typical radiographic doses from 1984 to 1995 and an average reduction of about 50% between 1985 and 2000 [451, 452]. While improvements in dose efficiency of the equipment may be reflected in these dose reductions, investigations triggered when a reference dose is exceeded can often determine dose reduction strategies that do not negatively impact the overall quality of each procedure. Thus, the data points above the 75th percentile value are gradually moved below this value resulting to a narrower dose distribution and a lower mean dose.

8.6 Radiation protection for patients and staff

The most important changes introduced by the ICRP in 2007 concerning the optimization of medical imaging, were the application of DRLs for interventional procedures [155, 156] and to consider the exposure to staff as part of the optimization process [24, 155]. The latter is particularly relevant to staff involved in fluoroscopically guided procedures, especially in the context of the ICRP statement on tissue reactions (deterministic effects) and the recommended changes to the occupational dose limits for the lens of the eye and the need to improve optimization for some high dose interventional procedures [429].

The ICRP drew attention to recent epidemiological evidence, which suggested that tissue reactions could occur when the threshold doses are at or might be lower than previously considered, for example 0.5 Gy for the lens of the eyes (radiation induced opacities) and 0.5 Gy for circulatory disease to the heart or brain. Doses of this magnitude to staff (lens of the eyes) and to patients could be reached in some complex interventional procedures and the ICRP recommended particular emphasis on optimisation in these circumstances. Therefore, when discussing optimization, it is important to consider the radiation protection of patients.
and staff together. The ICRP has recommended the reduction of the dose limit to the lens of the eyes from 150 to 20 mSv/year.

Other medical specialties in addition to radiology and cardiology also use interventional procedures as alternative to surgery, especially in some elderly patients unsuitable for general anesthesia or due to other clinical constraints. The increasing interest in these minimally invasive techniques together with the updated international recommendations on radiation safety have promoted several international research projects in patient and staff dosimetry that should help to improve radiation safety and quality when performing these procedures.

The ICRP’s recommendations and other improvements in the European regulation [172] will encourage the radiology community and users to develop strategies and software programs to improve dosimetric data processing, individual dose evaluation, automated analysis, and data transfer to patient record and dose tracking system.

8.7 Education, training and optimization strategies

Education and training in radiation protection by focusing on the need and means to apply appropriate exposure in radiation procedures is a key component to reduce dose to both patients and staff. The ICRP published recommendations on ‘Education and training in radiological protection for diagnostic and interventional procedures’ [37].

In recent years several scientific and professional societies have published guidelines on radiation safety, including patient dosimetry for interventional radiology. Some of these guidelines have been adopted simultaneously by the American and European societies of interventional radiology [112, 427, 453]. Other recommendations have also been produced by expert groups and later endorsed by the professional societies [454]. The role of the EC in the publication of guidelines and reports [444, 445] is particularly important in the optimization of interventional procedures.

DRLs are still a challenge especially for interventional radiology. The ICRP proposed their application to interventional radiology in 2001 and 2007 [155, 156], but it is still a long way from their effective application. The NCRP in USA has published a report on this issue [455]. The ICRP formed a working party in 2012 to provide more specific advice on the use of DRLs in interventional procedures and new imaging techniques.
The follow-up of patients suspected for potential radiation injuries arising from complex interventional is a performance indicator that should be incorporated into a quality program. Two recent papers reported the incidence and criteria for patient inclusion in the follow-up protocol. Applying the SIR and Cardiovascular and Interventional Radiological Society of Europe (CIRSE) recommendations [110], the first paper on cardiac procedures reported a follow-up rate of 0.31% and a skin injury rate of 0.03% [456]. An example of radiodermatitis after a complex interventional cardiology procedure is shown in Figure 8.1.

The second paper was on neuroradiology procedures performed in the same hospital. Following optimization and applying the peak skin dose criteria of > 3 Gy as stated in the CIRSE and SIR guidelines, a patient follow-up rate of 1% was reported [457].
CHAPTER 9

EVALUATION OF PATIENT DOSE IN FLUOROSCOPICALLY GUIDED CERVICAL DISCECTOMY AND FUSION

In this chapter, an evaluation of dose to patients undergoing single or multilevel fluoroscopically guided (FG) cervical discectomy and fusion (CDF) procedures is presented. Specifically, the dosimetric approach included data regarding fluoroscopy time (FT), air kerma area product (KAP) and cumulative dose (CD), which were recorded from the dose report of the fluoroscopy system. Patient entrance surface dose (ESD), thyroid absorbed dose and effective dose (ED) were estimated utilizing a Monte Carlo (MC) based software, the CALDoseX. Conversion coefficients (CCs) relating mean organ/tissue absorbed doses to readily measurable KAP values were also estimated. The results of the current study were compared to corresponding values reported in previous studies. Limitations of this study are mentioned in the discussion section.

9.1 Introduction

Cervical discectomy and fusion (CDF) is a minimally invasive procedure performed, on an elective basis, to re-establish stability, minimize or prevent neurological deficits, and immobilization - related complications [458, 459]. The medical indications for the CDF are described in detail in the literature [186, 460]. The level localization, assessment of the implants insertion, as well as the verification of their correct placement into the vertebral body is accomplished using X-ray fluoroscopic guidance [461]. This is for the benefit of the patient, since the misplacement of the implants may cause neurologic or vascular compromises. However, health effects may occur due to the exposure to ionizing radiation. These effects are divided into two categories, the deterministic and stochastic [24, 153, 284]. The onset of deterministic effects is only possible when the absorbed dose at a specific skin
area exceeds a fixed threshold value, and their severity increases proportionally to the dose over this threshold. Stochastic effects are related with radiation-induced solid cancer, leukaemia or genetic effects. There is no threshold and the likelihood of their occurrence, but not their severity, increases in a linear function with dose. This dose-response model is generally known as "linear-non-threshold" (LNT) and is considered to be the best practical approach to managing risks from low-dose radiation exposure [24, 153, 288].

Patients may be exposed to significant amounts of radiation dose, as a result of prolonged fluoroscopic exposures, due to the complexity of the clinical conditions, mainly affected by the patient's specific anatomical characteristics, as well as the severity and the extent of spinal roots dysfunction at multiple levels. The procedure is highly operator dependent, while under specific circumstances, the patient may be operated repeatedly, utilizing an opposite approach. As the number of spine interventions has been dramatically increased [462], the investigation of the radiation dose received by the patients and medical staff is of high importance [8, 9, 11, 70, 84, 87]. Towards this direction, several authorized Bodies and Organizations have proposed regulations and practical guidelines, aiming to develop a framework for patient radiation protection during several interventional procedures, including those performed outside the imaging department [25, 35, 110]. Although elderly patients are commonly subjected to CDF, even young adults may be treated for traumatic fractures, usually due to accidents. Therefore, it is of particular importance to evaluate radiation dose for this patients' group, and especially the dose absorbed by various radiosensitive organs, that are inside the X-ray field, such as the thyroid [288]. Patient dosimetry is usually performed using films [463], thermoluminescent dosemeters (TLDs) [107] and air KAP meters [464]. Estimation of the organ absorbed doses can be achieved with measurements using either anthropomorphic phantoms [8, 11, 122], or MC simulation methods [123].

Only a few studies have provided dosimetric data during cervical spine interventions [6, 13, 45-47, 174]. Giordano et al have evaluated patient and surgeon radiation exposure, in various geometrical configurations, during irradiation of a cadaveric cervical spine specimen, using a standard [45] and a mini C-arm system [46]. In these studies, patient entrance dose was measured with film badge dosemeters positioned at the center of the specimen. A dose mapping, in eight positions relative to the specimen, was also performed in order to estimate staff dose. Tsalafoutas et al have reported mean entrance dose to the patient and operating surgeon during bilateral pedicle screw placement in the cervical spine
[47]. Fransen has also reported FT and KAP values from anterior CDF and cervical total disk replacement (TDR) procedures [6]. However, to our knowledge, there are limited published data about patient ED, concerning cervical spine fusion interventions [13, 174].

The current study aims to calculate patient ESD, thyroid absorbed dose, as well as the ED, based on KAP measurements, during fluoroscopically guided CDF procedures, performed at the Neurosurgery Department of the University Hospital of Patras.

9.2 Materials and methods

9.2.1 Fluoroscopy equipment

The fluoroscopy X-ray system, utilized in the current study, was a mobile C-arm manufactured by Philips (Philips BV Endura, Philips Medical Systems, Netherlands, BV), designed to support routine surgical spine interventions. The system was operated using the automatic programmed fluoroscopy (APF) acquisition protocol ‘Head/Spine’, dedicated to provide consistent image quality for the specific operation. The continuous low dose fluoroscopy (LDF) mode was the most frequently used, but additionally high dose fluoroscopy (HDF) was implemented, in certain cases, to better visualize the inner structures. All the procedures were performed with the field diameter of 23 cm, fixed iris and shutters, as well as the last image hold function. Tube voltage and current were controlled through automatic exposure control (AEC). The system was also equipped with a software KAP meter, in order to provide real-time indication of the radiation dose, calculated using the pertinent radiological parameters and geometrical information [465]. A dose report was provided at the end of each procedure, which contained an overview of FT, KAP and CD [116], as a total and separately for each fluoroscopy mode used. CD is the total air-kerma accumulated at the interventional reference point (IRP), a point along the central axis of the X-ray beam, 15 cm back from the isocentre towards the focal spot.

In order to achieve adequate accuracy of KAP measurements, the KAP meter was calibrated in situ. A calibrated dosemeter (Radcal Accu Pro 9096, Monrovia, CA, USA,) connected to a cylindrical ionization chamber (model 10 x 6-6) was used, according to the method recommended by the International Atomic Energy Agency (IAEA) [296].

The X-ray fluoroscopy system was under a systematic quality control (QC) program [296, 466], in order to ensure the consistency of its performance. The half value layer (HVL) was
measured 4.35 mm Al at 70 kVp, corresponding to a total filtration equivalent to 7.9 mm Al. In the absence of any absorbing material, the X-ray tube output at the IRP, was measured 1.72, 5.54 and 9.11 mGy/min at 60 kVp and 1.24 mA, 70 kVp and 2.74 mA, and 80 kVp and 2.81 mA, respectively.

9.2.2 Patients and CDF technique

A total of 33 adult patients, who underwent single or multilevel CDF from January 2015 to January 2016, were enrolled in this study. Multilevel spondylotic myelopathy, cord compression or instability, herniated disk or osteophyte and unstable traumatic spine fractures were the main indications of the patients referred to the Neurosurgery Department of our Hospital. The patients included 22 men and 11 women with mean age 53 years (range 25-76 years). Treated levels ranged from C3 to C7. Single level fusion was performed in 21 patients, two levels fusion in 10 patients and three levels fusion in 2 patients.

The CDF technique has been standardized in our Hospital. All the procedures were performed by a neurosurgeon, who has more than thirty years of experience, assisted by a trainee neurosurgeon. Cages were generally used in routine practice, while plates and screws were additionally used, in certain cases, where intraoperative instability was observed, due to possible slip of cages if they were not supported by screws. Pedicle screws were exclusively used for unstable traumatic fractures, in order to provide the appropriate lordosis in the reconstructed cervical spine. Electrodes were used to allow the measurement of the evoked potentials throughout the procedure, due to the close proximity of many vital and neural structures. Preoperative planning included X-ray radiographs and magnetic resonance imaging (MRI) scans. Patients were placed in supine position (anterior approach), while a posterior approach (patient lying face down) was additionally used in the case of pedicle screws placement. The patient's head was fixed using a Mayfield mechanism, giving the cervical spine the required position, depending on the level accessed. The neurosurgeon stood on the right side of the operation table, while the X-ray tube was placed on the same side next to the surgeon, corresponding to a right lateral (RLAT) projection for anterior approaches and a left lateral projection (LLAT) for posterior approaches. Although it is not the recommended position from the point of view of radiation protection, this set-up provides larger working space, especially during instrumentation, due to the smaller size of the X-ray tube compared to the image intensifier. Furthermore, under normal clinical
conditions, the operator of the fluoroscopy system (wearing a lead apron and a thyroid collar) is usually the only person inside the room during irradiation. The focus skin distance (FSD) was about 56 cm, for all patients. The operation was performed using anatomic landmarks, fluoroscopic guidance and tactile feedback. Fluoroscopic guidance was used to confirm the anatomic starting point for the approach, to assess the path trajectory, location and final depth of the pedicle probe, tap and screw, as well as during implants advancement if it was necessary. Since the projection and the patient positioning did not vary significantly, the tube voltage was practically constant, throughout all procedures.

9.2.3 Dose calculations

The ESD, thyroid absorbed dose, as well as the patient ED were calculated using the KAP values [277] and appropriate CCs, provided by a MC based software (CALDoseX 5.0, desktop version) [123]. The software enables age- and posture-specific mesh-based phantoms of typical male and female adults [467], based on anatomical reference data provided by the International Commission on Radiological Protection (ICRP) [468]. Male adult mesh (MASH) and female adult mesh (FASH) phantoms [467] represent an adult male patient with 73 kg weight and 176 cm height (body mass index (BMI) 23.6 kg/m$^2$) and a female adult patient with 60 kg weight and 163 cm height (BMI 22.6 kg/m$^2$), respectively. These phantoms are realistic representations of the human body and the CCs resulting from the simulations were considered to be applicable to the individuals with similar anatomical characteristics. All patients included in the study were normal in body habitus, according to World Health Organization (WHO) criteria (BMI 18.5-24.99 kg/m$^2$), in order to have anatomical characteristics as close as possible to those of the phantoms utilized and to ensure reliable dose calculations, in view of the fact that the phantoms’ size is not adjustable [123, 467]. Since the CDF procedures were performed in the neck region, where wide variations to patients’ thickness do not practically exist, the CALDoseX software can be considered adequate for dose calculations during such procedures, especially for the particular group of patients included in this study. The phantoms were irradiated, using the cervical spine RLAT and LLAT projections for anterior and posterior approaches, in order to be compatible with the projections used in clinical practice, under clinical exposure conditions. The software provided the organ absorbed doses if the statistical error of the MC simulations was smaller than 10%. The simulated field size had a fixed value 18 x 24 cm$^2$ at the detector plane.
(focus-to-detector distance (FDD) 100 cm), which was practically equivalent to a circular field of 11.6 cm radius at the same distance, such as that used in the clinical practice. Furthermore, as the software uses a certain FSD value (84 cm for female and 83 cm for male), which is different than that used during the operations (56 cm), the inverse square law was applied in the calculation of the ESD values. However, the CCs were calculated for an equivalent circular cross section of about 9.6 cm radius for both male and female patients, while in clinical practice a smaller cross section was used (with radius of about 6.5 cm). The patient’s ED was calculated by multiplying the organ/tissue weighting factors [24] with the average dose to each organ/tissue, as derived from the simulations. An estimation of an individual’s cancer risk associated with the CDF procedure can be obtained by multiplying the calculated ED with highly speculative risk coefficients [24, 288]. However, the predictions of the hypothetical excess risks, either for cancer incidence or cancer mortality from such low-dose procedure is a quite controversial topic and are subject to a substantial level of uncertainty [469]. For this reason, the patient risk relating to the CDF procedure was not estimated.

Table 9.1 Operating and exposure parameters obtained from the CDF procedures.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube voltage (kVp)</td>
<td>65</td>
<td>61 - 70</td>
</tr>
<tr>
<td>Tube current (mA)</td>
<td>2.3</td>
<td>1.2 - 4.4</td>
</tr>
<tr>
<td>FSD (cm)</td>
<td>56</td>
<td>56</td>
</tr>
<tr>
<td>FT (seconds)</td>
<td>7.4</td>
<td>1 - 29</td>
</tr>
<tr>
<td>KAP (Gy·cm²)</td>
<td>0.21</td>
<td>0.01 - 1.46</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>0.96</td>
<td>0.04 - 6.58</td>
</tr>
</tbody>
</table>

FSD: focus skin distance; FT: fluoroscopy time; KAP: air kerma area product; CD: cumulative dose.

9.3 Results

The operating and exposure parameters recorded for the patients involved in the CDF procedures are presented in Table 9.1. Although, a great variation was observed (see Figure
9.1), a strong positive correlation was found between KAP and FT values (Pearson correlation test, $r=0.820, p<0.05$), as well as CD and FT values (Pearson correlation test, $r=0.816, p<0.05$), which means that high FT values go with high KAP and CD values and vice versa. However, the usage of the equations describing the fitted regression lines (Figure 9.1) constitutes an oversimplification of patient dose calculation, especially when applied to patients with different anatomical characteristics or under different clinical conditions.

![Figure 9.1 Correlation of KAP and CD with FT values obtained during CDF procedures.](image)

In order to calculate the patient ESD, dose absorbed in various organs and tissues, as well as the ED, the average KAP value was used as the normalization quantity to the CALDoseX software. The CCs derived from the simulations are shown in Table 9.2. The organs and tissues that received the highest amount of radiation dose were the skin, thyroid, salivary glands, oral mucosa, bone surface cells (BSC) and red bone marrow (RBM). The results for patient radiation doses are presented in Table 9.3, for both male and female patients and as a total. The mean patient ESD was 1.95 mGy (range 0.08 - 13.58 mGy). The mean total effective dose ranged between 0.001 and 0.097 mSv (average 0.015 mSv). The mean thyroid
dose was 0.194 mGy (range 0.01 - 1.12 mGy) and contributed about 46% to the total ED, due to the increased radiosensitivity of the thyroid gland. The FT, KAP, CD, ESD and ED values for single and multiple level CDF procedures are presented in Table 9.4. For the 21 patients who underwent single level procedures, the mean ESD and ED values were 24.1% and 20% lower compared to the aforementioned total values, while the mean dose received by the thyroid was 0.157 mGy (range 0.01 - 0.84 mGy). For the multiple level procedures (12 patients), the corresponding ESD and ED values were 42% and 33.3% higher compared to the total values, while the mean thyroid dose was 0.267 mGy (range 0.04 - 1.12 mGy).

**Table 9.2 Organ dose CCs normalized over KAP values, for male and female patients undergoing a CDF procedure.**

<table>
<thead>
<tr>
<th>Organ/Tissue</th>
<th>Male (mGy/Gy·cm²)</th>
<th>Female (mGy/Gy·cm²)</th>
<th>Total (mGy/Gy·cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>0.077</td>
<td>0.161</td>
<td>0.089</td>
</tr>
<tr>
<td>Oral mucosa</td>
<td>0.457</td>
<td>0.730</td>
<td>0.496</td>
</tr>
<tr>
<td>Breasts, glandular</td>
<td>-</td>
<td>0.011</td>
<td>0.005</td>
</tr>
<tr>
<td>Liver</td>
<td>0.004</td>
<td>0.011</td>
<td>0.005</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.035</td>
<td>0.053</td>
<td>0.041</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>0.065</td>
<td>0.121</td>
<td>0.083</td>
</tr>
<tr>
<td>Eyes</td>
<td>0.022</td>
<td>0.048</td>
<td>0.026</td>
</tr>
<tr>
<td>Skin entrance 7.2 x 7.2 cm²</td>
<td>4.369</td>
<td>4.354</td>
<td>4.927</td>
</tr>
<tr>
<td>Spleen</td>
<td>-</td>
<td>0.011</td>
<td>0.005</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.913</td>
<td>1.389</td>
<td>1.110</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.016</td>
<td>0.024</td>
<td>0.018</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.737</td>
<td>1.271</td>
<td>0.922</td>
</tr>
<tr>
<td>Extrathoracic airways</td>
<td>0.454</td>
<td>0.505</td>
<td>0.522</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>0.022</td>
<td>0.017</td>
</tr>
<tr>
<td>Lymphatic nodes</td>
<td>0.076</td>
<td>0.086</td>
<td>0.083</td>
</tr>
<tr>
<td>Maximum RBM Dose</td>
<td>0.609</td>
<td>0.747</td>
<td>0.712</td>
</tr>
<tr>
<td>Maximum BSC Dose</td>
<td>0.791</td>
<td>0.929</td>
<td>0.918</td>
</tr>
</tbody>
</table>

*RBM: red bone marrow; BSC: bone surface cells.*
9.4 Discussion

Organs and tissues that received the greatest amount of radiation dose during the CDF procedure were the skin, thyroid, salivary glands, oral mucosa, BSC and RBM (Table 9.2), that were inside the X-ray field. Due to the organ radiosensitivity, more important were the relatively higher doses delivered to the thyroid and RBM. The CALDoseX software calculated the RBM dose, as well as the BSC and entrance skin dose for a 7.2 x 7.2 cm² area along the central axis of the X-ray beam, where it enters the phantom. This is for radiation protection purposes, since whole body averaged absorbed doses to such tissues distributed

| Table 9.3 Patient ESD and ED values as a function of the sex during CDF procedures. |
|-------------------------------|-------------------------------|
|                               | ESD (mGy)                  | ED (mSv)                  |
|                               | Mean | Range       | Mean | Range       |
| Male                          | 2.50 | 0.08 - 13.58 | 0.017 | 0.001 - 0.097 |
| Female                        | 0.85 | 0.10 - 4.73  | 0.009 | 0.001 - 0.052 |
| Total                         | 1.95 | 0.08 - 13.58 | 0.015 | 0.001 - 0.097 |

ESD: entrance surface dose; ED: effective dose.

| Table 9.4 FT, KAP, CD, ESD and ED values for single and multiple level CDF procedures. |
|-------------------------------|-------------------------------|
| Parameters                   | Single Level | Multiple Level |
|                               | Mean      | Range       | Mean    | Range       |
| FT (sec)                      | 6.3       | 1 – 21      | 9.4     | 3 – 29      |
| KAP (Gy·cm²)                  | 0.16      | 0.01 – 1.11 | 0.30    | 0.03 – 1.46 |
| CD (mGy)                      | 0.73      | 0.04 – 5.00 | 1.35    | 0.13 – 6.58 |
| ESD (mGy)                     | 1.48      | 0.08 – 10.29| 2.77    | 0.28 – 13.58|
| ED (mSv)                      | 0.012     | 0.001 – 0.072| 0.020  | 0.003 – 0.097|

FT: fluoroscopy time; KAP: air kerma area product; CD: cumulative dose; ESD: entrance surface dose; ED: effective dose.
over the body, for a partial exposure such that during CDF, are not representative, leading to underestimation of the radiation dose. Keeping in mind that in the neck region there are no significant anatomical variations, the differences in shape, cross section and FSD between the actual and the simulated X-ray field do not significantly affect organs’ dose, due to the small corresponding changes that occur in the diffusion volume. However, this is not entirely true for organs located close to the boundaries of the X-ray field. According to Kramer et al [123], a variation of the FSD for the cervical spine RLAT or LLAT projection by ±10%, resulted to differences of the CCs less than ±10% for organs and tissues inside the diffusion volume, while for organs located on the boundaries that may be found inside or outside the X-ray field after the change of the FSD, these differences may be far more than 10%. However, since the actual FSD is smaller than that used in the simulations, the actual beam cross section is smaller than the simulated one and consequently the calculated doses for the supposedly out-of-field organs (brain, oral mucosa, salivary glands, extrathoracic airways, eyes, thymus and thyroid) are necessarily overestimated. From this point of view, despite the uncertainty introduced in the calculations, the organs’ absorbed doses, as well as the ED are on the “safe side”. The large differences observed for the CCs for brain, oral mucosa, eyes and thyroid, which are located in the head and neck region, where no significant anatomical variations between male and female patients exist, could be explained mainly due to the different field positions utilized, as well as the different anatomical characteristics and consequently to the different percentage of these organs, which are inside the diffusion volume during irradiation of MASH and FASH phantoms [123, 467]. Variations in patient’s size, as well as in the location and size of the organs between the actual patients and mathematical phantoms used in our simulations introduced an uncertainty in dose calculations. Furthermore, the projection used for the irradiation of the mathematical phantoms is a rough representation of the actual projection. Nevertheless, the results presented can be used as a preliminary basis for the evaluation of patient dose during CDF procedures.

The patient ESD was significantly lower compared to the values already reported [45-47], as summarized in Table 9.5. The dosimetric data reported by Giordano et al were obtained during simulation of cervical spine imaging, using a cadaveric cervical specimen irradiated for five minutes with exposure factors of 78 kVp/2.8 mA and 75 kVp/95 μA [45, 46]. Tsalafoutas et al estimated ESD of four patients undergoing bilateral pedicle screw placement in the cervical spine resulting to a mean FT of 4.2 minutes at mean tube
voltage/tube current combination of 76 kVp/2 mA [47]. The main reasons for the differences observed among the results of the current study and the other studies (see Table 9.5) include different clinical conditions, exposure factors and FT, as well as the technology of the fluoroscopy systems used. Introducing these data [45, 47] into the CALDoseX software, for the simulated fluoroscopy system of our study, resulted to ESD values in the range between 44-82 mGy. Regarding the KAP and FT values, the results of the present study were comparable (see Table 9.5) to those reported by Fransen [6] and Lee et al [13] for ACDF procedures and lower than the values reported by Crawley et al [174] and Fransen [6] corresponding to cervical spine fusion (CSF) and TDR procedures, respectively.

Table 9.5 Comparison of our results with corresponding values reported in previous studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure type</th>
<th>No of patients</th>
<th>FT (min)</th>
<th>KAP (Gy·cm²)</th>
<th>ESD (mGy)</th>
<th>ED (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current study</td>
<td>CDF</td>
<td>33</td>
<td>0.12</td>
<td>0.21</td>
<td>1.95</td>
<td>0.015</td>
</tr>
<tr>
<td>Giordano et al 45</td>
<td>Experimental study</td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>164.3</td>
<td>-</td>
</tr>
<tr>
<td>Giordano et al 46</td>
<td>Experimental study</td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>98.11</td>
<td>-</td>
</tr>
<tr>
<td>Tsalafoutas et al 47</td>
<td>Bilateral pedicle screw placement</td>
<td>4</td>
<td>4.2</td>
<td>-</td>
<td>173</td>
<td>-</td>
</tr>
<tr>
<td>Fransen 6</td>
<td>ACDF</td>
<td>17</td>
<td>0.17</td>
<td>0.169</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fransen 6</td>
<td>TDR</td>
<td>11</td>
<td>0.41</td>
<td>0.456</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Crawley et al 174</td>
<td>CSF</td>
<td>5</td>
<td>0.80a</td>
<td>0.42a</td>
<td>-</td>
<td>0.07</td>
</tr>
<tr>
<td>Lee et al 13</td>
<td>ACDF</td>
<td>15</td>
<td>0.16</td>
<td>0.20</td>
<td>-</td>
<td>0.04</td>
</tr>
</tbody>
</table>

FT: fluoroscopy time; KAP: air kerma area product; ESD: entrance surface dose; ED: effective dose; CSF: cervical spine fusion; TDR: total disk replacement.

The average ED resulting from a CDF procedure (Table 9.3) in our hospital was comparable to that delivered to the patient from a lateral X-ray radiograph of the cervical spine [470, 471]. The ED was significantly low (Table 9.3), due to the short FT achieved.
This fact may be attributed to the increased familiarization of the neurosurgeon with the specific technique. However, complex clinical conditions may result to prolonged fluoroscopic exposures and consequently to substantial radiation dose to the patient. As revealed during this study, the dose delivered to those patients was extremely higher than the mean values reported (Table 9.3), due to the complexity of the pathology and difficulties in the visualization of the anatomical structures. The highest reported values for ESD and ED were 13.58 mGy and 0.097 mSv, respectively. Several studies have reported, that both patient and staff doses were lower, when surgeon had gained additional experience after performing a number of interventions [8, 59, 63, 65]. Other factors that may influence fluoroscopic exposure include the surgeon’s technique, the performance of the available equipment and the way that it is implemented (selection of fluoroscopy mode, zoom, FSD, beam collimation and filtration). The procedures were also divided into single and multiple level procedures (see Table 9.4), in order to further differentiate patient’s dose levels associated with these procedures. In general, the multiple level procedures resulted to higher patient dose values, due to longer FT required.

The ED values were much lower compared to the values reported in the literature [13, 174] (Table 9.5). Crawley et al [174] calculated an approximate ED value 0.07 mSv corresponding to a median KAP value 0.42 Gy·cm², using the ODS60 software package. Lee et al [13] calculated the ED using a conversion factor 0.2 mSv/Gy·cm² to convert the KAP value into ED. Furthermore, a common feature of the studies reported was the relatively small number of patients. It is also worth to notice, that the estimated doses were lower than those associated to other surgical operations of the spine, such as vertebroplasty, kyphoplasty and pedicle screw internal fixation [8, 9, 11, 12]. In this study, the dose values were estimated for a FSD 56 cm, which however is not fixed during normal clinical practice. This introduces an uncertainty in dose estimations. For example, a change of FSD ±2 cm introduces an uncertainty ±7% in the calculation of the ESD values. Even in case considering all above mentioned limitations, the estimated dose values can be considered conservative regarding patients’ dose during CDF procedures. In general, the radiation dose may be considered negligible with respect to the benefit gained by the patient. Consequently, there is no contraindication for the specific technique in cases that it is considered necessary. However, none radiation dose should be ignored, no matter how small it is, if we consider the stochastic pattern of carcinogenesis. Special concerns need to be taken into consideration, especially when young patients with many years of expected life are involved,
mainly due to the fact that during this technique a highly radiosensitive organ, the thyroid, is in the primary X-ray field, along with skin and salivary glands that both have a smaller contribution to the ED. Thus, further investigation is needed, involving larger number of patients from several institutions, different fluoroscopy systems (and especially systems operating in pulsed fluoroscopy mode), as well as neurosurgeons with different levels of experience in order to achieve more accurate results. The main framework should include the implementation of optimization strategies to keep patient dose ‘As Low As Reasonably Achievable’ (ALARA), without compromising the efficacy and the safety of the procedure. In line with ALARA principle, a series of guidelines have been recommended by IAEA [472], in order to ensure the radiation protection of patients during all fluoroscopically guided procedures.

9.5 Conclusion

The patients undertaking fluoroscopically guided CDF in our study received relatively low radiation dose than those previously reported, while most important was the dose received by the thyroid, considering its high radiosensitivity. Therefore, these values should not be considered as a contraindication for the use of fluoroscopic guidance in the performance of the CDF technique, since the net benefit gained by the patient greatly outweighs the associated radiation risk. However, it is important to notice that additional studies need to be conducted to further investigate and optimize the CDF procedure.
CHAPTER 10

OPTIMIZATION OF PATIENT DOSE AND IMAGE QUALITY IN FLUOROSCOPICALLY GUIDED CERVICAL SPINE SURGERY: A PHANTOM BASED STUDY

In a previous dosimetric survey (see chapter 9), the wide range of radiation doses that can be delivered to the patient because of the fluoroscopic guidance implemented in CDF procedures was demonstrated. In this chapter, an experimental study simulating cervical spine surgery (CSS) conditions is carried out, utilizing a polymethyl methacrylate (PMMA) phantom and the TOR 18FG test object, in order to optimize patient dose, image quality (IQ) and figure of merit (FOM) with respect to patient thickness, simply by varying several technical parameters. The KAP and CD values were recorded and the ESD rate on the phantom and image intensifier (II) were measured, for a lateral projection, for all available fields of view (FOVs), fluoroscopy modes, two geometric magnifications and various phantom thicknesses. The corresponding test object images acquired were subjectively evaluated in terms of low-contrast detectability (LCD) and high-contrast resolution (HCR), Signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), high contrast spatial resolution (HCSR), as well as the overall performance in terms of FOMs combining SNR and HCSR with the corresponding ESD values were estimated. Based on these results, a preliminary protocol proposed maximizing the quality of images while delivering radiation doses to the patient that are as low as reasonably achievable, according to the clinical conditions. Limitations of this study are illustrated in the discussion section.

10.1 Introduction

Recently, an increasing number of minimally invasive techniques, such as vertebroplasty, kyphoplasty, anterior cervical discectomy and fusion, cervical total disc replacement,
percutaneous insertion of interspinous process devices, transforaminal lumbar interbody fusion, axial lumbar interbody fusion, lumbar discectomy, laminectomy have been introduced into the field of neurosurgery [1, 8, 473, 474]. In the majority of the cases, they are performed to treat degenerative spinal disorders, tumors and traumatic fractures of the spine. Although their many advantages, they are associated with serious risks (stochastic or deterministic) arising from the intraoperative use of ionizing radiation [8, 24, 107, 475]. Some of these procedures may result, not only to significant amount of radiation dose to the patient, but also to the medical staff involved [8, 45, 69, 107]. Thus, the optimization process is of critical importance, if we consider that most of these procedures are performed outside the imaging department [37] by non-radiologist professionals, usually with insufficient training and awareness of radiation protection [35].

An optimal interventional technique should result to the lowest possible patient dose, while maintaining clinically acceptable image quality, in order to ensure the safety and efficacy of the procedure. However, wide variations of patient doses, even for the same procedure at the same department have been reported [157]. This is attributed mainly to the complex clinical conditions [476] affected by the patient’s anatomy and severity status, surgeon’s technique and experience, imaging protocols, technology, operation and performance of the fluoroscopy equipment, as well as staff training in radiation protection issues [157].

The characterization of the performance of a fluoroscopy system in terms of dose and image quality is an important step towards the optimization process. Experimental studies using test objects and PMMA slabs to simulate patients of different sizes may provide useful data regarding the patient’s ESD and the corresponding image quality [131,133, 135, 137]. The overall performance can be described by estimating a FOM, which combines image and dose indices during the implementation of different acquisition protocols, fluoroscopy modes, exposure factors and magnification FOVs [131, 133, 135, 137]. This information may help the neurosurgeons to select the optimal settings of their systems, in order to minimize patient dose during the procedures with respect to their body size [151, 477], clinical conditions [476] and their personal preferences. Previous studies have investigated the performance of different fluoroscopy systems equipped with either II or flat panel (FP) detectors for several interventional procedures [131, 133, 135, 137, 146, 148, 151, 478]. However, only a few experimental data are available, considering the radiation dose and image quality indices during intraoperative fluoroscopy in spinal surgery [69, 106].
The purpose of this study is to evaluate patient dose and image quality and to estimate the corresponding FOM values, in terms of operator-selectable parameters, for fluoroscopically guided cervical spine surgery procedures.

**Table 10.1** Technical specifications of the fluoroscopy system, Philips BV Endura.

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generator</td>
<td>DC, 3.15 kW at 110 kVp</td>
</tr>
<tr>
<td>Evaluated acquisition protocols</td>
<td>Head/Spine</td>
</tr>
<tr>
<td>Fluoroscopy modes</td>
<td>LDF and HDF: Continuous, Half dose, Quarter Dose</td>
</tr>
<tr>
<td>Pulse rate</td>
<td>12.5 pps for Half Dose, 6.25 pps for Quarter Dose</td>
</tr>
<tr>
<td>Pulse width</td>
<td>40 ms</td>
</tr>
<tr>
<td>Collimation</td>
<td>Iris, two independent lead shutters</td>
</tr>
<tr>
<td>Image intensifier</td>
<td>9-inch</td>
</tr>
<tr>
<td>Fields of view</td>
<td>23, 17 and 14 cm</td>
</tr>
<tr>
<td>Interventional reference point</td>
<td>69.5 cm distance from the focal spot</td>
</tr>
<tr>
<td>Isocentre</td>
<td>84.5 cm distance from the focal spot</td>
</tr>
</tbody>
</table>

**10.2 Materials and methods**

**10.2.1 Fluoroscopy system description**

The fluoroscopy system used in the present study was a mobile C-arm, Philips BV Endura (Philips Medical Systems, Netherland, BV), dedicated for spinal interventional procedures. The system included a high frequency generator controlled by microprocessor, dual focus X-ray tube with 12° anode angle, a 9-inch II and a mobile view station. The source-to-image intensifier distance was 100 cm and three magnification FOVs were available with field diameter sizes 23, 17 and 14 cm. The half value layer was measured 4.35 mm Al at 70 kVp, corresponding to a total filtration of 7.9 mm Al equivalent. The X-ray tube output was measured at the IRP [116] without the interference of the operating table 1.66, 5.49 and 8.38 mGy/min at 60 kVp and 1.24 mA, 70 kVp and 2.74 mA, and 80 kVp and 2.81 mA,
respectively. IRP is a point located along the central axis of the x-ray beam, 15 cm from the isocentre towards the focal spot [116]. The technical specifications of the x-ray system are summarized in Table 10.1.

The system provided six fluoroscopy modes: continuous LDF and HDF, as well as half dose (1/2) and quarter dose (1/4). The LDF and HDF were operated in continuous mode, while the half dose modes were operated with the pulsed rate of 12.5 pulses per second (pps) and quarter dose modes with 6.25 pps. Tube voltage (TV) and tube current (TC) were altered through automatic brightness control (ABC), as required to compensate for patient attenuation with respect to the thickness of the anatomical region to be examined, in order to provide consistent image quality for each acquisition protocol used. The dose control (kVp/ma) curves for each fluoroscopy mode are shown in Figure 10.1. Additionally the last image hold function was also available. The system was under a periodic quality control program based on national and international protocols [296], in order to ensure the reliability and the reproducibility of its dosimetric and imaging performance.

![Figure 10.1 Dose control (kV/mA) curves for the six default fluoroscopy modes of the fluoroscopy system.](image)

**10.2.2 Dose evaluation**

The evaluation of the system was performed for the automated programmed fluoroscopy acquisition protocol ‘‘Head/Spine’’, used in routine practice for cervical spine interventions. To assess the radiation dose, dosimetric quantities such as the KAP and ESD rate were used
The magnification FOVs were kept constant at their nominal values without any collimation. The system was equipped with an integrated KAP meter, in order to provide a real-time display of the patient dose during the procedure. The KAP meter was calibrated in situ according to the method recommended by the IAEA [296]. The calibration was performed using a calibrated Radcal Accu Pro 9096 dosemeter (Radcal Corp., Monrovia, USA) and a cylindrical ionization chamber (model 10 x 6-6). At the dose report provided by the system, there was also an overview of the FT and CD for each fluoroscopy mode used. The CD is the total air kerma without backscatter, accumulated at the IRP [116]. Although, this is an approximate estimation of patient’s ESD, it is possible to estimate the actual incident dose by using the inverse square law between the IRP and the actual FSD. This is an important advantage when the x-ray beam enters a single area of the skin during the entire procedure, since it can be used as an indicator of deterministic injuries. If the projection is adjusted, resulting to multiple irradiated areas, which may not overlap, the maximum skin dose is lower than the CD, leading to an overestimation of the radiation risk [131].

Patients were simulated using PMMA slabs with dimensions 30 cm x 30 cm x 1 cm. The phantom constructed with different thicknesses in the range between 6 and 20 cm (with 2 cm increment), in order to simulate the whole range of the patients undergoing cervical spinal surgery. The ESD rate on the phantom was measured with an ionization chamber (model 10 x 6-6), while the dose rate was simultaneously measured in contact with the grid using a solid state detector R100B (RTI Electronics AB, Sweden) connected to a Barracuda electrometer (RTI Electronics AB, Sweden) operating with the Ocean software (RTI Electronics AB, Sweden). The inverse square law and the backscatter factor of 1.3 were applied to these measurements, in order to estimate the ESD rate on the II [277]. The attenuation of the grid was not considered in these estimations. The detectors were positioned in an area to minimize their interference with the AEC system. It was also tested so that small displacements of the detectors in various magnification FOVs did not affect the exposure parameters significantly. The dosemeters were calibrated to the secondary standard laboratory of the Greek Atomic Energy Commission. The measurements were performed with the middle of the phantom positioned either at the isocentre or the IRP. In the first case, the distance of the posterior side of the phantom from the II was decreased from 11 to 5 cm, as the phantom thickness increased from 6 to 20 cm. In the second case, for the phantom thickness of 20 cm, the distance of the posterior side of the phantom from the II was 20 cm. The focus to phantom surface distance was 59 cm, which is approximately equal to FSDs
reported in the literature [69]. A lateral projection was selected for the measurements, which is representative to certain clinical practices, such as anterior cervical discectomy and fusion. A graphical representation of the irradiation geometry is presented in Figure 10.2.

![Figure 10.2 Graphical representation of the irradiation geometry, showing the TOR-18FG test object at the isocentre (in the middle of the PMMA phantom).](image)

### 10.2.3 Image quality evaluation and FOM

Image quality was evaluated using the test object TOR-18FG (Leeds Test Objects, UK) [http://www.leedstestobjects.com/index.php/phantom/tor-18fg/], positioned at the middle of the phantom. This object is designed to check the LCD by measuring the number of visible low-contrast circles. It contains 18 circles with diameter 8 mm, each one with different thickness, corresponding to contrast levels between 0.009 and 0.167. It also contains a bar pattern for the evaluation of HCR by detecting the group of line-pairs (lps) clearly distinguished. The pattern includes 21 groups of lps corresponding to HCR values between 0.5 and 5 lp/mm. As the presence of the test object inside the x-ray field affects the AEC system, the dose measurements and the acquisition of the images were performed separately, under the same exposure conditions. During each acquisition, a fluoroscopic exposure of at least 5 seconds was used to achieve the stabilization of the AEC system. All acquired images were visualized and scored in the monitor of the view station (1280 x 1024 pixels, 8 bits) by two observers from which the intra-observer variability was calculated. To determine the inter-observer variation, all the images were scored independently two times. The viewing conditions, such as ambient room light and viewing distance, were similar as those in clinical practice, while the visualisation parameters were not adjusted during the evaluation process.
The individual scores were averaged in order to obtain the mean LCD and mean HCR values for each image.

The imaging performance was also characterised by using objective metrics, based on physical measurements in selected regions of interest (ROIs) inside the acquired images. All the images were archived in DICOM format (1280 x 1024 pixels, 8 bits) and analyzed using the ImageJ software [http://imagej.nih.gov/ij/]. The influence of matrix size and bit depth reduction on the image quality indices has been previously investigated [479, 480]. The physical characterisation was performed in terms of the SNR, CNR and HCSR [131, 133, 135, 137].

![Image](image.png)

**Figure 10.3** A typical radiograph of the TOR 18FG test object acquired with the continuous LDF mode and FOV of 23 cm, indicating the ROIs used for the calculation of the image quality indices.
The SNR was calculated using the formula:

\[
\text{SNR} = \frac{\text{ROI}_{BG} - \text{ROI}_1}{\sqrt{\text{STD}^2_{\text{ROI}} + \text{STD}^2_{\text{ROI}_{BG}}}}
\]

\[ (10.1) \]

where ROI$_1$ and STD$_{\text{ROI}_1}$ are the mean pixel values and their standard deviation (STD) inside the first low-contrast circle, while ROI$_{BG}$ and STD$_{\text{ROI}_{BG}}$ are the mean pixel values and their STD in the selected ROI near to the first low-contrast circle. A representative radiograph of the test object containing the ROIs, used for the calculation of the image quality metrics is presented in Figure 10.3. The ROI$_1$ was circular and selected to cover the central part of the circle and had the same size as the ROI$_{BG}$.

The CNR was defined as:

\[
\text{CNR} = \frac{\text{ROI}_{BG} - \text{ROI}_1}{\text{ROI}_{BG}^2}
\]

\[ (10.2) \]

The HCSR was defined as:

\[
\text{HCSR} = \text{STD}^2_2 - \text{STD}^2_3
\]

\[ (10.3) \]

where STD$_2$ and STD$_3$ are the standard deviations of the mean pixel values of the ROI$_2$ inside the seventh group of the high contrast lps and ROI$_3$ outside this (Figure 10.3). The ROI$_2$ and ROI$_3$ were also circular and had the same size as the ROI$_1$ and ROI$_{BG}$.

The overall performance was evaluated by introducing the FOM, which combined the image quality metrics resulted from the different combinations of operating parameters (fluoroscopy modes, FOVs and phantom thicknesses), with the corresponding dose measurements [131, 133, 135, 137]. The FOM was defined as:

\[
\text{FOM}_{\text{SNR}} = \frac{\text{SNR}^2}{\text{ESD}}
\]

\[ (10.4) \]

\[
\text{FOM}_{\text{HCSR}} = \frac{\text{HCSR}^2}{\text{ESD}}
\]

\[ (10.5) \]

where FOM$_{\text{SNR}}$ and FOM$_{\text{HCSR}}$ are the FOMs relating the ESD required to obtain low contrast detectability and HCSR values, respectively.

### 10.2.4 Statistical analysis

The normality of the data was tested with the Kolmogorov-Smirnov goodness-of-fit test. The Mann-Whitney test was used in order to evaluate the intra-observer variability, while the
inter-observer variability was evaluated with the Wilcoxon signed-rank test. The Kruskal-Wallis test was used to check the statistical difference between three or more samples of data. Pairwise statistical comparisons were also carried out in order to check the difference of dosimetric and image quality indices among the fluoroscopy modes used. Statistical analysis was performed with SPSS v.21 statistical package (IBM Corp, Armonk, NY). A p-value of less than 0.05 (p < 0.05) was considered statistically significant.

10.3 Results

The phantom ESD rate, for all phantom thicknesses, fluoroscopy modes and magnification FOVs evaluated, are presented in Figure 10.4. The corresponding ESD rate values at the II are presented in Table 10.2.

Table 10.3 presents the average values of LCD and HCR obtained from the subjective scoring of all test object images. No statistically significant difference was found for intra-observer variability (p > 0.05, Mann-Whitney test) and inter-observer variability (p > 0.05, Wilcoxon signed-rank test) between the fluoroscopy modes investigated. The corresponding exposure parameters (TV and TC), as well as the KAP and CD values are presented in Table 10.4.

The SNR, CNR and HCSR values, for all phantom thicknesses, fluoroscopy modes and magnification FOVs evaluated are presented in Table 10.5. The dosimetric quantities (phantom and II ESD rate), as well as image quality indices (SNR, HCSR) showed statistically significant difference between the fluoroscopy modes investigated (p < 0.05, Kruskal Wallis test). No statistically significant difference was found for CNR values (p = 0.911, Kruskal Wallis test). The least values that gave rise to the differences were observed for the quarter dose fluoroscopy modes (p < 0.05, Mann-Whitney post hoc test).

The $FOM_{SNR}$ and $FOM_{HCSR}$ values, for all fluoroscopy modes, phantom thicknesses and FOV sizes are presented in Figures 10.5 and 10.6, respectively. In order to investigate the influence of geometric magnification [481] on dosimetric and imaging performance of the system, the test object at the centre of the 20 cm phantom was moved from the isocentre (magnification 1.18) to the IRP (magnification degree 1.44), which is approximately similar to that implemented to certain spinal surgery procedures, such as the anterior cervical discectomy and fusion. This influence is presented in Table 10.6.
Figure 10.4 Phantom ESD rate for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.
Table 10.2 II ESD rate for all fluoroscopy modes, FOVs and phantom thicknesses used.

<table>
<thead>
<tr>
<th>Fluoroscopy Mode</th>
<th>FOV (cm)</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
<th>14</th>
<th>16</th>
<th>18</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDF</td>
<td>23</td>
<td>1.21</td>
<td>1.22</td>
<td>1.37</td>
<td>1.38</td>
<td>1.51</td>
<td>1.53</td>
<td>1.62</td>
<td>1.68</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>1.52</td>
<td>1.53</td>
<td>1.57</td>
<td>1.63</td>
<td>1.69</td>
<td>1.70</td>
<td>1.84</td>
<td>1.91</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1.70</td>
<td>1.80</td>
<td>1.80</td>
<td>1.83</td>
<td>1.93</td>
<td>2.00</td>
<td>2.01</td>
<td>2.06</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>0.63</td>
<td>0.64</td>
<td>0.69</td>
<td>0.69</td>
<td>0.75</td>
<td>0.80</td>
<td>0.85</td>
<td>0.86</td>
</tr>
<tr>
<td>1/2 LDF</td>
<td>17</td>
<td>0.78</td>
<td>0.80</td>
<td>0.80</td>
<td>0.83</td>
<td>0.86</td>
<td>0.88</td>
<td>0.93</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.85</td>
<td>0.88</td>
<td>0.90</td>
<td>0.96</td>
<td>0.98</td>
<td>0.99</td>
<td>1.01</td>
<td>1.03</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>0.31</td>
<td>0.32</td>
<td>0.33</td>
<td>0.36</td>
<td>0.40</td>
<td>0.40</td>
<td>0.41</td>
<td>0.42</td>
</tr>
<tr>
<td>1/4 LDF</td>
<td>17</td>
<td>0.38</td>
<td>0.40</td>
<td>0.40</td>
<td>0.41</td>
<td>0.44</td>
<td>0.44</td>
<td>0.46</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.43</td>
<td>0.44</td>
<td>0.46</td>
<td>0.47</td>
<td>0.49</td>
<td>0.51</td>
<td>0.51</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>2.77</td>
<td>2.88</td>
<td>3.16</td>
<td>3.26</td>
<td>3.57</td>
<td>3.66</td>
<td>3.88</td>
<td>3.98</td>
</tr>
<tr>
<td>HDF</td>
<td>17</td>
<td>3.57</td>
<td>3.61</td>
<td>3.72</td>
<td>3.93</td>
<td>4.09</td>
<td>4.20</td>
<td>4.33</td>
<td>4.54</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>4.15</td>
<td>4.21</td>
<td>4.24</td>
<td>4.35</td>
<td>4.46</td>
<td>4.48</td>
<td>4.77</td>
<td>4.84</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>1.52</td>
<td>1.54</td>
<td>1.62</td>
<td>1.65</td>
<td>1.78</td>
<td>1.86</td>
<td>1.96</td>
<td>2.07</td>
</tr>
<tr>
<td>1/2 HDF</td>
<td>17</td>
<td>1.90</td>
<td>1.95</td>
<td>1.95</td>
<td>1.98</td>
<td>2.11</td>
<td>2.16</td>
<td>2.20</td>
<td>2.26</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>2.03</td>
<td>2.12</td>
<td>2.15</td>
<td>2.31</td>
<td>2.35</td>
<td>2.37</td>
<td>2.42</td>
<td>2.46</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>0.77</td>
<td>0.79</td>
<td>0.82</td>
<td>0.85</td>
<td>0.90</td>
<td>0.94</td>
<td>1.00</td>
<td>1.09</td>
</tr>
<tr>
<td>1/4 HDF</td>
<td>17</td>
<td>0.94</td>
<td>0.95</td>
<td>0.95</td>
<td>0.95</td>
<td>1.06</td>
<td>1.09</td>
<td>1.10</td>
<td>1.12</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1.05</td>
<td>1.06</td>
<td>1.11</td>
<td>1.12</td>
<td>1.20</td>
<td>1.20</td>
<td>1.22</td>
<td>1.25</td>
</tr>
</tbody>
</table>
Table 10.3 LCD and HCR for all fluoroscopy modes, FOVs and phantom thicknesses used.

<table>
<thead>
<tr>
<th>Fluoroscopy mode</th>
<th>FOV (cm)</th>
<th>Phantom thickness (cm)</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
<th>14</th>
<th>16</th>
<th>18</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LCD (lp/mm)</td>
<td>HCR (lp/mm)</td>
<td>LCD (lp/mm)</td>
<td>HCR (lp/mm)</td>
<td>LCD (lp/mm)</td>
<td>HCR (lp/mm)</td>
<td>LCD (lp/mm)</td>
<td>HCR (lp/mm)</td>
<td>LCD (lp/mm)</td>
</tr>
<tr>
<td>LDF</td>
<td>23</td>
<td>0.016</td>
<td>2.12</td>
<td>0.017</td>
<td>2.12</td>
<td>0.022</td>
<td>2.00</td>
<td>0.022</td>
<td>2.00</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.015</td>
<td>2.80</td>
<td>0.017</td>
<td>2.65</td>
<td>0.020</td>
<td>2.50</td>
<td>0.022</td>
<td>2.50</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.015</td>
<td>2.98</td>
<td>0.017</td>
<td>2.98</td>
<td>0.017</td>
<td>2.80</td>
<td>0.020</td>
<td>2.65</td>
<td>0.025</td>
</tr>
<tr>
<td>1/2 LDF</td>
<td>23</td>
<td>0.017</td>
<td>2.12</td>
<td>0.017</td>
<td>2.12</td>
<td>0.022</td>
<td>2.00</td>
<td>0.022</td>
<td>2.00</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.016</td>
<td>2.65</td>
<td>0.017</td>
<td>2.65</td>
<td>0.022</td>
<td>2.50</td>
<td>0.022</td>
<td>2.50</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.015</td>
<td>2.98</td>
<td>0.017</td>
<td>2.98</td>
<td>0.020</td>
<td>2.80</td>
<td>0.022</td>
<td>2.65</td>
<td>0.025</td>
</tr>
<tr>
<td>1/4 LDF</td>
<td>23</td>
<td>0.017</td>
<td>2.12</td>
<td>0.017</td>
<td>2.12</td>
<td>0.022</td>
<td>2.00</td>
<td>0.027</td>
<td>2.00</td>
<td>0.027</td>
</tr>
<tr>
<td>HDF</td>
<td>23</td>
<td>0.015</td>
<td>2.24</td>
<td>0.015</td>
<td>2.24</td>
<td>0.017</td>
<td>2.24</td>
<td>0.017</td>
<td>2.12</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.013</td>
<td>3.15</td>
<td>0.013</td>
<td>2.98</td>
<td>0.015</td>
<td>2.80</td>
<td>0.017</td>
<td>2.80</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.013</td>
<td>3.15</td>
<td>0.013</td>
<td>3.15</td>
<td>0.014</td>
<td>3.15</td>
<td>0.017</td>
<td>2.98</td>
<td>0.017</td>
</tr>
<tr>
<td>1/2 HDF</td>
<td>23</td>
<td>0.015</td>
<td>2.24</td>
<td>0.015</td>
<td>2.24</td>
<td>0.017</td>
<td>2.24</td>
<td>0.017</td>
<td>2.00</td>
<td>0.022</td>
</tr>
<tr>
<td>HDF</td>
<td>23</td>
<td>0.015</td>
<td>2.24</td>
<td>0.015</td>
<td>2.24</td>
<td>0.017</td>
<td>2.24</td>
<td>0.020</td>
<td>2.00</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.013</td>
<td>3.15</td>
<td>0.013</td>
<td>2.80</td>
<td>0.015</td>
<td>2.80</td>
<td>0.020</td>
<td>2.80</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.013</td>
<td>3.15</td>
<td>0.013</td>
<td>3.15</td>
<td>0.015</td>
<td>3.15</td>
<td>0.017</td>
<td>3.15</td>
<td>0.017</td>
</tr>
</tbody>
</table>
Table 10.4 Exposure parameters (TV and TC), KAP rate and CD rate values corresponding to all fluoroscopy modes, phantom thicknesses and FOVs used.

<table>
<thead>
<tr>
<th>Fluoroscopy mode</th>
<th>Phantom thickness (cm)</th>
<th>23</th>
<th>17</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TV (kVp)</td>
<td>TC (mA)</td>
<td>KAP rate (mGy·m⁻¹·s⁻¹)*</td>
<td>CD rate (mGy/s)*</td>
</tr>
<tr>
<td>LDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>71</td>
<td>2.74</td>
<td>0.00201</td>
<td>0.090</td>
</tr>
<tr>
<td>18</td>
<td>67</td>
<td>2.3</td>
<td>0.00154</td>
<td>0.069</td>
</tr>
<tr>
<td>16</td>
<td>64</td>
<td>1.86</td>
<td>0.00106</td>
<td>0.047</td>
</tr>
<tr>
<td>14</td>
<td>62</td>
<td>1.42</td>
<td>0.00077</td>
<td>0.034</td>
</tr>
<tr>
<td>12</td>
<td>59</td>
<td>1.14</td>
<td>0.00050</td>
<td>0.023</td>
</tr>
<tr>
<td>10</td>
<td>56</td>
<td>0.933</td>
<td>0.00037</td>
<td>0.017</td>
</tr>
<tr>
<td>8</td>
<td>54</td>
<td>0.726</td>
<td>0.00024</td>
<td>0.011</td>
</tr>
<tr>
<td>6</td>
<td>52</td>
<td>0.54</td>
<td>0.00016</td>
<td>0.007</td>
</tr>
<tr>
<td>1/2 LDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>70</td>
<td>1.37</td>
<td>0.00101</td>
<td>0.045</td>
</tr>
<tr>
<td>18</td>
<td>67</td>
<td>1.13</td>
<td>0.00072</td>
<td>0.032</td>
</tr>
<tr>
<td>16</td>
<td>64</td>
<td>0.897</td>
<td>0.00053</td>
<td>0.024</td>
</tr>
<tr>
<td>14</td>
<td>61</td>
<td>0.677</td>
<td>0.00033</td>
<td>0.015</td>
</tr>
<tr>
<td>12</td>
<td>59</td>
<td>0.562</td>
<td>0.00023</td>
<td>0.010</td>
</tr>
<tr>
<td>10</td>
<td>56</td>
<td>0.458</td>
<td>0.00018</td>
<td>0.008</td>
</tr>
<tr>
<td>8</td>
<td>54</td>
<td>0.351</td>
<td>0.00012</td>
<td>0.005</td>
</tr>
<tr>
<td>6</td>
<td>52</td>
<td>0.278</td>
<td>0.00008</td>
<td>0.004</td>
</tr>
<tr>
<td>1/4 LDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>71</td>
<td>0.686</td>
<td>0.00050</td>
<td>0.022</td>
</tr>
<tr>
<td>18</td>
<td>67</td>
<td>0.571</td>
<td>0.00038</td>
<td>0.017</td>
</tr>
<tr>
<td>16</td>
<td>64</td>
<td>0.453</td>
<td>0.00025</td>
<td>0.011</td>
</tr>
<tr>
<td>14</td>
<td>61</td>
<td>0.346</td>
<td>0.00017</td>
<td>0.008</td>
</tr>
<tr>
<td>12</td>
<td>59</td>
<td>0.285</td>
<td>0.00012</td>
<td>0.006</td>
</tr>
<tr>
<td>10</td>
<td>56</td>
<td>0.231</td>
<td>0.00009</td>
<td>0.004</td>
</tr>
<tr>
<td>8</td>
<td>54</td>
<td>0.184</td>
<td>0.00006</td>
<td>0.003</td>
</tr>
<tr>
<td>6</td>
<td>52</td>
<td>0.139</td>
<td>0.00004</td>
<td>0.002</td>
</tr>
</tbody>
</table>
Table 10.4 (continued)

<table>
<thead>
<tr>
<th>HDF</th>
<th>20</th>
<th>70</th>
<th>6.58</th>
<th>0.00499</th>
<th>0.224</th>
<th>76</th>
<th>6.67</th>
<th>0.00323</th>
<th>0.268</th>
<th>80</th>
<th>6.73</th>
<th>0.00284</th>
<th>0.339</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18</td>
<td>67</td>
<td>5.44</td>
<td>0.00375</td>
<td>0.169</td>
<td>71</td>
<td>6.59</td>
<td>0.00261</td>
<td>0.215</td>
<td>75</td>
<td>6.65</td>
<td>0.00220</td>
<td>0.260</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>64</td>
<td>4.34</td>
<td>0.00271</td>
<td>0.123</td>
<td>67</td>
<td>5.52</td>
<td>0.00199</td>
<td>0.165</td>
<td>69</td>
<td>6.31</td>
<td>0.00165</td>
<td>0.194</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>62</td>
<td>3.26</td>
<td>0.00172</td>
<td>0.077</td>
<td>64</td>
<td>4.34</td>
<td>0.00143</td>
<td>0.119</td>
<td>66</td>
<td>4.29</td>
<td>0.00113</td>
<td>0.134</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>59</td>
<td>2.7</td>
<td>0.00112</td>
<td>0.051</td>
<td>61</td>
<td>3.29</td>
<td>0.00097</td>
<td>0.080</td>
<td>63</td>
<td>3.89</td>
<td>0.00081</td>
<td>0.094</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>56</td>
<td>2.2</td>
<td>0.00077</td>
<td>0.037</td>
<td>59</td>
<td>2.7</td>
<td>0.00063</td>
<td>0.052</td>
<td>60</td>
<td>3.05</td>
<td>0.00058</td>
<td>0.068</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>54</td>
<td>1.7</td>
<td>0.00055</td>
<td>0.025</td>
<td>56</td>
<td>2.14</td>
<td>0.00045</td>
<td>0.037</td>
<td>57</td>
<td>2.46</td>
<td>0.00039</td>
<td>0.046</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>52</td>
<td>1.3</td>
<td>0.00037</td>
<td>0.017</td>
<td>53</td>
<td>1.64</td>
<td>0.00029</td>
<td>0.024</td>
<td>55</td>
<td>1.94</td>
<td>0.00027</td>
<td>0.032</td>
</tr>
<tr>
<td>1/2 HDF</td>
<td>20</td>
<td>72</td>
<td>3.3</td>
<td>0.00255</td>
<td>0.115</td>
<td>77</td>
<td>3.34</td>
<td>0.00169</td>
<td>0.139</td>
<td>82</td>
<td>3.38</td>
<td>0.00154</td>
<td>0.182</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>68</td>
<td>2.83</td>
<td>0.00183</td>
<td>0.083</td>
<td>72</td>
<td>3.3</td>
<td>0.00142</td>
<td>0.118</td>
<td>76</td>
<td>3.33</td>
<td>0.00118</td>
<td>0.140</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>65</td>
<td>2.25</td>
<td>0.00137</td>
<td>0.062</td>
<td>68</td>
<td>2.83</td>
<td>0.00099</td>
<td>0.082</td>
<td>70</td>
<td>3.29</td>
<td>0.00098</td>
<td>0.115</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>62</td>
<td>1.74</td>
<td>0.00092</td>
<td>0.042</td>
<td>65</td>
<td>2.25</td>
<td>0.00070</td>
<td>0.059</td>
<td>66</td>
<td>2.61</td>
<td>0.00066</td>
<td>0.077</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>59</td>
<td>1.39</td>
<td>0.00063</td>
<td>0.028</td>
<td>62</td>
<td>1.72</td>
<td>0.00047</td>
<td>0.039</td>
<td>63</td>
<td>2.02</td>
<td>0.00044</td>
<td>0.051</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>56</td>
<td>1.13</td>
<td>0.00043</td>
<td>0.020</td>
<td>59</td>
<td>1.36</td>
<td>0.00034</td>
<td>0.028</td>
<td>61</td>
<td>1.54</td>
<td>0.00028</td>
<td>0.034</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>54</td>
<td>0.871</td>
<td>0.00029</td>
<td>0.013</td>
<td>56</td>
<td>1.1</td>
<td>0.00022</td>
<td>0.018</td>
<td>58</td>
<td>1.25</td>
<td>0.00020</td>
<td>0.024</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>52</td>
<td>0.677</td>
<td>0.00021</td>
<td>0.009</td>
<td>54</td>
<td>0.851</td>
<td>0.00015</td>
<td>0.012</td>
<td>55</td>
<td>0.981</td>
<td>0.00013</td>
<td>0.015</td>
</tr>
<tr>
<td>1/4 HDF</td>
<td>20</td>
<td>73</td>
<td>1.66</td>
<td>0.00132</td>
<td>0.059</td>
<td>78</td>
<td>1.67</td>
<td>0.00093</td>
<td>0.077</td>
<td>83</td>
<td>1.69</td>
<td>0.00078</td>
<td>0.092</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>68</td>
<td>1.47</td>
<td>0.00100</td>
<td>0.045</td>
<td>73</td>
<td>1.65</td>
<td>0.00071</td>
<td>0.059</td>
<td>77</td>
<td>1.67</td>
<td>0.00062</td>
<td>0.073</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>65</td>
<td>1.17</td>
<td>0.00069</td>
<td>0.031</td>
<td>68</td>
<td>1.46</td>
<td>0.00055</td>
<td>0.045</td>
<td>71</td>
<td>1.65</td>
<td>0.00049</td>
<td>0.058</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>62</td>
<td>0.897</td>
<td>0.00047</td>
<td>0.021</td>
<td>65</td>
<td>1.13</td>
<td>0.00035</td>
<td>0.029</td>
<td>67</td>
<td>1.34</td>
<td>0.00033</td>
<td>0.038</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>59</td>
<td>0.709</td>
<td>0.00030</td>
<td>0.014</td>
<td>62</td>
<td>0.859</td>
<td>0.00025</td>
<td>0.021</td>
<td>63</td>
<td>1</td>
<td>0.00021</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>57</td>
<td>0.574</td>
<td>0.00022</td>
<td>0.010</td>
<td>59</td>
<td>0.694</td>
<td>0.00017</td>
<td>0.014</td>
<td>61</td>
<td>0.793</td>
<td>0.00015</td>
<td>0.017</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>54</td>
<td>0.451</td>
<td>0.00015</td>
<td>0.007</td>
<td>56</td>
<td>0.555</td>
<td>0.00012</td>
<td>0.010</td>
<td>58</td>
<td>0.639</td>
<td>0.00010</td>
<td>0.012</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>52</td>
<td>0.343</td>
<td>0.00010</td>
<td>0.005</td>
<td>54</td>
<td>0.426</td>
<td>0.00008</td>
<td>0.006</td>
<td>55</td>
<td>0.505</td>
<td>0.00007</td>
<td>0.008</td>
</tr>
</tbody>
</table>

* Normalized to the corresponding fluoroscopy time.
10.4 Discussion

10.4.1 Radiation dose

Regarding the ESD rate measurements, both on the phantom (Figure 10.4) and II (Table 10.2), it was observed that HDF modes resulted to higher ESD rate values (2.4 times on average) than the respective values in LDF modes. When the pulse rate decreased to 6.25 pps (1/4 dose), a reduction of 3.8 times (on average) was observed in the ESD rates compared to those for the continuous mode. Thus, it is advisable the neurosurgeons start the fluoroscopic exposure in LDF modes and then altering to HDF, if it is necessary, according to the clinical conditions [473, 474]. A practical way to reduce patient dose further is to use pulsed instead of continuous fluoroscopy, especially in cases of ‘‘thin’’ patients, where the image quality required to ensure the safety and efficacy of the procedure can be obtained with a lower dose [94]. It can also be noticed, that the ESD rates increased with increasing phantom thickness and with the use of magnification FOVs. This could be justified by the fact that for each fluoroscopy mode, the ABC system increases TV and TC with increasing phantom thickness and use of magnification FOVs (Table 10.4). Additionally, in pulsed modes the TV remained almost constant and only the TC values were altered with respect to phantom thickness [482]. For the normal FOV of 23 cm which is the most frequently used in clinical practice, the increase factors due to increase in phantom thickness (from 6 to 20 cm) were roughly 40 and 1.4 for phantom and II ESD rate, in continuous mode, respectively. The slight increase in the II ESD rate is attributed to the different attenuation of the x-ray beam for the various phantom thicknesses. Similar trends were observed in pulsed modes and in magnification FOVs. For the 12 cm phantom, which represents the mean neck width in height-matched men and women [483], the increase factors when applying electronic magnification (FOVs from 23 to 14 cm) were roughly 1.7 and 1.3 for phantom and II ESD rate, respectively. Electronic magnification should therefore not be used, especially in ‘‘thin’’ patients, unless it is necessary to perform the procedure. In general, these increase factors in dose are important aspects that need to be considered by the neurosurgeons, when they select fluoroscopy mode and electronic magnification with respect to the different patient sizes.

Several experimental studies have investigated the dosimetric performance of fluoroscopy systems equipped with either FP or II detectors, under conditions simulating several interventional procedures [131, 133, 135, 137, 146, 148, 151, 478]. A wide variation was
observed, mainly due to the different technology, protocols and initial settings of the fluoroscopy systems. An approach towards optimisation of fluoroscopically guided spine interventions is to provide neurosurgeons with data, in order to understand the influence of the different fluoroscopy modes, electronic magnification and patient sizes on the patient dose [477]. However, the concept of radiation protection is more complex and includes a larger number of factors [476] that have to be considered by neurosurgeons, such as the beam-on time, collimation of the X-ray field, beam filtration, positioning of the patient and orientations [484], tube angulations, pulse rate [94] and width, e.t.c. The results reported in this study, despite the fact that they have emerged for the specific settings of our system, can be utilised as a preliminary basis for the management of patient dose during cervical spinal surgery procedures, performed at a lateral projection, as a function of operator-selectable parameters.

A point that is worth to be discussing is the reliability of the CD values displayed by the system (Table 10.4) as a skin dose indicator. For the phantom thickness of 20 cm, the ESD rate was measured at a distance 74 cm from the phantom, which is only 4.5 cm distant from the IRP (where the CD is estimated). Indicatively, if a backscatter factor of 1.3 is applied to the CD rate values presented in Table 10.4, the difference between the ESD and CD rate values was +0.6% (for LDF mode and FOV = 23 cm). However, this difference becomes +25% for a phantom thickness of 6 cm, since in this case the phantom entrance is 11.5 cm distant from the IRP towards the II. This means that neurosurgeons should take into account the exposure geometry and patient size when using this value as a skin dose indicator, in order to avoid the overestimation or underestimation of the actual skin dose [131].

10.4.2 Image quality and FOM

Regarding the subjective evaluation [485] of the test object images (Table 10.3), it is noticed that the increase in phantom thickness resulted in LCD decrease, while the HCR remained almost constant. On the other hand, when using electronic magnification the LCD remained almost the same, while the HCR increased. Moreover, it can be noticed that both LCD and HCR did not change significantly, when pulsed fluoroscopy was used. These results are also verified by the exposure parameters presented in Table 10.4.

Regarding the objective measurements of image quality (Table 10.5), it can be noticed that the SNR values were higher (1.3 times on average) in HDF modes, while the CNR
values were practically constant compared to those obtained with LDF modes. This is due to the increase of the dose that improves the ‘‘signal’’ in the image and decreases the noise in the background. Both SNR and CNR values decreased (2-2.5 times on average) when the phantom thickness is increased. This can be justified by the fact that although the ESD rate increased, the adjustment of the exposure parameters by the ABC system cannot maintain the same SNR as the phantom thickness increases. Additionally, the SNR and CNR showed no significant variation when utilizing pulsed fluoroscopy. Regarding the magnification FOVs, it seems that the FOV of 17 cm should be reconfigured, in order to provide better SNR with respect to the dose delivered. As far as the HCSR measurements (Table 10.5) are concerned, it is observed that HDF resulted to higher HCSR (1.3 times on average) than the respective values in LDF modes, due to the increase in the ESD rate and the corresponding low noise [326]. Increasing phantom thickness, the HCSR decreased (3 times on average), due to the effect of scattered radiation [326]. Additionally, the HCSR remained nearly constant in pulsed fluoroscopy modes, while when applying electronic magnification (FOVs from 23 to 14 cm) clearly improved, but also resulted to an increase of the ESD rate about 1.7 times (for the 12 cm phantom). These are important aspects, that may help neurosurgeons in the good management of image quality by selecting LDF or HDF, pulsed or continuous fluoroscopy, as well as normal or magnification FOVs with respect to patient thickness and clinical conditions.

The FOM values (FOM_{SNR} and FOM_{HCSR}) decreased in HDF modes and with increasing phantom thickness (Figures 10.5 and 10.6). This is attributed to the fact that the SNR and HCSR changes are small compared to the corresponding changes in the ESD rate with phantom thickness. A decreasing trend was also observed when applying electronic magnification. The FOM_{SNR} values obtained with the magnification FOV of 17 cm verified the need to reconfigure this setting of the system, as also was evident in the SNR values (Table 10.5). The optimization of spinal surgery can be achieved by performing the procedures utilizing pulsed LDF [94] modes and/or normal FOVs, since the FOM values are higher in these cases, except the clinical conditions request the opposite. In general, the FOM relates the quality of an image with the dose required to obtain this image. It has been used for the optimization of several interventional procedures [131, 133, 135, 137], but the results of these studies are not directly comparable, since they depend on several different parameters such as the fluoroscopy system capture technology, initial settings, functional protocol, setup, e.t.c.
Table 10.5 SNR, CNR and HCSR values for all fluoroscopy modes, phantom thicknesses and FOVs used.

<table>
<thead>
<tr>
<th>Fluoroscopy mode</th>
<th>Phantom thickness (cm)</th>
<th>23</th>
<th>17</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SNR</td>
<td>CNR</td>
<td>HCSR</td>
</tr>
<tr>
<td>LDF</td>
<td>20</td>
<td>2.79</td>
<td>4.63</td>
<td>6.41</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>3.23</td>
<td>4.94</td>
<td>9.01</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>3.83</td>
<td>6.10</td>
<td>10.90</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>4.81</td>
<td>6.43</td>
<td>12.59</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>5.26</td>
<td>7.31</td>
<td>14.43</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>5.52</td>
<td>8.03</td>
<td>16.33</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>7.02</td>
<td>9.51</td>
<td>17.52</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>7.88</td>
<td>9.99</td>
<td>19.36</td>
</tr>
<tr>
<td>1/2 LDF</td>
<td>20</td>
<td>3.03</td>
<td>4.85</td>
<td>7.16</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>3.47</td>
<td>5.27</td>
<td>9.18</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>3.93</td>
<td>6.08</td>
<td>10.28</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>4.21</td>
<td>6.59</td>
<td>12.71</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>4.68</td>
<td>7.08</td>
<td>14.20</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>5.63</td>
<td>8.47</td>
<td>15.88</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>7.06</td>
<td>9.48</td>
<td>17.10</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>7.86</td>
<td>10.19</td>
<td>19.11</td>
</tr>
<tr>
<td>1/4 LDF</td>
<td>20</td>
<td>2.90</td>
<td>4.35</td>
<td>6.72</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>3.69</td>
<td>5.41</td>
<td>9.25</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>3.82</td>
<td>6.15</td>
<td>10.33</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>4.63</td>
<td>6.69</td>
<td>12.52</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>4.88</td>
<td>7.41</td>
<td>13.89</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>5.69</td>
<td>8.39</td>
<td>15.78</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>6.68</td>
<td>9.18</td>
<td>17.22</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>7.05</td>
<td>9.98</td>
<td>18.78</td>
</tr>
</tbody>
</table>
## Table 10.5 (continued)

<table>
<thead>
<tr>
<th></th>
<th>HDF</th>
<th>1/2 HDF</th>
<th>1/4 HDF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>HDF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>3.67</td>
<td>4.59</td>
<td>5.48</td>
</tr>
<tr>
<td>18</td>
<td>4.71</td>
<td>5.23</td>
<td>5.90</td>
</tr>
<tr>
<td>16</td>
<td>2.57</td>
<td>3.14</td>
<td>3.99</td>
</tr>
<tr>
<td>14</td>
<td>4.34</td>
<td>5.04</td>
<td>5.71</td>
</tr>
<tr>
<td>12</td>
<td>8.67</td>
<td>12.89</td>
<td>15.46</td>
</tr>
<tr>
<td>10</td>
<td>3.21</td>
<td>3.63</td>
<td>4.51</td>
</tr>
<tr>
<td>8</td>
<td>4.16</td>
<td>4.67</td>
<td>5.61</td>
</tr>
<tr>
<td>6</td>
<td>9.51</td>
<td>12.16</td>
<td>14.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/2 HDF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>4.33</td>
<td>4.79</td>
<td>5.11</td>
</tr>
<tr>
<td>18</td>
<td>4.64</td>
<td>5.35</td>
<td>5.85</td>
</tr>
<tr>
<td>16</td>
<td>10.11</td>
<td>12.64</td>
<td>15.06</td>
</tr>
<tr>
<td>14</td>
<td>2.71</td>
<td>3.92</td>
<td>4.68</td>
</tr>
<tr>
<td>12</td>
<td>4.71</td>
<td>5.67</td>
<td>6.34</td>
</tr>
<tr>
<td>10</td>
<td>9.49</td>
<td>11.60</td>
<td>15.25</td>
</tr>
<tr>
<td>8</td>
<td>28.26</td>
<td>3.32</td>
<td>4.06</td>
</tr>
<tr>
<td>6</td>
<td>28.79</td>
<td>4.93</td>
<td>5.73</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/4 HDF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>3.95</td>
<td>4.20</td>
<td>4.80</td>
</tr>
<tr>
<td>18</td>
<td>4.81</td>
<td>4.93</td>
<td>5.46</td>
</tr>
<tr>
<td>16</td>
<td>10.64</td>
<td>13.00</td>
<td>15.21</td>
</tr>
<tr>
<td>14</td>
<td>2.91</td>
<td>3.22</td>
<td>4.06</td>
</tr>
<tr>
<td>12</td>
<td>9.06</td>
<td>4.93</td>
<td>5.73</td>
</tr>
<tr>
<td>10</td>
<td>12.27</td>
<td>12.27</td>
<td>15.38</td>
</tr>
<tr>
<td>8</td>
<td>5.68</td>
<td>12.27</td>
<td>4.24</td>
</tr>
<tr>
<td>6</td>
<td>4.30</td>
<td>5.03</td>
<td>5.53</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 10.5 $FOM_{SNR}$ values for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.
**Figure 10.6** $FOM_{HCSR}$ values for all phantom thicknesses and fluoroscopy modes used, for the FOVs (a) 23 cm, (b) 17 cm, and (c) 14 cm.
The geometric magnification resulted to increased ESD rate (up to 1.8 times), since the phantom was moved 15 cm towards the focal spot (Table 10.6). In this case, the ABC system produces a higher tube output, in order to compensate the degradation of image contrast and brightness, due to the projection of a smaller part of the test object (patient) to the II. The SNR and CNR values significantly improved (up to 2.3 times) when the normal FOV of 23 cm is used, while a decrease was observed (up to 30%) for the magnification FOV of 14 cm. A slight increase (up to 30%) was also observed for HCSR values. In terms of FOM values, the best performance was observed for pulsed LDF modes and especially for the normal FOV of 23 cm, while they significantly decreased for the magnification FOV of 14 cm (Table 10.6). These are important aspects to be known in neurosurgeons when using geometric magnification. However, it is desirable to use geometric magnification only when increased resolution is required. It is generally preferable to minimize geometric magnification, by keeping the patient as close as possible to the II [45], especially for prolonged fluoroscopic exposures, in order to minimize patient and staff dose.

The main limitations of our study are the usage of only one fluoroscopy system, only one projection and a phantom which does not adequately mimic the anatomy of the neck where there is a lot of bone tissue. Useful information should be obtained using more fluoroscopy systems with a different capture technology (FP or II detectors), phantoms (with different materials [486] and dimensions), test objects [485], projections [484], pulse rates [94] and widths, as well as with removal of the antiscatter grid. Additional practical considerations, such as training in radiation protection issues, minimizing fluoroscopy time, maximizing focus skin distance, keeping the patient as close to the II, the use of intermittent fluoroscopy and collimation e.t.c., need to be taken into account. Such phantom-based studies make medical staff aware about the levels of radiation dose and image quality and could contribute towards the optimisation of spinal surgery procedures, as well as to the establishment of radiological protection culture.
### Table 10.6: Dosimetric and imaging performance for all fluoroscopy modes and FOVs, for the 20 cm phantom and two geometric magnifications.

<table>
<thead>
<tr>
<th>Fluoroscopy mode</th>
<th>FOV (cm)</th>
<th>II ESD rate (μGy/s)</th>
<th>Phantom ESD rate (mGy/min)</th>
<th>SNR</th>
<th>CNR *10000</th>
<th>HCSR</th>
<th>FOM&lt;sub&gt;SNR&lt;/sub&gt; *100 (μGy⁻¹)</th>
<th>FOM&lt;sub&gt;HCSR&lt;/sub&gt; *10 (μGy⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>IRP¹</td>
<td>ISOCE</td>
<td>NTRE²</td>
<td>IRP¹</td>
<td>ISOCE</td>
<td>NTRE²</td>
<td>IRP¹</td>
</tr>
<tr>
<td>LDF</td>
<td>23</td>
<td>0.85</td>
<td>1.68</td>
<td>11.39</td>
<td>7.01</td>
<td>5.27</td>
<td>2.79</td>
<td>10.70</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.92</td>
<td>1.91</td>
<td>13.99</td>
<td>8.32</td>
<td>2.74</td>
<td>2.19</td>
<td>5.61</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1.02</td>
<td>2.06</td>
<td>16.09</td>
<td>9.53</td>
<td>2.03</td>
<td>2.95</td>
<td>4.03</td>
</tr>
<tr>
<td>1/2 LDF</td>
<td>23</td>
<td>0.41</td>
<td>0.86</td>
<td>5.83</td>
<td>3.71</td>
<td>5.21</td>
<td>3.03</td>
<td>11.12</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.45</td>
<td>0.94</td>
<td>7.07</td>
<td>4.44</td>
<td>2.85</td>
<td>2.40</td>
<td>5.84</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.51</td>
<td>1.03</td>
<td>8.20</td>
<td>5.11</td>
<td>1.84</td>
<td>2.73</td>
<td>4.16</td>
</tr>
<tr>
<td>1/4 LDF</td>
<td>23</td>
<td>0.20</td>
<td>0.42</td>
<td>2.97</td>
<td>1.67</td>
<td>5.35</td>
<td>2.90</td>
<td>10.56</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.22</td>
<td>0.48</td>
<td>3.62</td>
<td>2.32</td>
<td>3.02</td>
<td>2.18</td>
<td>5.77</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.25</td>
<td>0.52</td>
<td>4.14</td>
<td>2.45</td>
<td>1.91</td>
<td>2.77</td>
<td>4.07</td>
</tr>
<tr>
<td>HDF</td>
<td>23</td>
<td>1.86</td>
<td>3.98</td>
<td>25.75</td>
<td>16.07</td>
<td>6.99</td>
<td>3.67</td>
<td>10.74</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>2.09</td>
<td>4.54</td>
<td>32.09</td>
<td>19.95</td>
<td>3.82</td>
<td>2.57</td>
<td>5.52</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>2.40</td>
<td>4.84</td>
<td>37.60</td>
<td>22.69</td>
<td>2.61</td>
<td>3.21</td>
<td>3.92</td>
</tr>
<tr>
<td>1/2 HDF</td>
<td>23</td>
<td>0.99</td>
<td>2.07</td>
<td>13.57</td>
<td>8.77</td>
<td>7.31</td>
<td>4.33</td>
<td>10.71</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>1.08</td>
<td>2.26</td>
<td>16.62</td>
<td>10.49</td>
<td>3.73</td>
<td>2.71</td>
<td>5.33</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1.23</td>
<td>2.46</td>
<td>19.33</td>
<td>12.08</td>
<td>2.51</td>
<td>3.40</td>
<td>3.94</td>
</tr>
<tr>
<td>1/4 HDF</td>
<td>23</td>
<td>0.49</td>
<td>1.09</td>
<td>6.88</td>
<td>4.41</td>
<td>7.94</td>
<td>3.95</td>
<td>10.87</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>0.53</td>
<td>1.12</td>
<td>8.53</td>
<td>5.28</td>
<td>3.52</td>
<td>3.02</td>
<td>5.07</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0.61</td>
<td>1.25</td>
<td>9.83</td>
<td>6.17</td>
<td>2.26</td>
<td>3.22</td>
<td>3.61</td>
</tr>
</tbody>
</table>

¹Magnification: 1.44, ²Magnification: 1.18.
10.5 Conclusion

Knowledge of radiation dose with respect to image quality should be unambiguously part of the decision of the neurosurgeon for the selection of the appropriate operational parameters (fluoroscopy mode, electronic or geometric magnification) during spinal surgery regarding patient size. The increase in dose with increasing phantom thickness, applying electronic or geometric magnification and/or HDF modes may provide useful information and awareness to the neurosurgeons for the management of patient dose. Increments in FOM values when using pulsed fluoroscopy, LDF or normal FOVs must be considered, in order to optimize spinal surgery. The CD values displayed by the system should be implemented with caution as a skin dose indicator, especially for ‘‘thinner’’ patients. In summary, it is an essential need that neurosurgeons know how to operate the fluoroscopy system in order to perform effective surgery with the least amount of radiation dose. Further work is necessary towards establishment of radiation protection culture, taking into account additional factors that could contribute to the optimization of spinal surgery procedures.
In this chapter, institutional (local) diagnostic reference levels (LDRLs) and action levels (ALs) are reported, in order to further optimize spine interventional procedures. FT, KAP, cumulative dose CD, as well as anatomical, clinical and technical factors affecting procedure complexity were recorded for 156 patients who underwent both cervical and thoraco-lumbar interventions. Patient ESD, ED, thyroid absorbed dose and gonadal dose were also estimated, based on KAP measurements. The LDRLs and ALs were calculated as the 75th and 10th percentile of FT, KAP and CD values for the total sample of patients, as well as utilizing the weight banding method and the size correction method. The influence of the complexity factors on the reference levels was also investigated. The results presented were compared to corresponding values previously reported in the literature. Practical hints are also provided in the discussion section, in order to reduce both patient and staff doses during such procedures. These results could contribute in the effort for establishing national diagnostic reference levels (DRLs) and increasing neurosurgeons awareness regarding patient dose and radiation protection issues. Limitations of this study are discussed in the results and discussion section.

11.1 Introduction

Over the last two decades, interventional radiology (IR) has exhibited an impressive expansion of the spectrum of intervention types to the field of spine surgery. Currently, CDF and lumbar spine fusion (LSF) have shown a trend towards a rapid growth in the number of interventions performed annually [462]. They are considered as the standard treatment of various degenerative spinal pathologies and have been proven effective in decompressing
and stabilizing the spine [18]. In addition, the development of many novel spinal fixation devices, the availability of new bone grafting materials, better understanding of the pathophysiology of myelopathy, as well as technological advances of fluoroscopy systems have opened new horizons for these minimally invasive procedures.

Generally, spine interventions are performed outside the imaging department by non-radiologist professionals, usually with insufficient knowledge and awareness of radiation protection [35]. Although several clinical benefits are indisputable, including less bleeding and pain, small skin incision, early ambulation and shorter hospital stay, fluoroscopic guidance is required, in order to prevent the misplacement of the cages and pedicle screws and limit the complications. In addition, these procedures are complex and surgeon-dependent, involving extensive fluoroscopic exposures that may result to significant patient and staff radiation dose [1, 7-9, 41, 45, 69, 96, 106, 478]. There are also a number of clinical situations where the x-ray beam is targeted at a fixed entrance surface area for a lengthy period throughout the procedure, increasing the risk for skin injuries. Therefore, patient dose management becomes an important issue [29] regarding the detrimental effects of radiation [24].

The concept of reference doses has been introduced in the 1990s, as part of a quality assurance (QA) program for certain types of diagnostic examinations. The DRLs were defined by the ICRP, as a dosimetric quantity determined by authorized organizations for typical examinations of standard-sized patients or standard phantoms. They serve to manage the patient dose, to compare local with national or international practice, as well as for the identification of those practices resulting to unjustified higher or lower doses compared to the reference values. Each procedure should be revised when they are consistently exceeded during routine practice or with the installation of new equipment [24]. The DRLs cannot be applied to individual exposures of individual patients and do not provide a distinction between good and bad practice. Patient doses below the DRLs do not always mean optimum performance, but they are an indication of acceptable practice, in cases which the clinical outcome is intended.

Several authorized bodies have provided guidance on monitoring patient dose and setting DRLs for both diagnostic and interventional procedures [24, 157]. The KAP is the recommended dosimetric quantity for defining DRLs for interventional procedures [277]. For a specific procedure, the DRLs are usually established at the 75% percentile of the distribution of patients’ KAP values, including a sufficient number of typical patients.
The establishment and proper use of the DRLs in fluoroscopically guided procedures is a difficult task, due to the wide variation of patient doses, even for the same procedure at the same department [168, 487]. This may be attributed to several factors, including problems in the definition of typical interventional procedures, limited number of patients, implementation at a few hospitals, procedure complexity mainly affected by the patient anatomy and severity status, surgical techniques and imaging protocols, operators’ experience and training in the field of radiation protection [157, 162, 168, 487, 488]. However, the DRLs is somewhat different from Reference Levels (RLs), which can either be defined taking into consideration the complexity of the procedure [157, 162] or with a dose audit approach [29, 168, 169]. In order to obtain a reliable value of DRL for an interventional procedure, size-corrected KAP distributions have to be used [168, 171].

At present, various published reference dose data are related to well-established procedures of IR [162, 168, 171, 487-489] and interventional cardiology (IC) [162, 169, 489]. These data have been obtained from surveys conducted at local, national or international level. In Greece, the Greek Atomic Energy Commission (GAEC) has recently published national DRLs including IC procedures [173]. However, there is lack of reference data concerning spine interventions. In the literature, only a few DRL values dealing with spine interventions have been reported [174, 175]. Therefore, monitoring and reporting DRL values regarding routine spine interventions are of extraordinary importance, since there is a substantial need to provide reference dose data in view of the increased usage of these procedures, as well as limited awareness and medical staff training in radiation protection.

In this study, institutional (local) DRLs (LDRLs) for cervical and thoraco-lumbar spine interventions, performed at the Neurosurgery Department of the University Hospital of Patras, are reported and compared to published values. The influence of patient characteristics, technical and exposure factors on the derived DRLs is investigated. Patient ESD, ED, thyroid absorbed dose and gonadal dose are also estimated.
11.2 Materials and methods

11.2.1 Dosimetric quantities

In order to assess patient dose, five quantities were used: FT, KAP, CD, ESD and ED [277, 296]. KAP is the integral of the air-kerma over the entire area of the x-ray beam at a plane perpendicular to the central beam axis and it measured with a software KAP meter.

CD, also known as reference air-kerma, is the total air-kerma without backscatter accumulated at the IRP during the entire procedure. For standard C-arm systems, the IRP is located along the central axis of the x-ray beam, 15 cm from the isocentre towards the focal spot [29]. Although this point is an approximate location of patients’ entrance surface, the actual ESD can be estimated from CD values utilizing the inverse square law to correct the differences between the IRP and the actual FSD.

The ED is the weighted sum of the equivalent dose for all organs and tissues of the human body and is related to the risk for stochastic effects (radiation induced cancers, genetic effects). These effects depend on the age and sex of the exposed person, their probability is proportional to the ED and may occur many years after irradiation, even for low-dose radiation exposure. In addition, the potential of genetic effects increases linearly with dose received by the gonads. It is also of critical importance to estimate the dose absorbed in the thyroid, in all cases, that is inside the x-ray field, like in cervical interventions. As patient’s body is partly irradiated during cervical or lumbar interventions, the dose received by such organs that are located inside the x-ray field may considerably exceed the mean whole body absorbed dose [24, 277]. However, the ED is not intended as a measure of deterministic (acute) effects (erythema, epilation, dermal necrosis). The severity of the acute damage rather than its probability is certain to occur only if the absorbed dose exceeds a specific threshold and usually appears a few days after exposure. The ESD in the most exposed area of the patient’s skin is related to the dose threshold for the development of deterministic effects [24, 277].

11.2.2 Fluoroscopy system

A Philips BV Endura (Philips Medical Systems, The Netherlands, BV), mobile C-arm system with a 9-inch image intensifier was used during all interventions. The system consists of a high frequency generator controlled by microprocessor, dual focus x-ray tube with 12°
anode angle and iris-type collimator. The source-to-image intensifier distance was 100 cm and three fields of view (FOVs) were available with field diameter sizes 23, 17 and 14 cm. The HVL was measured 4.35 mm Al at 70 kVp corresponding to a total filtration of 7.9 mm Al equivalent. The system provided the ability to choose between six available fluoroscopy modes: continuous LDF, continuous HDF, as well as half dose (1/2) and quarter dose (1/4) LDF or HDF and various APF acquisition protocols with respect to the anatomic region to be examined. The x-ray tube output was measured at IRP without the interference of the operating table 1.72, 5.54 and 9.11 mGy/min at 60 kVp and 1.24 mA, 70 kVp and 2.74 mA, and 80 kVp and 2.81 mA, respectively.

All the procedures were performed with the APF acquisition protocols ‘‘Head/Spine’’ and ‘‘Lumbar Spine’’. Tube voltage and current were altered through automatic brightness control (ABC), in order to provide clinically acceptable image quality with respect to the patient’s specific anatomical characteristics. The last image hold function was also used. The system provided a dose report with FT, KAP and CD delivered to the patient, for each fluoroscopy mode used (LDF or HDF).

The period of the use for the system was 6 years. During this time was under a periodic QC program based on national and international protocols [296], in order to ensure the reliability and reproducibility of its dosimetric and imaging performance. All measured parameters were within acceptable limits with respect to the reference values recommended on the protocols and the system’s technical specifications.

### 11.2.3 Calibration of the KAP meter

In order to achieve adequate measurement accuracy, the software KAP meter was calibrated in situ. The calibration was performed using a Radcal Accu Pro 9096 dosemeter (Radcal Corp., Monrovia, CA, USA) and a cylindrical ionization chamber (model 10 x 6-6), according to the method proposed by IAEA [296].

The reference value of the KAP ($P_{KA}^{ref}$) was determined as the product of the measured air-kerma ($K_a$) along the central axis of the x-ray beam and the field area (A) at the plane of the measurement:

$$P_{KA}^{ref} = K_a \cdot A$$  \hspace{1cm} (11.1)

$K_a$ was measured under free-in-air geometry, at a distance 69 cm from the focal spot. A block of Styrofoam was used to support the ionization chamber 20 cm above the patient.
couch, in order to avoid backscatter radiation. The x-ray field was collimated to an area of approximately 10 x 10 cm² at the plane of the ionization chamber. The beam area (A) was determined by irradiating a radiographic film perpendicular to the central axis of the x-ray beam, placed at the same position with the ionization chamber. The nominal area was taken as the area within the 50% of the maximum optical density on the developed film. The calibration coefficient (N) of the KAP meter was calculated as the ratio of the reference KAP value (P⁰refKA) and the reading of the software KAP meter (P⁰softKA):

\[
N = \frac{P_{\text{ref}}^{\text{KA}}}{P_{\text{soft}}^{\text{KA}}} = K_a \cdot A
\]

(11.2)

The KAP meter was calibrated at the beginning, the middle and the end of the study. The variation between the obtained calibration coefficients was less than 2%. The actual KAP value of each procedure, was calculated by multiplying the software KAP meter (P⁰softKA) value with averaged calibration coefficient.

11.2.4 Patients and data collection

Data were collected from 156 spine interventional procedures, performed at the Neurosurgery Department of the University Hospital of Patras during a period of sixteen months. The operations were carried out by three senior neurosurgeons assisted by one trainee neurosurgeon. The patients were randomly referred to the neurosurgeons to undergo the procedure, according to their availability. The neurosurgeons were equally expertised and yielded similar competence and efficiency in spine surgery. The fluoroscopy system was controlled by the neurosurgeons via a footswitch. The continuous LDF mode was generally implemented, while the HDF modes were additionally used in certain cases, when improved image quality was necessary due to complex clinical conditions. The normal magnification FOV was the most frequently used, without any additional collimation using the iris or shutters.

All procedures were indexed to two categories, according to the spinal region; cervical (neck) and thoraco-lumbar (middle and lower back). The patients included in the study were treated for neck, arm or low back pain, degenerative diseases (herniated disks or osteophytes, spinal stenosis), fractures and dislocations, as well as tumors and infections. For the cervical interventions, an anterior approach was generally implemented, while combined anterior and posterior approaches were performed in certain clinical circumstances, with a high degree of
spinal instability, such as fractures or in revision surgery. Thoraco-lumbar interventions were performed through posterior, posterolateral or transforaminal interbody approaches, alone or in combination if a significant degree of instability existed in structural integrity of the spine. Interbody fusion cages were used either as stand-alone devices or combined with plates, screws, pedicle screws and rods, for both cervical and thoraco-lumbar interventions. If a patient was re-operated, these cases were considered as separate procedures in order to determine the intraoperative patient dose. A procedure was excluded from the sample if there was a digression from the standard routine practice.

During each procedure, a medical radiation physicist recorded the type of intervention, patient-related data such as age, gender, weight, height and BMI, as well as the FT, KAP and CD from the dose report of the fluoroscopy system. The tube voltage ranged between 60-110 kVp, while the tube current between 1.24-7.20 mA for all procedures studied. The FSD was about 56 cm and 40 cm for cervical and thoraco-lumbar interventions, respectively. Data collection also included the neurosurgeon who performed the procedure, as well as the clinical (type of fusion, treated levels) and technical factors (type of implants) influencing the complexity of each procedure and consequently the intraoperative usage of fluoroscopic guidance. The correlations between KAP and CD with FT values were investigated for each type of intervention, using various statistical indices. The fitting equations with the highest value of $R^2$ were used to describe the relationships between KAP and CD with FT. Statistical analysis was performed with SPSS v.21 statistical package (IBM Corp, Armonk, NY). A p-value < 0.05 was considered statistically significant.

11.2.5 Dose calculations

For cervical interventions, the patient ESD, thyroid absorbed dose (which is the most radiosensitive organ inside the x-ray field), as well as the ED were calculated according to the method used in a previous study [478].

For thoraco-lumbar interventions, the ESD was calculated, based on the recorded KAP values [9]:

$$ESD = \frac{KAP}{FS} \times BSF$$ (11.3)

where FS (in cm$^2$) is the field size on the patients’ skin and BSF is the backscatter factor in order to take into account the radiation backscattered by the patient. An average value of BSF = 1.5 was used [277].
Additionally, the dose absorbed to gonads, which is the most radiosensitive organ inside or in the proximity of the irradiated area, as well as the ED were calculated along with the KAP values and appropriate sex-specific conversions coefficients previously published [12]:

\[
ED = KAP \times CC_{ED, KAP}
\]  

where \( CC_{ED, KAP} \) (in mSv·Gy\(^{-1}\)·cm\(^{-2}\)) is the KAP to ED conversion coefficient.

### 11.2.6 Reference Levels (RLs)

For each category of spine interventions (cervical, thoraco-lumbar), all the patients were considered as one statistical sample for the calculations, since there were no significant statistical differences between the neurosurgeons regarding the FT, KAP, and CD values (Kruskal-Wallis test, \( p > 0.05 \)). The range, mean, median, 10th, 25th, and 75th percentiles of the total distribution of the FT, KAP, and CD values were estimated. The 75th percentiles of these values were proposed as the preliminary LDRLs for spine interventions in our institution. The 10th percentiles of the FT, KAP, and CD values were considered as ALs below which an investigation of the quality of the procedure is recommended [157, 162, 169]. The potential association of the LDRLs with the series of the recorded anatomical, clinical and technical factors affecting the complexity of the procedures was evaluated with analysis of the statistical differences between specifically designed subgroups within each factor. These subgroups were established from the collaboration of the neurosurgeons with the radiation physicists, taking into account some possible causal agents that significantly affect patient dose during spine interventions. The subgroups were defined on the basis of the recorded factors of age (< 60 or ≥ 60 years), gender (male or female), BMI (< 18.5 or 18.5- 24.9 or 25-29.9 or ≥ 30 kg/m\(^2\)), type of fusion (single or multiple level), treated levels (cervical: C1- C5 or C5-C7, thoraco-lumbar: T1-T12 or L1-L4 or L4-L5 or L5-S1) for single level interventions, as well as type of implants used (without implants, cages or cages plus plates, rods or pedicles screws). The statistical comparisons were performed using either the Mann-Whitney test (for two subgroups) or Kruskal-Wallis test (for three or more subgroups).

In addition, the LDRLs were estimated utilizing the weight banding method (LDRL\(_{wb}\)) [169, 171, 175, 489] and the size correction method (LDRL\(_{sc}\)) [169, 171, 489, 490], in order to reduce the variability of the dosimetric data due to patient weight and size, respectively. The weight banding method was applied by selecting a group of patients with weights between 60 and 80 kg [171, 175]. In the size-correction method, the k-factor used for the
normalization of KAP and CD values was determined experimentally using the technique described by Chapple et al [490] and applied separately for each patient [169]. No corrections for patient size were performed for cervical interventions [175] as well as for the FT, since they are not affected by the patient size [169].

### 11.3 Results and discussion

Fourty five patients (27 men and 18 women) underwent cervical interventions and one hundred and eleven patients (60 men and 51 women) thoraco-lumbar interventions. The patients’ characteristics are presented in Table 11.1. The mean age and BMI were 54 ± 16 years (range 20-82 years) and 26.5 ± 3.5 kg/m$^2$ (range 17.6-37.3 kg/m$^2$), respectively. One hundred and nine patients underwent single level intervention, thirty nine patients two levels intervention, seven patients three levels intervention and one patient four levels intervention. Regarding the surgical approach, 8.9% of the cervical and all of thoraco-lumbar interventions were performed with a posterior approach, while cages as stand-alone implants were used in 64% of the cervical and none of the thoraco-lumbar interventions.

#### Table 11.1 Patients’ characteristics.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Age (years)</th>
<th>Weight (kg)</th>
<th>Height (m)</th>
<th>BMI (kg/m$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>53 ± 14</td>
<td>83 ± 12</td>
<td>1.72 ± 0.05</td>
<td>28.0 ± 3.3</td>
</tr>
<tr>
<td></td>
<td>(25-76)</td>
<td>(69-120)</td>
<td>(1.60-1.83)</td>
<td>(22.5-36.6)</td>
</tr>
<tr>
<td>Female</td>
<td>50 ± 13</td>
<td>75 ± 12</td>
<td>1.65 ± 0.06</td>
<td>27.4 ± 4.4</td>
</tr>
<tr>
<td></td>
<td>(27-75)</td>
<td>(56-104)</td>
<td>(1.51-1.75)</td>
<td>(21.3-37.3)</td>
</tr>
<tr>
<td>Total</td>
<td>52 ± 13</td>
<td>80 ± 12</td>
<td>1.69 ± 0.07</td>
<td>27.7 ± 3.7</td>
</tr>
<tr>
<td></td>
<td>(25-76)</td>
<td>(56-120)</td>
<td>(1.51-1.83)</td>
<td>(21.3-37.3)</td>
</tr>
<tr>
<td><strong>Thoraco-lumbar</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>56 ± 17</td>
<td>80 ± 11</td>
<td>1.74 ± 0.06</td>
<td>26.6 ± 2.8</td>
</tr>
<tr>
<td></td>
<td>(20-82)</td>
<td>(50-108)</td>
<td>(1.60-1.94)</td>
<td>(19.5-34.9)</td>
</tr>
<tr>
<td>Female</td>
<td>54 ± 16</td>
<td>67 ± 10</td>
<td>1.64 ± 0.06</td>
<td>25.1 ± 3.7</td>
</tr>
<tr>
<td></td>
<td>(24-77)</td>
<td>(48-90)</td>
<td>(1.50-1.82)</td>
<td>(17.6-33.2)</td>
</tr>
<tr>
<td>Total</td>
<td>55 ± 16</td>
<td>75 ± 12</td>
<td>1.69 ± 0.08</td>
<td>26.0 ± 3.4</td>
</tr>
<tr>
<td></td>
<td>(20-82)</td>
<td>(48-108)</td>
<td>(1.50-1.94)</td>
<td>(17.6-34.9)</td>
</tr>
</tbody>
</table>

Values are expressed as mean ± SD. Minimum and maximum values are indicated in brackets.
The mean values of FT, KAP and CD per level for patients who underwent single or multiple level interventions are presented in Table 11.2. KAP and CD values showed no statistically significant difference between single and multiple level interventions for both cervical and thoraco-lumbar interventions (Mann-Whitney test, p > 0.05), while FT values showed statistically significant difference only for cervical interventions (Mann-Whitney test, p < 0.05). The wide variation observed in the range of these values was attributed mainly to technical operative factors, due to the complexity of each procedure. The reduction observed in FT per level for multiple level interventions was due to the simultaneous visualization and management of adjacent levels with the same operative set-up [9].

**Table 11.2 FT, KAP and CD values per treated level for cervical and thoraco-lumbar interventions.**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Type</th>
<th>FT (s) / level</th>
<th>KAP (Gy·cm(^2)) / level</th>
<th>CD (mGy) / level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td>Single</td>
<td>5.6 ± 4.9</td>
<td>0.12 ± 0.23</td>
<td>0.56 ± 1.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1.0-21.0)</td>
<td>(0.0001-1.11)</td>
<td>(0.0004-5.0)</td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td>4.1 ± 2.5</td>
<td>0.12 ± 0.20</td>
<td>0.52 ± 0.90</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1.5-9.7)</td>
<td>(0.01-0.73)</td>
<td>(0.07-3.3)</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td>Single</td>
<td>17.7 ± 34.9</td>
<td>0.87 ± 2.05</td>
<td>3.9 ± 9.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1.0-236.0)</td>
<td>(0.0005-14.65)</td>
<td>(0.002-66.6)</td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td>14.8 ± 38.5</td>
<td>0.67 ± 2.01</td>
<td>3.3 ± 10.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(0.5-177.0)</td>
<td>(0.0001-8.64)</td>
<td>(0.0004-46.8)</td>
</tr>
</tbody>
</table>

Values are expressed as mean ± SD. Minimum and maximum values are indicated in brackets.

The range, mean, median, 10\(^{th}\), 25\(^{th}\) and 75\(^{th}\) percentile of the total distribution of FT, KAP and CD values corresponding to cervical and thoraco-lumbar interventions are presented in Table 11.3. In general, thoraco-lumbar interventions demonstrated 3.2 times longer FT compared to cervical interventions (Mann-Whitney test, p < 0.05) and thus resulted to 6.0 - 6.3 times higher KAP and CD values (Mann-Whitney test, p < 0.05). The LDRLs proposed for FT, KAP and CD values are 0.15 min, 0.10 Gy·cm\(^2\) and 0.47 mGy, as well as 0.29 min, 0.71 Gy·cm\(^2\) and 3.24 mGy for cervical and thoraco-lumbar interventions, respectively. If the KAP meter calibration factors were not applied to the KAP measurements, patient doses might be underestimated up to 28%. The ALs proposed for FT, KAP and CD values were 0.03 min, 0.01 Gy·cm\(^2\) and 0.05 mGy, as well as 0.03 min, 0.07 Gy·cm\(^2\) and 0.33 mGy for cervical and thoraco-lumbar interventions, respectively. If the mean values are below the ALs, an investigation of the quality of the procedures is
recommended [157, 162, 169]. The mean values estimated were above the ALs for both types of interventions (Table 11.3). On the other hand, if the mean values are greater than DRL, the entrance dose rate at the image intensifier and dose/image should be investigated first by comparing the current values with those obtained during the acceptance test. As a second step, the examination protocol should be verified [449]. The mean values estimated in this study were above the DRLs for both types of interventions (Table 11.3), identifying the need for optimization measures to be targeted. In addition, the median values can be utilized to check the effectiveness of local dose reduction strategies. The reduction of patient doses below the DRLs should be performed in line with ALARA principle, but with caution, in order to avoid loss of clinical information.

**Figure 11.1** Histograms of the total distribution of KAP and CD values for (a) cervical and (b) thoraco-lumbar interventions.
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
<th>10&lt;sup&gt;th&lt;/sup&gt; percentile</th>
<th>25&lt;sup&gt;th&lt;/sup&gt; percentile</th>
<th>75&lt;sup&gt;th&lt;/sup&gt; percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FT (s)</td>
<td>6.7</td>
<td>5.0</td>
<td>1.0 - 29.0</td>
<td>2.0</td>
<td>3.0</td>
<td>9.0</td>
</tr>
<tr>
<td>KAP (Gy·cm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>0.17</td>
<td>0.06</td>
<td>0.0001 - 1.46</td>
<td>0.01</td>
<td>0.02</td>
<td>0.10</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>0.76</td>
<td>0.26</td>
<td>0.0004 - 6.58</td>
<td>0.05</td>
<td>0.13</td>
<td>0.47</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FT (s)</td>
<td>21.6</td>
<td>9.0</td>
<td>1.0 - 354.0</td>
<td>2.0</td>
<td>3.0</td>
<td>17.5</td>
</tr>
<tr>
<td>KAP (Gy·cm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>1.02</td>
<td>0.31</td>
<td>0.0002 - 17.29</td>
<td>0.07</td>
<td>0.14</td>
<td>0.71</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>4.75</td>
<td>1.40</td>
<td>0.001 - 93.5</td>
<td>0.33</td>
<td>0.64</td>
<td>3.24</td>
</tr>
</tbody>
</table>
Chapter 11 LDRLs in FG spine surgery

The histograms of KAP and CD values for cervical and thoraco-lumbar interventions are presented in Figure 11.1. The shape of the distributions was asymmetrical with some extreme values, corresponding to procedures that involved prolonged fluoroscopic exposures, due to their complexity. Since the KAP and CD values did not follow normal distribution (Smirnov-kolmogorov goodness of fit test, p < 0.01), the Spearman’s Rho correlation test was applied to evaluate their correlation with FT values. In the case of cervical interventions there was a very strong correlation between KAP and FT (Spearman Rho correlation coefficient $r_s = 0.8129$, $p < 0.05$) and a strong correlation between CD and FT values (Spearman Rho correlation coefficient $r_s = 0.7578$, $p < 0.05$). In the case of thoraco-lumbar interventions there was a very strong correlation between KAP and FT (Spearman Rho correlation coefficient $r_s = 0.8421$, $p < 0.05$), as well as CD and FT values (Spearman Rho correlation coefficient $r_s = 0.8413$, $p < 0.05$). The differences in the correlation between the cervical and thoraco-lumbar interventions can be explained, due to the different cross sections defined during the procedures involving the torso, compared to that involving the smaller parts of head and neck, which are more uniform even for patients with different BMI, as well as different indications, patient thicknesses, pathological findings and number of patients included in each group. In total, the highest patient doses were associated with the most complex procedures performed at the thickest parts of the body, especially for overweight and obese patients [96].
Figure 11.2 Fitting curves describing the relationship between KAP and CD values with FT for (a) cervical and (b) thoraco-lumbar interventions.

The fitting curves resulted to the best fit among the data, together with the equations describing the relationship between the KAP and CD values with FT are presented in Figure 11.2. For the cervical spine interventions, the best fits were provided by the sixth order polynomial equations:

\[
KAP = 4E-07 \cdot FT^6 - 3E-05 \cdot FT^5 - 0.010 \cdot FT^3 + 0.059 \cdot FT^2 - 0.121 \cdot FT + 0.094 \quad (R^2 = 0.777) \quad (11.5)
\]

and

\[
CD = 2E-06 \cdot FT^6 - 0.003 \cdot FT^4 - 0.044 \cdot FT^3 + 0.243 \cdot FT^2 - 0.482 \cdot FT + 0.402 \quad (R^2 = 0.775), \quad (11.6)
\]

while for the thoraco-lumbar interventions by the sixth order polynomial equations:

\[
KAP = 2E-12 \cdot FT^6 - 2E-09 \cdot FT^5 + 9E-07 \cdot FT^4 + 0.008 \cdot FT^2 - 0.126 \cdot FT + 0.584 \quad (R^2 = 0.927) \quad (11.7)
\]

and

\[
CD = 1E-11 \cdot FT^6 - 1E-08 \cdot FT^5 + 4E-06 \cdot FT^4 + 0.040 \cdot FT^2 - 0.581 \cdot FT + 2.672 \quad (R^2 = 0.936) \quad (11.8)
\]

These relationships were attributed to the different fluoroscopy modes and FOVs implemented by the neurosurgeons during the procedures. Furthermore, KAP and CD values are not only related to FT, but also to the tube voltage and tube current as defined by the ABC system, with respect to the thickness of the anatomical region treated. This is the main reason that some KAP and CD values scatter considerably along the fitted curves, as revealed in Figure 11.2. Although the estimation of KAP and CD using these equations was subject to significant uncertainty, it can be considered the best approximation taking into that a number of potential factors may change during these procedures [1, 9].

222
The three neurosurgeons participated in the study had more than twenty years of experience in spine surgery and an annual workload of about 50 procedures. Concerning surgeon dependency, this inclusion was “the best case scenario” for patient dose, because the intraoperative usage of fluoroscopy per case for less experienced surgeons, especially those who are in training, could be significantly higher [7]. No significant variability was found among the neurosurgeons with regard to FT, KAP and CD values (Kruskal-Wallis test, p > 0.05), due to the standardization of the imaging technique. However, as demonstrated by the standard deviation of the FT, KAP and CD values, even these experienced surgeons may rely to heterogeneous usage of fluoroscopic exposure depending on complex clinical conditions. According to ICRP [35], spine interventions are usually performed outside the imaging department and patient as well as staff doses can be significantly increased, due to the lack of radiation protection training of the staff working with fluoroscopy. From this point of view, training programs are essential for neurosurgeons, while experimental studies concerning image quality and radiation dose may also contribute towards optimization process during these procedures [45, 69, 106].

The distributions of the patients into different subgroups for each of the considered potential factors, as well as the degree of the association with the LDRLs are presented in Table 11.4. The age and treated levels showed significant influence on LDRLs only for cervical interventions (Mann-Whitney test, p < 0.05), whereas no significant association was found for all other factors studied. For thoraco-lumbar interventions, none of the included factors significantly influenced the LDRLs (p > 0.05). Furthermore, the p-values for patient gender (p = 0.093), type of fusion (p = 0.078) and type of implants (p = 0.088) were close to statistical significance. The association of these factors with the LDRLs could probably be validated in a larger sample of patients. For both types of interventions, the group of male patients showed higher LDRL values (although not significantly) compared to female patients most likely due to increased BMI (Table 11.1). Various additional factors such as the sample size for each type of intervention, surgical approach, grade of myelopathy, neck length and diameter and waist circumference may also contribute to the complexity of these procedures. Although the analysis of the association of the LDRLs with all mentioned potential factors affecting the complexity is useful towards optimization process, these factors should not be analyzed individually when establishing DRLs.
### Table 11.4 Association of the LDRLs with the investigated anatomical, clinical and technical factors influencing procedure complexity.

<table>
<thead>
<tr>
<th>Factors</th>
<th>Cervical</th>
<th>Thoraco-lumbar</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>LDRL (Gy·cm²)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 60</td>
<td>33</td>
<td>0.08</td>
</tr>
<tr>
<td>≥ 60</td>
<td>12</td>
<td>0.44</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>27</td>
<td>0.14</td>
</tr>
<tr>
<td>Female</td>
<td>18</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 18.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>18.5 - 24.9</td>
<td>9</td>
<td>0.09</td>
</tr>
<tr>
<td>25 - 29.9</td>
<td>26</td>
<td>0.11</td>
</tr>
<tr>
<td>≥ 30</td>
<td>10</td>
<td>0.13</td>
</tr>
<tr>
<td><strong>Type of fusion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single (1-level)</td>
<td>31</td>
<td>0.09</td>
</tr>
<tr>
<td>Multiple (≥ 2 levels)</td>
<td>14</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Treated levels</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1-C5</td>
<td>16</td>
<td>0.04</td>
</tr>
<tr>
<td>C5-C7</td>
<td>15</td>
<td>0.17</td>
</tr>
<tr>
<td>T1-T12</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>L1-L4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>L4-L5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>L5-S1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Type of implants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without implant</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cages</td>
<td>31</td>
<td>0.10</td>
</tr>
<tr>
<td>Cages &amp; plates &amp; screws</td>
<td>14</td>
<td>0.18</td>
</tr>
</tbody>
</table>
The range, mean, median, 10th, 25th and 75th percentile of FT, KAP and CD values for the distribution of the patients in the weight band 60-80 kg (29 patients) [168, 171, 490] are presented in Table 11.5. In this way, a good indication of the dose to the reference patient (70 ± 10 kg) can be obtained, but it could be less representative, if a large number of patients are excluded from the sample. In this study, the distributions of KAP and CD values obtained from the weight banding method were comparable to that of the total population for both types of interventions, while mean FT values were comparable only for cervical interventions and about 1.8 times lower for thoraco-lumbar interventions (Table 11.3). The LDRLwb values obtained for FT, KAP and CD values are 0.15 min, 0.09 Gy·cm² and 0.42 mGy, as well as 0.27 min, 0.61 Gy·cm² and 2.77 mGy for cervical and thoraco-lumbar interventions, respectively. The ALwb obtained for FT, KAP and CD values are 0.03 min, 0.01 Gy·cm² and 0.05 mGy, as well as 0.03 min, 0.07 Gy·cm² and 0.33 mGy for cervical and thoraco-lumbar interventions, respectively.

The range, mean, median, range, 10th, 25th and 75th percentile of KAP and CD values normalized to the size of reference man are presented in Table 11.6. The k-factor used for patient size correction of KAP and CD values was 0.182 cm⁻¹ and was only applicable for dosimetric data obtained with fluoroscopy carried out under AEC [490]. It was calculated as the gradient in the graph illustrating the logarithm of the KAP rate values versus PMMA thickness, as presented in Figure 11.3. It was different compared to the values reported in other studies [489, 490], mainly due to the different phantom materials used and settings of the fluoroscopy systems. This type of normalization is relevant only for procedures involving thoracic and lumbar spine, where a strong correlation between patients’ dose and body size exists. As reported by Miller et al [168] for small parts of the body (e.g. head and neck), weight banding and size normalization yielded similar results compared to uncorrected values. The LDRLsc values for KAP and CD are 0.57 Gy·cm² and 2.59 mGy, while the corresponding ALsc are 0.05 Gy·cm² and 0.24 mGy, respectively. These values are 20-29% lower compared to those for the whole population (Table 11.3).
Table 11.5 Mean, median, range, 10th, 25th, 75th percentile of FT, KAP and CD values, for cervical and thoraco-lumbar interventions, obtained from weight banding method.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
<th>10th percentile</th>
<th>25th percentile</th>
<th>75th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>FT (s) Cervical</td>
<td>6.3</td>
<td>4.0</td>
<td>1.0 – 29.0</td>
<td>1.8</td>
<td>3.0</td>
<td>9.0</td>
</tr>
<tr>
<td>KAP (Gy·cm²)</td>
<td>0.16</td>
<td>0.05</td>
<td>0.0001 – 1.46</td>
<td>0.01</td>
<td>0.02</td>
<td>0.09</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>0.70</td>
<td>0.23</td>
<td>0.0004 – 6.58</td>
<td>0.05</td>
<td>0.11</td>
<td>0.42</td>
</tr>
<tr>
<td>FT (s) Thoraco-lumbar</td>
<td>12</td>
<td>8.0</td>
<td>1.0 – 72.0</td>
<td>2.0</td>
<td>3.0</td>
<td>16.0</td>
</tr>
<tr>
<td>KAP (Gy·cm²)</td>
<td>0.59</td>
<td>0.31</td>
<td>0.0002 – 10.24</td>
<td>0.07</td>
<td>0.13</td>
<td>0.61</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>2.7</td>
<td>1.40</td>
<td>0.001 – 46.3</td>
<td>0.33</td>
<td>0.61</td>
<td>2.77</td>
</tr>
</tbody>
</table>

Table 11.6 Mean, median, range, 10th, 25th, 75th percentile of FT, KAP and CD values for thoraco-lumbar interventions, obtained with size correction method.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
<th>10th percentile</th>
<th>25th percentile</th>
<th>75th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoraco-lumbar KAP (Gy·cm²)</td>
<td>0.79</td>
<td>0.29</td>
<td>0.0001 – 11.66</td>
<td>0.05</td>
<td>0.13</td>
<td>0.57</td>
</tr>
<tr>
<td>CD (mGy)</td>
<td>3.7</td>
<td>1.32</td>
<td>0.0006 – 56.1</td>
<td>0.24</td>
<td>0.58</td>
<td>2.59</td>
</tr>
</tbody>
</table>
Fig. 11.3 Experimental determination of k-factor used for patient size corrections.

The LDRLs estimated were compared to corresponding results previously reported, although a direct comparison was not possible, due to the different categorization of the procedures. Crawley et al [174] reported LDRLs for cervical spine fusion (0.85 Gy·cm²), cervical spine injection facets (2.78 Gy·cm²), thoracic spine fusion (3.51 Gy·cm²), lumbar spine fusion (14.69 Gy·cm²), lumbar spine discectomy (2.51 Gy·cm²), lumbar spine decompression (4.17 Gy·cm²), lumbar spine laminectomy (3.59 Gy·cm²) and lumbar spine injection facets (5.38 Gy·cm²). Lichtherte et al [175] utilizing data from six hospitals reported DRLs for cervical/lumbar epidurals (0.5 Gy·cm² and 12s), cervical/lumbar facet joint nerve blocks (2.5 Gy·cm² and 60 s), as well as for cervical/lumbar transforaminal procedures (3 Gy·cm² and 50s). The preliminary LDRLs estimated in this study were broadly lower than these reported values for both cervical and thoraco-lumbar interventions.

The average patient ESD and ED values, as well as the dose absorbed to the thyroid and gonads during cervical and thoraco-lumbar interventions, respectively, are presented in Table 11.7, for both male and female patients and as a total. Regarding the cervical interventions, the results are in accordance with those reported in a previous study [478]. The ESD and ED values for thoraco-lumbar interventions were 15 and 10 times higher compared to those obtained from cervical interventions. This is mainly attributed to the longer FT (3.2 times higher) required, as well as to the higher exposure parameters (tube voltage, tube current), due to the increased body thickness compared to that of the neck region. The highest reported values for ESD and ED were 13.58 mGy and 0.097 mSv, as well as 390.3 mGy and 2.11 mSv for cervical and thoraco-lumbar interventions, respectively. The latter values correspond to complex procedures in obese patients [96]. However, even these
extreme ESD values are quite lower compared to the threshold dose for deterministic effects (2 Gy for skin erythema). The ED and ESD values during thoraco-lumbar interventions were significantly lower compared to those associated with similar procedures in the lumbar spine [1, 7, 8, 9, 12]. Regarding the patient’s gender, males showed higher ESD and ED values for both types of interventions, while the gonadal dose was higher for females because of their increased radiosensitivity. The mean thyroid and gonadal dose values were 0.14 mGy (range 0.002 - 1.12 mGy) and 0.044 mGy (range 0.000003 - 1.56 mGy), respectively. Despite the fact that these values are relatively small, dose reduction strategies are of priority concern regarding the radiosensitivity of these two organs that are located inside the x-ray field and the stochastic pattern for carcinogenesis and hereditary effects. However, special concerns also need to be taken into consideration, when young adults with complex spinal pathology are involved, requiring prolonged fluoroscopic exposure, since in these cases the dose may be extremely higher than the mean values reported. In addition, the overweight or obese patients requiring higher tube output, in order to maintain clinically acceptable image quality, while the FSD may be reduced, as the focus to image intensifier distance is fixed.

**Table 11.7** Patient ESD, ED, thyroid absorbed dose and gonadal dose values for cervical and thoraco-lumbar interventions.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(mGy)</td>
<td>(mSv)</td>
<td>(mGy)</td>
</tr>
<tr>
<td>Cervical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESD</td>
<td>2.12</td>
<td>0.71</td>
<td>1.58</td>
</tr>
<tr>
<td>(0.08 – 13.58)</td>
<td>(0.02 – 4.73)</td>
<td>(0.02 – 13.58)</td>
<td></td>
</tr>
<tr>
<td>ED</td>
<td>0.015</td>
<td>0.008</td>
<td>0.012</td>
</tr>
<tr>
<td>(0.001 – 0.097)</td>
<td>(0.001 – 0.052)</td>
<td>(0.001 – 0.097)</td>
<td></td>
</tr>
<tr>
<td>Thyroid Dose</td>
<td>0.169</td>
<td>0.095</td>
<td>0.140</td>
</tr>
<tr>
<td>(0.006 – 1.12)</td>
<td>(0.002 – 0.65)</td>
<td>(0.002 – 1.12)</td>
<td></td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESD</td>
<td>27.1</td>
<td>18.1</td>
<td>23.0</td>
</tr>
<tr>
<td>(0.004 – 372.7)</td>
<td>(0.573 – 390.3)</td>
<td>(0.004 – 390.3)</td>
<td></td>
</tr>
<tr>
<td>ED</td>
<td>0.138</td>
<td>0.104</td>
<td>0.124</td>
</tr>
<tr>
<td>(0.00002 – 1.899)</td>
<td>(0.003 – 2.248)</td>
<td>(0.00002 – 2.11)</td>
<td></td>
</tr>
<tr>
<td>Gonadal Dose</td>
<td>0.020</td>
<td>0.072</td>
<td>0.044</td>
</tr>
<tr>
<td>(0.000003 – 0.281)</td>
<td>(0.002 – 1.56)</td>
<td>(0.000003 – 1.56)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as mean values. Range values are indicated in parenthesis.

With the dramatic increase of fluoroscopy in spine surgery procedures, it becomes critical the neurosurgeons and assisting staff to have training in radiation protection issues, in order to ensure that both the patient and staff exposure to radiation are kept as low as reasonably
achievable without compromising the efficacy of each procedure [35]. The effective
management of dose implies the proper use of fluoroscopy system, including the
implications of each fluoroscopy mode (continuous or pulse fluoroscopy), magnification
FOV and filtration to both image quality and dose, as well as the implementation of a
systematic QC program. The most effective method for decreasing patient dose is to
minimize FT. Use of the LDF modes is recommended and HDF modes should be used, only
if it is necessary, according to the clinical conditions. Last image hold function, ABC and
pulsed fluoroscopy modes should also be utilized. It is generally preferred to minimize
geometric magnification, especially in prolonged procedures, by keeping the patient as close
as possible to the image intensifier, while electronic magnification should be used only if
increased resolution is required. The FSD should always be the maximum possible, and
never less than 30 cm, while the x-ray field should be collimated in order to include only the
anatomic region of interest. It is also important to notice that both patient and staff doses are
dependent on the experience of the neurosurgeon. Neurosurgeons should always keep in
mind that reducing patient dose, staff doses will also be reduced. The evaluation of staff
radiation doses is an important topic that has to be studied in order to obtain data that will
contribute to the establishment of a complete radiation protection system during such
procedures. Thus, further investigation is needed towards this direction, through clinical or
experimental studies taking into account all the aforementioned factors affecting patient and
staff doses, the usage of radiation protection devices, as well as the implementation of direct
dose measurements (for ESD, patient thyroid and gonadal dose as well as staff doses) by
using TLDs, in order to achieve more accurate results. The main limitations of this study
were the usage of only one fluoroscopy system, operated mainly to continuous fluoroscopy
modes (LDF or HDF) and the limited number of patients included. A larger number of
patients could contribute to a more accurate evaluation of patient dose during different
treatments of the spine, such as anterior cervical discectomy and fusion, lumbar spinal
fusion, posterior lumbar discectomy, transforaminal lumbar interbody fusion, etc. The
inclusion of a system with a flat panel detector and the implementation of appropriately
configured pulsed fluoroscopy modes [41] could result to lower patient doses. Additional
data from other hospitals may also contribute towards a universal evaluation of patient
radiation dose during such procedures. In the current study, ‘‘a best case scenario’’ was
considered with respect to the neurosurgeons’ experience and higher doses are expected if
less experienced surgeons are (such as trainees) involved in the procedures. As future work,
the estimation of the dose received by the operating neurosurgeon and medical staff during routine procedures and consequently the number of allowable procedures without exceeding the annual dose limits is of particular importance, because of their frequent exposition to radiation. The estimated LDRLs could contribute in the effort of developing a radiation protection culture and optimization of the spine interventions in our hospital. Additionally, they could contribute in the effort for establishing national DRLs for spine interventional procedures.

11.4 Conclusion

In this study, LDRLs and ALs were estimated for cervical and thoraco-lumbar interventions, utilizing three different methods. With regard to ESD, ED as well as thyroid absorbed dose and gonadal dose values cervical and thoraco-lumbar interventions are safe procedures. The estimated LDRL values for both interventions were influenced by various anatomical, clinical and technical factors affecting the complexity of the procedures. An investigation of the local practice should be performed in cases that the mean FT, KAP and CD values are above the LDRL or below the AL values. The estimated reference levels is expected to increase the awareness of the neurosurgeons regarding patient dose and radiation protection issues in view of the optimization of these procedures. Additional studies need to be conducted towards this direction to further investigate both patient and staff doses. This survey could also contribute in the effort of establishing DRLs and radiation protection programs for spine interventional procedures at a national level.
12.1 General discussion

In recent years, the use of fluoroscopy outside imaging departments is increasing rapidly, but there has been general neglect of radiological protection considerations about the safe and effective use of fluoroscopy systems. In some cases, radiological protection training of medical staff is lagging behind, resulting in increased radiation risks to both medical staff and patients [35]. Towards this direction, several international organizations and especially the ICRP publish guidelines, which dealt with several aspects of radiological protection in medicine [24, 25, 31, 35-37, 152, 153, 155, 157, 160, 277, 292, 293, 296, 472, 491-494]. Recently, an ICRP publication targeted at cardiologists [430], as well as paediatric diagnostic and interventional radiology [431].

This thesis was primarily developed to address radiological protection aspects related to fluoroscopically guided procedures in the cervical spine, performed to the neurosurgery operating theatre, outside imaging department [478]. It aims to improve the safety and radiation protection through the survey and evaluation of patient radiation dose. It also provides practical guidelines that will help neurosurgeons to select the optimal parameters of the fluoroscopy system, in terms of dose reduction and improvement of image quality [495]. In these series of studies preliminary LDRLs and ALs were also established as a crucial step in the process of optimizing these procedures [479]. For comparison purposes patient dose during thoraco-lumbar interventions were also investigated [479].

The conversion coefficients estimated, for the derivation of organs absorbed dose from KAP values are dependent on beam quality and the field size in the anatomic area of interest (see Table 9.2). The input parameters used in the simulations include the X-ray tube voltage, tube output, FSD, field size and FDD (see Table 9.1). In general, the conversion coefficients increasing with tube voltage. This is attributed to the increased penetration of the X-ray photons which in turn decreases the ED. From a point of view this value is affected by any
difference in the irradiation projection, field size or organ position between different mathematical phantoms and actual patients. From another point of view, uncertainties may be introduced in dose calculations when the conversion coefficients are used under clinical exposure conditions that does not completely met the standard conditions from which they derived [478]. Organ doses of actual patients may differ from those calculated with CALDoseX because of their different body sizes. This is particularly important for overweight and obese patients, due to the greater amount of tissue irradiated, requiring increased tube voltage and tube current. However, due to the limited imaging of the head and neck region reasonable conversion coefficients are obtained for these groups. There are also uncertainties due to the different attenuation properties between phantom materials and actual patients. The tube voltage considered relatively constant throughout the procedures. This is another point that introduced an uncertainty to the estimates.

Although projection angles are not frequently implemented in the cervical interventions, the conversion coefficients will be relatively unaffected by tube angulations, due to the fact that the head and neck are symmetric structures with fewer radiosensitive organs affecting the conversion coefficients, while this would be the case in thoraco-lumbar interventions. Therefore, it would be necessary to obtain conversion coefficients for the different projection angles. The conversion coefficients will be greater in the thoraco-lumbar interventions, due to the larger number of radiosensitive organs that will be exposed.

The calculation of conversion coefficients is performed for a sex specific standard-sized phantom [478]. In clinical practice, every case is unique. For the same tube voltage, field size and filtration (which mean the same KAP value) thicker patients will have smaller conversion coefficients because the organ doses are smaller compared to that of the phantom. The field size and position are important parameters, especially in cases where highly radiosensitive organs are inside or close to the proximity of the X-ray field. In the case of cervical interventions, the dose received by thyroid which is the most radiosensitive organ in the neck region contributes almost 46% to the patient ED [478]. The location of the X-ray field around the thyroid results in higher dose to salivary glands and oral mucosa. Since they are considered as remainder organs by the ICRP 103, their effect in ED is much lower. The use of large fields not only impairs the image contrast and resolution by the increasing amount of the scattered radiation, but most importantly results in an increase in both patient and staff dose. For cervical procedures, the average ED was comparable to that delivered to the patient from a lateral X-ray radiograph of the cervical spine [471]. Given
that the exposure parameters can be varied and controlled by the surgeon, dose calculations can also varied widely.

The dose received by the brain and eyes mirrors the effect of the field displacement on the edge organs. For the mean tube voltage of 65 kVp, the dose absorbed by the brain decreases about 62% and 63%, when utilizing two centimeter field displacement downward, in the simulations performed with CALDoseX 5.0 software, for MASH and FASH phantoms, respectively (see Appendix A). The dose received by the eyes decreases 45% for the FASH phantom, while no value is reported for the MASH phantom. In the case of a two centimeter field displacement upward, the amount of radiation absorbed by the brain and eyes increases about 82% and 28%, and 121% and 100% time for female and male patients, respectively. This increase is attributed to the fact that a larger part of the brain is inside the X-ray field, while the eyes are closer to the central axis of the X-ray field compared to the standard position.

In many studies, no difference is made between dose conversion coefficients for the male and female patients. However, our results show that there is a significant difference [478]. The organ dose conversion coefficients for male patients are lower than those for the female patients. The reason for this difference is that the MASH phantom representing male patients has higher BMI compared to the FASH phantom representing female patients. This is due to the position and size of the organs with respect to the central axis of the X-ray beam. This means that the usage of a conversion coefficient averaged over the two genders may result to overestimation of male organ doses (up to 29%), but however to an underestimation of female organ doses up to 57%. The CALDoseX provided the organ doses if the statistical error of the MC simulations was smaller than 10%. For organs located inside the X-ray field the statistical errors were smaller than 2%.

For the 45 patients who underwent cervical interventions, averaged KAP to ED and KAP to ESD conversion coefficients of 0.07 mSv·Gy⁻¹·cm⁻² and 9.3 mGy·Gy⁻¹·cm⁻² were reported. Regarding the male patients (27 patients), conversion coefficients were 0.07 mSv·Gy⁻¹·cm⁻² and 9.2 mGy·Gy⁻¹·cm⁻², while for female patients (18 patients) the corresponding coefficients were 0.11 mSv·Gy⁻¹·cm⁻² and 10.1 mGy·Gy⁻¹·cm⁻². The difference in conversion coefficients between female and averaged values is higher than for male and averaged values. For the 111 patients who underwent thoraco-lumbar interventions, averaged KAP to ED and KAP to ESD conversion coefficients of 0.12 mSv·Gy⁻¹·cm⁻² and 22.5 mGy·Gy⁻¹·cm⁻² were reported. In a recent literature review, KAP to ED conversion
coefficients of 0.13 mSv·mGy$^{-1}$·cm$^{-2}$, 0.19 mSv·mGy$^{-1}$·cm$^{-2}$ and 0.21 mSv·mGy$^{-1}$·cm$^{-2}$ were reported for fluoroscopically guided cervical, thoracic and lumbar spinal instrumentation, respectively [105]. The conversion coefficients vary between the different projections field sizes and locations of the X-ray field that can be used during these procedures. This variation is generally related with the increase of exposure parameters in lateral projection, where the deeper organs received higher dose in relation to the KAP value.

The mobile C-arm system that was used, the Philips BV Endura allows the operator to control the fluoroscopy mode, size of the FOV, while the exposure parameters were automatically selected through the ABC system. Selecting the FOV of 14 cm, ESD rate increases up to 70% with all other factors being equal. Reducing tube current values by selecting pulsed fluoroscopy modes with all other factors being equal, a reduction of 3.8 times was found in the ESD rate. These findings are in general agreement with other published studies and demonstrate that altering the technical parameters can significantly reduce the patient dose [69, 106, 124-151, 496].

Several articles have appeared in the scientific literature that predict cancer incidence and cancer mortality caused by imaging procedures using fluoroscopy [8-12, 107]. These predictions are estimated by multiplying highly speculative risk factors by large populations of patients resulting to impressive numbers of “cancer victims.” The risk factors are acquired from the Biological Effects of Ionizing Radiation (BEIR) VII report without attention to the caveats about their use presented in the BEIR VII report [288]. The risk factors are based on data from the ongoing study of the Japanese atomic bomb survivors, a population that is greatly different from individuals undergoing imaging procedures. For the purpose of risk assessment, doses to the patients are converted to EDs, although the ICRP warns against the use of ED for epidemiologic studies or for estimation of individual risks [24, 153]. The LNT model is used to estimate cancer risks from low doses of ionizing radiation [497], although the extrapolation from doses greater than 100 mSv to doses of a few millisieverts could be not reliably done, thereby challenging its use in cancer risk assessment [498, 499]. Because predictions of cancer incidence and mortality in populations exposed to doses less than 100 mSv are highly controversial, the Health Physics Society [500]: “recommends against quantitative estimation of health risks below an individual dose of 50 mSv in one year, or a lifetime dose of 100 mSv, above that received from natural sources. For doses below 50-100 mSv risks of health effects are either too small to be observed or are nonexistent.” Additionally, the American Association of Physicists in
Medicine (AAPM) [501]: “acknowledges that medical imaging procedures should be appropriate and conducted at the lowest radiation dose consistent with acquisition of the desired information. Discussion of risks related to radiation dose from medical imaging procedures should be accompanied by acknowledgment of the benefits of the procedures. Risks of medical imaging at patient doses below 50 mSv for single procedures or 100 mSv for multiple procedures over short time periods are too low to be detectable and may be nonexistent. Predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged. These predictions are harmful because they lead to sensationalistic articles in the public media that cause some patients and parents to refuse medical imaging procedures, placing them at substantial risk by not receiving the clinical benefits of the prescribed procedures.” Following the above statements, the risk for cancer incidence and cancer mortality were not estimated in the framework of this thesis. This does not mean that spine interventional procedures should be conducted without concern about the dose delivered to patients and associated cancer risks [502, 503]. On the contrary, a continuous effort to improve each procedure is recommended, by lowering radiation dose levels and maximizing benefits of the patients involved. Three principles should be considered when utilizing fluoroscopic guidance during such procedures: to keep radiation doses ALARA, to keep medical procedures as safe as reasonably achievable (ASARA), and to keep medical benefits as high as reasonably achievable (AHARA) [469].

Regarding the thyroid absorbed dose, it is inevitable that the thyroid gland will receive the greatest amount of radiation dose during these procedures because of its anatomic proximity. This may be of critical importance because of the relative high radiosensitivity of the thyroid gland, especially in younger and female patients [24, 153, 288]. However, it would be rare that a young individual will require a cervical discectomy and fusion procedure because of a degenerative disk disease, but there are some cases, such as traumatic fractures after accidents, where younger individuals being subjected to such procedures [478]. As for the risk of thyroid cancer in adults associated with medical exposure, the data are inconclusive and no studies have prove a causal relationship or a statistically significant association [504]. Special concerns need to be taken into consideration, especially when young patients with many years of expected life are involved or complex clinical conditions, that may result to prolonged fluoroscopic exposures and consequently to substantial radiation dose to the patient [478]. From a radiation safety perspective, no radiation dose should be ignored, no
matter how small it is, if we consider the stochastic pattern of carcinogenesis. The ED and thyroid absorbed dose reported here, may prove to be valuable for assessing the radiation risks and benefits associated with these procedures. A dilemma for neurosurgeons should be introduced in all cases, in order to achieve a balance between the excess risk of imaging versus anticipated benefit to improved patient care and management.

Effective doses in the spine surgery vary greatly depending on the experience of the surgeon, as well as the complexity of the procedure [470]. The large differences observed are related to variations in the methodology of measuring the absorbed dose and calculating the ED. In addition using the theory that the surgeon’s eye dose can be calculated as 75% of the patient’s thyroid dose, a dose of about 0.105 mGy per procedure to the neurosurgeon’s eyes is estimated [505]. This dose obtained from 31 single level and 16 multiple level procedures corresponding to an average FT of 6.7 seconds. Regarding the procedures involving male or female patients, the corresponding values were 0.127 mGy and 0.071 mGy per procedure, respectively. However, higher doses could be revealed due to complex procedures requiring prolonged fluoroscopic exposures. For example, a dose of 0.84 mGy to the surgeon’s eye obtained from a complex procedure (18 seconds). The lower doses could be indicative of good radiation reduction techniques or simply shorter less complex procedures. Tracking dose data over a greater time period would allow the institution to determine the cause of these low doses and to identify any particular practices or individuals that may need radiation reduction.

Regarding the influence of patient BMI to the radiation dose for cervical interventions, a positive but also weak correlation was found for ESD (Pearson correlation test, r = 0.009, p = 0.953) and ED (Pearson correlation test, r = 0.023, p = 0.89), although not statistically significant (Figure 12.1). For thoraco-lumbar interventions, this influence is presented in Figure 12.2. However, a statistically significant positive correlation was found in this case (Pearson correlation test, r = 0.191, p = 0.04). A varying amount of radiation dose among patients of different BMI can be explained by the corresponding exposure factors. A higher tube current value indicates more X-ray photons, whereas increasing tube voltage resulting in the production of more penetrating radiation. Although using higher tube voltage values reduces patient dose, it also reduces the image contrast between different tissues. Setting the fluoroscopy system either under automatic or manual mode can substantially affect the amount of patient dose. When the manual mode is used, the exposure rate is independent of the patient’s size; but also, the brightness of the image is adversely influenced. Thus, the
fluoroscopy system is generally used in ABC. Whenever less radiation reaches the detector, to produce a sufficiently bright image the system adjusts its tube current, tube voltage, or both values, which either increases the radiation exposure or the penetration of the radiation or both, respectively, which also explains the greater radiation dose in cases in which obese patients are involved in the procedures [7, 99]. It is also observed greater radiation dose during thoraco-lumbar interventions, which required longer fluoroscopic exposure (21.6 seconds) compared to cervical interventions (6.7 seconds) [479].

*Figure 12.1 Influence of BMI to patient ESD and ED for cervical interventions.*
During thoraco-lumbar interventions, the FT, KAP and CD values were consistently higher for obese patients. Except a decrease in the median FT value in the group of overweight patients, there was a gradual increase in FT, KAP and CD values from lower to higher BMI groups. A substantial increase was observed in cases involving obese patients, although it is not statistically significant (Kruskal-Wallis test, p > 0.05). Apart from more radiation absorption in larger patients, intraoperative technical challenges are also associated

Figure 12.2 Influence of BMI to patient ESD and ED for thoraco-lumbar interventions.
with more radiation exposure in these patients. Greater skin-to-fascia and fascia-to-spine depth obstructs the maneuvering of the instruments, which is also responsible for further increase in the operative time and consequently to radiation exposure.

Table 12.1 Influence of patient BMI in FT, KAP and CD values during thoracolumbar interventions.

<table>
<thead>
<tr>
<th>BMI (kg·m⁻²)</th>
<th>Group</th>
<th>size</th>
<th>FT (sec)</th>
<th>KAP (Gy·cm²)</th>
<th>CD (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>Underweight</td>
<td>3</td>
<td>Mean</td>
<td>13.0</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>6.0</td>
<td></td>
<td>0.17</td>
<td>0.77</td>
</tr>
<tr>
<td></td>
<td>SD (±)</td>
<td>14.8</td>
<td></td>
<td>0.10</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>Max</td>
<td>30.0</td>
<td></td>
<td>0.31</td>
<td>1.40</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>3.0</td>
<td></td>
<td>0.11</td>
<td>0.52</td>
</tr>
<tr>
<td>18.5-24.9</td>
<td>Normal</td>
<td>40</td>
<td>Mean</td>
<td>13.5</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>9.0</td>
<td></td>
<td>0.28</td>
<td>1.28</td>
</tr>
<tr>
<td></td>
<td>SD (±)</td>
<td>15.1</td>
<td></td>
<td>1.67</td>
<td>7.56</td>
</tr>
<tr>
<td></td>
<td>Max</td>
<td>72.0</td>
<td></td>
<td>10.24</td>
<td>46.34</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>1.0</td>
<td></td>
<td>0.0005</td>
<td>0.002</td>
</tr>
<tr>
<td>25-29.9</td>
<td>Overweight</td>
<td>55</td>
<td>Mean</td>
<td>20.1</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>8.0</td>
<td></td>
<td>0.32</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>SD (±)</td>
<td>45.6</td>
<td></td>
<td>2.25</td>
<td>10.2</td>
</tr>
<tr>
<td></td>
<td>Max</td>
<td>296.0</td>
<td></td>
<td>16.51</td>
<td>75.1</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>1.0</td>
<td></td>
<td>0.0002</td>
<td>0.001</td>
</tr>
<tr>
<td>≥ 30</td>
<td>Obese</td>
<td>13</td>
<td>Mean</td>
<td>50.8</td>
<td>2.66</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>9.5</td>
<td></td>
<td>0.38</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>SD (±)</td>
<td>106.3</td>
<td></td>
<td>5.67</td>
<td>28.9</td>
</tr>
<tr>
<td></td>
<td>Max</td>
<td>354.0</td>
<td></td>
<td>17.29</td>
<td>93.5</td>
</tr>
<tr>
<td></td>
<td>Min</td>
<td>1.0</td>
<td></td>
<td>0.11</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Radiation dose management is just one factor that has to consider when assessing the efficacy and safety of an interventional technique. Equally important is the investigation of how the technical factors, selected by the operator of the fluoroscopy system to optimize radiation dose, affect the corresponding image quality. Thus, the image quality was subjectively evaluated in terms of LCD and HCR by simply measuring the number of low-contrast objects and detecting the group of lps clearly distinguished in a phantom-based study utilizing the TOR 18FG test object [495]. Two experienced observers who were blind to each set of exposure parameters were asked to evaluate independently the phantom images. A total of 144 images were respectively assessed by each observer. The final score of LCD of and HCR was calculated by averaging the results of the two observers. The time
for reading the images was not limited while the window levels and window width is not adjusted on the monitor screen as usually done by the neurosurgeons during clinical practice.

For the task of evaluating image quality, objective image quality metrics were also used [495]. The SNR is a relative measure of true image signal to the background noise. Not unexpectedly, the SNR increased in HDF modes compared to LDF modes, due to the increase in tube current values, while the tube voltage values remained constant. This is attributed to the greater number of X-ray photons per unit area reaching the detector, that improves the signal in the image and decreases noise in the background. A negative relationship was also noted between increases in SNR values and decreases in tube voltage and tube current values, where within the investigated range of phantom thicknesses, the SNR increased by a factor of approximately \( \sqrt{5} \) when tube current values increased by a factor of 5. This relationship indicates that quantum noise if the dominant factor affecting the performance of each operation mode considered in the experimental study. The CNR is a relative measure of image contrast to the background noise. The CNR remained almost constant for both LDF and HDF modes since the tube voltage that significantly affect subject contrast remained constant [495]. The HCSR depicts how the image contrast and resolution change, as the structures being imaged get smaller and closer together. The HCSR increased in HDF modes compared to LDF modes due to the decreased noise related to the greater number of X-ray photons per unit area reaching the detector [495].

The objective and subjective results in this thesis had a close relationship for all operation modes investigated [495]. A number of factors may affect the observer’s performance including viewing conditions (ambient light, viewing distance), monitor brightness, post-processing techniques (window and level), as well as human factors, such as observer’s experience or fatigue. Generally, some studies have shown no correlation between physical measurements and observers’ performance at typical dose levels, whereas others had a clear correlation between them [144, 506]. Both clinical patient images and detection tests using simple phantom radiographs are usually used. Vano et al demonstrated that image quality from the phantom has a good correlation with clinical images [507]. Often these phantoms and details are highly simplified embedded in uniform background, and the detection task may not be reasonably related to clinically meaningful tasks. Metz et al. stress that the evaluation of the imaging systems requires going also beyond phantom/experimental measurements into the clinical setting [508]. The same conclusions have been reported in International Commission on Radiation Units and Measurements (ICRU) Report 54 [347].
is also noted that even good quality image data can be easily spoiled at the display stage. Therefore, it is a necessity that images are also assessed by observers at some stage of the evaluation process. However, the objective measurements cannot replace the subjective assessment in judging the quality of clinical images, whereas they are indispensable in the specification and testing of the imaging performance of the fluoroscopy system [337, 509]. The performance of the imaging system is often reported in terms of visibility thresholds and limiting resolution obtained by observers with respect to the phantom and the test object used.

A generally accepted principle is that image quality is most meaningfully defined and measured in relationship with the intended task. Thus, the best way of assessing the image quality should be to measure the clinical performance by quantitative methods, such as receiver operating characteristic (ROC) analysis [337]. This is not a practical option, however, if clinical images are used, subjective evaluations instead of a quantitative measurement are usually preferred. However, subjective evaluation usually suffers from inter-observer, intra-observer and case-sample variability, which limits its use to identify only large image quality differences [337]. This is the case in the framework of this thesis, since experienced observers scored the images in order to avoid inter-observer and intra-observer variability, but only large differences on LCD or HCR are detected especially when moving to larger PMMA thicknesses to simulate larger patients or when using HDF modes of electronic magnification accompanied by an increase in patient dose [495].

For the task of imaging technique optimization, a FOM [129-137] was calculated, which is the ratio of SNR or HCSR to the corresponding radiation dose [495]. If the anatomic background is not an issue, then optimal imaging conditions can be identified by finding the exposure parameters where the $\text{FOM}_{\text{SNR}}$ values are maximum. If spatial resolution aspects are of interest, then the $\text{FOM}_{\text{HCSR}}$ values should be used for optimization purposes. If resolution-related aspects are not of interest, the CNR instead of the SNR values may be used to evaluate the imaging performance of the fluoroscopy system. These results should be verified by clinical experiments and the dose level must be set so such that the image noise does not compromise the clinical performance. Mansson et al. criticize the use of test methods that are based on homogeneous phantoms for optimisation studies, and suggest that their use should be limited to constancy checks [510]. Optimisation studies based on such test methods is not relevant to the actual clinical practice, where detectability is more limited by the anatomical background than quantum and electronic noise. Therefore, optimisation
studies need to be performed with actual patients or high-quality anthropomorphic phantoms. This approach enables reduction of radiation doses in cases where details detection is not quantum-limited. Busch and Faulkner concluded that optimisation must be based on clinical studies, whereas test phantom imaging is useful for quality control and standardisation purposes [511]. Test object performance data have been collected in a number of x-ray departments [512]. Although such data are not directly related to clinical requirements, they should be useful for indicating typical and/or acceptable x-ray system performance [513].

The final step in this thesis was to establish LDRLs and ALs for spine interventional procedures [479]. It supplies useful data for both cervical and thoraco-lumbar interventions. The 75th percentile and 10th percentile of dose data provides a reasonable set of preliminary reference levels [157, 162, 169]. Each individual department should compare its own median values against these levels. An investigation should be performed if the department’s dose values are too high. Reference levels are expected to change over time. They may decrease if the equipment becomes more dose efficient or if the instruments and techniques become more proficient. On the other hand, they may increase if the complexity of the procedures increases [157, 162-167]. Very low patient dose is not desirable if clinical performance is compromised. For spine surgery, too low dose may indicate an incomplete procedure, inadequate image quality, low complexity, or excellent technical settings. Departments with mean values below the ALs should investigate the quality of their procedures [157]. In general, the neurosurgery departments should undertake dose surveys as part of a quality assurance program. Dose optimization should not necessarily complete when LDRLs complying with regulatory values, but medical physicists should continue the efforts to further optimize the procedures.

The concept of DRLs is defined as representative dose levels for typical examinations of “standard-sized” patients [171]. Implicit, in this definition the patient size along with the variation in the complexity of the procedures are important factors affecting patient dose. In the framework of this thesis, the size correction was used to effectively remove the variation due to patient size and leave only the variation due to case complexity [514]. This method uses the concept of equivalent diameter and its experimentally determined relationship with KAP rate, through a series of phantom experiments where a range of PMMA thicknesses were exposed using fluoroscopy under AEC, in order to derive a factor to convert a patient KAP to that which would expected had the patient been similar in size to the ICRP Reference Man [168, 169, 171, 489, 490, 515]. The effect of applying the size correction
method to patient KAP and CD values, for thoracolumbar interventions is presented in
Figure 12.3. A linear regression line is fitted for each set of values, although the relationship
between uncorrected KAP and CD values with patient weight would not be expected to be
linear, hence the need for a correction factor based on more factors than just patient weight.
The dependence of KAP and CD values on patient weight is reduced using the correction.
The gradients of the linear regression lines before and after correction are given in Table
12.2. Despite the weakness of the correlation the results illustrate that the application of size
correction to lumbar spine surgery dose data can reduce the variation between the patients
sampled for the purposes of dose audit. However, the complexity of these procedures tends
to dominate the variation of the patient, as presented in Chapter 11 [479]. Thus, data
collection for the setting of DRLs in spine surgery can be performed for all patients rather
than just ‘standard-sized’ patients with a restricted weight range, thus increasing the amount
of data available for infrequent procedures and forcing normalization to a standard patient
weight [516]. The recommended number of patients varies from 10 to more than 50, with the
latter number suggested because of the high individual variability of cases of interventional
procedures [168, 487, 517].

Another method to reduce the dispersion of data due simply to spread in patient weight is
the weight banding method [158, 169, 171, 175, 189, 518]. In the framework of this thesis
patients with weights in the band 60-80 kg were selected [171, 175]. This method reduced
sample size by a factor of about 1.5 for cervical (29 from 45 patients) and 1.3 (89 from 111
patients) for thoraco-lumbar interventions. However, for cervical interventions the mean FT,
KAP and CD values were identical with uncorrected values. An independent two-tailed t-test
on the FT, KAP and CD distributions indicated that their means were not significantly
different (p > 0.05) and the two data sets will be seen to overlap each other when plotted as
histograms. For body parts, such as the head and neck, where the size changes relatively
little with body weight, weight banding and size correction yielded similar results to
uncorrected values. For thoraco-lumbar interventions, the FT, KAP and CD values obtained
with weight banding method reduced by about 50%. However, these differences were not
statistically significant (independent two-tailed t-test, p >0.05), but the p-values were close
to statistical significance and probably will be validated in a larger sample of patients. When
weight banding data compared with size corrected data, the mean KAP and CD values were
lower about 30%, although this difference is not statistically significant (independent two-
tailed t-test, p > 0.05), while the weight banding method appears to reduce the standard
deviation of the dosimetric data more successfully (standard deviation are 5.4 vs 8.8 and 1.19 vs 1.8 for CD and KAP values, respectively) [168, 171]. As shown in Tables 11.3, 11.5 and 11.6, the weight banding values could be larger, smaller or approximately the same compared to those obtained with size correction, while the uncorrected values, were usually, but not always higher than those obtained with size correction or weight banding. Because weight banding only normalizes weight, whereas size correction also eliminates the dose increase caused by automatic adjustments in exposure parameters, the distribution percentiles are lower for size correction than they are for weight banding [168].

Figure 12.3 Patient dose in terms of KAP and CD values plotted against patient weight for thoraco-lumbar interventions. The crosses and solid show the uncorrected results and the circles and dotted lines the size-corrected results.
Table 12.2 Gradients of the linear regression lines for KAP and CD values against patient weight shown in Figure 12.3.

<table>
<thead>
<tr>
<th>Gradient of linear regression line</th>
<th>Uncorrected</th>
<th>Size-corrected</th>
</tr>
</thead>
<tbody>
<tr>
<td>KAP (\text{Gy} \cdot \text{cm}^2 \cdot \text{kg}^{-1})</td>
<td>0.041</td>
<td>0.016</td>
</tr>
<tr>
<td>CD (\text{mGy} \cdot \text{kg}^{-1})</td>
<td>0.196</td>
<td>0.081</td>
</tr>
</tbody>
</table>

The concept of reference levels refers to “common examinations” [156] performed on large numbers of patients in a relatively standardized manner. In addition to technical variables (patient size, equipment performance, and operational technique), fluoroscopically guided interventions are often non-standard for several clinical reasons. The complexity of a procedure is affected by factors related to the patient’s anatomy and to the severity of the treated pathology. An index related to patient-specific clinical factors could reflect the complexity of each procedure. Appropriate scaling of reference levels provides an additional tool for optimization processes. Since the complexity of the procedure strongly influences patient exposure it is not appropriate to develop a reference level without taking complexity into account [157, 162].

Fluoroscopy systems should incorporate an appropriate method of dose monitoring. Irrespective of the approach to dose monitoring, it should be capable of indicating FT, KAP and CD values. This information should be stored in the DICOM header and DICOM Radiation Dose Structured Report in a format which meets the International Electrotechnical Commission (IEC)’s standard [519, 520]. The Greek radiation protection regulations require all fluoroscopy systems to incorporate KAP meters (software or transmission chambers) to provide real time indication of patient dose. In addition, it is also appropriate during routine patient dose monitoring to document all the examination related parameters for comparison purposes with other departments and as a QC measure with the aim of investigating their influence on radiation dose levels of each procedure. In addition the surgeon can be notified on those patients with a high KAP or CD values for further long-term monitoring and follow-up. The ICRP recommends recording of cumulative skin dose for two groups of patients [25]:

- Those who have undergone procedures with entrance skin dose above 1 Gy and they are likely to have repeated procedures.
- Those who have undergone procedures with entrance skin dose above 3 Gy and they are unlikely to have repeated procedures.
The fluoroscopy system may also have a dose alarm, which would alert the surgeon after five minutes of FT. The surgeon would respond to this alarm without compromising the efficacy of the procedure.

Fluoroscopy system provides post-processing techniques. For example, images can be cropped to show only the region of interest. However, it is bad practice to rely on cropping images instead of collimating the X-ray beam, as this results in unnecessary patient dose. In addition, proper collimation will result in noise reduction, which will potentially lead to better image quality.

The CD values displayed in the dosimetric report of the fluoroscopy system are an approximation of the patient skin dose. It is the air-kerma accumulated at the IRP, which is a point 15 cm from the isocentre towards the focal spot [31, 116, 519, 521]. However, an important drawback is that it does not include backscattered radiation. Moreover, the position of the IRP depends on the irradiation projection, the angulations of the X-ray beam and the size of the patient. Depending on the exposure geometry, the IRP may lie outside or inside the patient, or may coincide with the patient skin surface. Since the IRP moves relative to the patient, the CD is usually an overestimate of skin dose. However, for situations where the IRP is at the skin or closer to the skin, it will be a good approximation of the skin dose. An important point that should be noticed is that the FT itself is not an appropriate indicator for the patient dose. It is of limited use as it makes no allowance for the influence of dose rate or field size. In this thesis, the KAP and CD values showed a strong correlation with FT values. This is can be explained by the fact that these procedures do not include digital acquisitions that significantly contribute to the KAP reading, but not to the FT. If KAP values are high but CD values are within the acceptable range, this finding may indicate insufficient collimation [168].

In order to investigate the feasibility of the CD values as skin dose indicator [131], the corrected and uncorrected values were compared (Table 12.3). In order to obtain the corrected values of the CD, a BSF of 1.3 and 1.5 based on the actual exposure conditions was used, to include radiation backscattered by the patient for cervical and thoraco-lumbar interventions, respectively [277]. In addition, the inverse square law was applied to these values in order to correct for the differences between the IRP, which is located 69.5 cm from the X-ray source and the actual FSDs of 56 cm and 40 cm for cervical and thoraco-lumbar interventions, respectively. For cervical interventions, the use of uncorrected CD values may underestimate skin dose about 100%, while for thoraco-lumbar interventions about 352%.
From this point of view, the uncorrected CD values as displayed by the system should be implemented with caution as skin dose indicator. The corrected CD values were only 3.9% and 7.1% lower compared to the mean ESD values (see Chapter 11).

Table 12.3 Feasibility of CD values as skin dose indicator for cervical and thoracolumbar interventions

<table>
<thead>
<tr>
<th>Interventions</th>
<th>CD (mGy)</th>
<th>Difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Uncorrected</td>
<td>Corrected</td>
</tr>
<tr>
<td>Cervical</td>
<td>0.76</td>
<td>1.52</td>
</tr>
<tr>
<td>Thoraco-lumbar</td>
<td>4.75</td>
<td>21.47</td>
</tr>
</tbody>
</table>

*Mean values

In Publication 85, the ICRP dealt with avoidance of radiation injuries from interventional procedures [25]. Therefore, the maximum skin dose (MSD) should be recorded or calculated in order to avoid skin injuries, such as skin erythema and skin burns, especially in cases that a patient may undergo repeated procedures [115]. Since real time monitoring is unavailable in most X-ray systems, it is recommended that physicians to record FT for patients undergoing interventional procedures [25, 493]. Miller et al reported that MSD and KAP were correlated for fluoroscopically guided procedures, except cardiac interventions [42]. Some technical factors strongly influence MSD are patient size (weight and height) and surgeon differences which are reflected in differences in FSD, beam motion during the procedure and superimposition of X-ray beams from different projections [162].

In the framework of this thesis, the correlations between the MSD and FT, body weight, BMI, and weight-FT product (WFP) were investigated using linear regressions, to examine whether these factors could prove useful in estimating MSD in fluoroscopically guided spine surgery. For cervical interventions (45 patients), the MSD is calculated using the CALDoseX 5.0 software, inside a 7.2 cm × 7.2 cm square of skin tissue centered around the central axis of the beam where it enters the phantom. For radiation protection purposes, this quantity is considered to be more appropriate for risk evaluation than the skin absorbed dose averaged over the whole body, which is usually much smaller than the absorbed doses to those parts of the body located inside the irradiated volume. The average MSD was calculated 1.64 mGy (range 0.02 - 14.1 mGy). Even the maximum value of the MSD, it is significantly lower than the threshold of 2 Gy for the induction of skin injuries. A strong positive correlation was found between MSD and FT (Pearson correlation test, $r = 0.789$, $p < 0.00001$) and WFP (Pearson correlation test, $r = 0.779$, $p < 0.00001$), as well as between KAP and WFP.
Chapter 12  General discussion, conclusions and future work

(Pearson correlation test, $r = 0.781, p < 0.00001$) (Figure 12.4). These results suggest that for cervical interventions FT and WFP can be used as rough predictors of MSD than FT alone. Furthermore, KAP correlated well with WFP, although this applies only for a fixed FOV and projection. This can be explained by the increase that might be occur in the skin dose with patient weight. We also found very weak negative correlation between the MSD and body weight (Pearson correlation test, $r = -0.009, p = 0.953$) and very weak positive correlation with BMI (Pearson correlation test, $r = 0.009, p = 0.953$), which however are not statistically significant. This is attributed to the fact that the neck region is quite uniform even for patients with different body weight or BMI. In total, neurosurgeons should record not only FT, but also the KAP and WFP for estimating MSD in cervical interventions.
Figure 12.4 Graphs show correlation between MSD and FT, WFP as well as KAP and WFP in cervical interventions.

For thoraco-lumbar interventions, the ESD was estimated using conversion coefficients, based on KAP measurements (see Chapter 11) [12]. The average ESD was calculated 23 mGy (range 0.004 - 390.3 mGy). Even the maximum value of the ESD, it is significantly lower than the threshold of 2 Gy for the induction of skin injuries. A very strong positive correlation was found between MSD and FT (Pearson correlation test, \( r = 0.926, p < 0.00001 \)) and WFP (Pearson correlation test, \( r = 0.929, p < 0.00001 \) (Figure 12.5). We also found very weak correlation between the ESD and body weight (Pearson correlation test, \( r = 0.187, p = 0.04 \)) and BMI (Pearson correlation test, \( r = 0.191, p = 0.04 \)), which however are statistically significant (Figure 12.2).

Despite the fact that the results of this thesis are obtained from a single university hospital, there was a wide variation in patient doses for both cervical and thoraco-lumbar interventions. This variation could be a result of the proportion of complex procedures although they carried out by three senior neurosurgeons which have more than twenty years of experience in spine surgery. Doses are likely to be higher when these procedures are performed by less experienced surgeons or not adequately trained on the technical details of the fluoroscopy equipment [522, 523]. This can be ameliorated by continuous training of the staff in radiation safety issues both at medical school and vigorous on-job training [35, 37]. In addition, the direct involvement of appropriately trained radiographers in these procedures may contribute to patient dose and image quality optimization through the correct implementation of the fluoroscopy system, but also provide awareness to the surgeons about
radiation safety issues. Historically, in many hospitals, the X-ray systems were only located in imaging departments, so professionals who performed interventional procedures had radiographers/technologists available for advice and consultation. With time, as the use of radiation increased and X-ray systems were installed in other departments of the hospital, outside the control of imaging departments, the absence of training has become evident and needs attention [35].

![Graphs show correlation between ESD and FT, WFP in thoraco-lumbar interventions.](image)

**Figure 12.5** Graphs show correlation between ESD and FT, WFP in thoraco-lumbar interventions.
Table 12.4 FT, KAP and CD values for each operator in thoraco-lumbar interventions.

<table>
<thead>
<tr>
<th>Group size</th>
<th>FT (sec)</th>
<th>KAP (Gy·cm²)</th>
<th>CD (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon 1</td>
<td>Mean 20.9</td>
<td>0.74</td>
<td>3.35</td>
</tr>
<tr>
<td></td>
<td>Median 10.0</td>
<td>0.43</td>
<td>1.95</td>
</tr>
<tr>
<td></td>
<td>SD (±) 32.8</td>
<td>0.83</td>
<td>3.75</td>
</tr>
<tr>
<td></td>
<td>Max 178.0</td>
<td>4.06</td>
<td>18.4</td>
</tr>
<tr>
<td></td>
<td>Min 1.0</td>
<td>0.01</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Mean 31.2</td>
<td>1.80</td>
<td>8.59</td>
</tr>
<tr>
<td></td>
<td>Median 10.0</td>
<td>0.35</td>
<td>1.59</td>
</tr>
<tr>
<td>Surgeon 2</td>
<td>SD (±) 76.2</td>
<td>4.23</td>
<td>20.97</td>
</tr>
<tr>
<td></td>
<td>Max 354.0</td>
<td>17.29</td>
<td>93.53</td>
</tr>
<tr>
<td></td>
<td>Min 1.0</td>
<td>0.02</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>Mean 14.3</td>
<td>0.62</td>
<td>2.81</td>
</tr>
<tr>
<td></td>
<td>Median 6.5</td>
<td>0.26</td>
<td>1.19</td>
</tr>
<tr>
<td>Surgeon 3</td>
<td>SD (±) 36.0</td>
<td>2.23</td>
<td>10.12</td>
</tr>
<tr>
<td></td>
<td>Max 236.0</td>
<td>14.65</td>
<td>66.61</td>
</tr>
<tr>
<td></td>
<td>Min 1.0</td>
<td>0.0002</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Taking as criterion the surgeon, the total sample of patients was categorized into three groups. The differences in FT, KAP and CD values are not statistically significant (kruskal-Wallis test, p > 0.05), although the p-values are close to the threshold of statistical significance. For cervical interventions, thirty-three procedures were performed by the same neurosurgeon (see chapter 9), while the other two groups included only twelve procedures and an accurate comparison of the dosimetric data between these groups is not feasible, due to the limited number of patients. For thoracolumbar interventions, thirty-five (31.5%) of the procedures were performed by the first neurosurgeon, thirty-four (30.6%) by the second neurosurgeon and forty-two procedures (37.9%) by the third one. The mean, median, minimum and maximum and standard deviation of FT, KAP and CD values are presented in Table 12.4. All the surgeons carried out procedures with different levels of complexity. It is observed that the third surgeon had the lowest mean and median FT, KAP and CD values. This can be attributed to increased awareness in radiation protection issues, in combination with the increased familiarisation of the fluoroscopy system, which results to better implementation of its capabilities, such as by selecting normal FOV, pulsed fluoroscopy mode, LDF mode, etc. The first surgeon achieved lower mean FT, KAP and CD values compared with the second surgeon. However, although their median FT values were the
same, the median KAP and CD values of the second surgeon were lower than those of the first surgeon.

Training and lifelong learning is crucial in the effort to optimize these procedures. For example, radiation protection aspects should be taught to medical and paramedical students during their studies as well as to all medical professionals using ionizing radiation inside or outside the imaging departments [35]. For this to succeed, it also would entail changes in curricula being taught at training institutions and having relevant scientific meetings and seminars putting emphasis on this concept. In most cases, neurosurgeons have either minimal or no training in radiological protection, and may not have regular access to medical physicists. Radiographers/technologists working in these facilities may only be familiar with fluoroscopy systems used in the facility. Thus, their skills, knowledge, and awareness may be limited. Nurses in these facilities typically have limited skills, knowledge, and awareness of radiological protection. The lack of radiological protection culture in these settings adds to patient and occupational risk [35]. In surveys conducted by the IAEA in training courses for non-radiologists and non-cardiologists [524], it is clear that most non-radiologists and non-cardiologists have not undergone training in radiological protection, and that medical meetings and conferences of these specialists typically include no lectures on, or component of, radiological protection. This lack of training in radiological protection needs to be corrected. The ICRP recommends that the level of training in radiological protection should be commensurate with the use of radiation [37].

The primary trainer in radiological protection should normally be an expert in radiological protection, usually a medical physicist [35]. This is a person with knowledge about the use of radiation, the nature of radiation, the way in which it is measured, how it interacts with the tissues, what type of effects it can lead to, principles and philosophies of radiological protection, and international and national guidelines. The medical physicist should become familiar with the clinical aspects of the spine procedures performed at the neurosurgery department. There are a number of technicalities that require involvement of or consultation with a medical physicist. These include radiation dose assessment, dose management in day-to-day practice, understanding of different radiation dose quantities, and estimating and communicating risks. An effective radiological protection programme implies teamwork between clinical professionals and radiological protection professionals. Such a programme should exist in every hospital or clinic, supervised by a medical physicist. It requires a good QC programme to ensure that the equipment is well designed and suited for
the purpose for which it is applied and continues to be both functional and safe throughout its life, and involvement of the medical physicist in patient and occupational dose optimisation and audit, particularly for higher dose procedures.

KAP calibration is important for the interpretation of dose audit results. The IEC have recommended an acceptable margin ±35% in the calibration factor [116], and that is the margin most likely to be applied to the manufacturers’ protocols. However, in clinical practice, more accurate results are required. Thus, calibration should be checked regularly and a calibration factor provided for dose audit. It is also important to establish a standard technique for KAP calibration in order that the dose audit provides consistent results. In this thesis, the KAP was calibrated in situ [525-527], for clinical radiation qualities, using a reference ionization chamber (RadCal Accu Pro) according to the method proposed by the IAEA [296]. If the KAP meter calibration factors were not applied to the KAP measurements, patient doses might be underestimated up to 28%. The calibration procedure used in this thesis is documented in Appendix C.

In interventional radiology, a problem which deserves specific attention for KAP calibration is the energy dependence of the KAP chamber, especially when the equipment includes copper filters, which substantially harden the X-ray spectrum. However, such a problem is not addressed in this thesis. This effect, together with the X-ray tube voltage variation, can change the calibration factor about 20% or more. In certain equipment and for some operational modes, the copper filters are automatically inserted or changed. If a built-in KAP meter is available, the software automatically corrects the displayed values for the energy dependence. This automatic correction does not affect the external KAP meters. Since these filters are inserted or changed during the procedure, it is impracticable to keep track of these changes. For this reason, the only solution for external KAP meters is to choose a mid-value for the calibration factor and give the range associated to it. This range can be obtained by measuring without and with the maximum copper filter [157].

In summary, the use of radiation is increasing outside the imaging departments. There was a near absence of patient dose monitoring in the neurosurgery operating theatre of our hospital. Overexposures from digital x-ray equipment may not be detected, systems that are not checked under a QC program can give higher radiation doses and poor image quality, and repeated radiological procedures increase cumulative patient radiation doses. There are a number of image quality factors that, if not taken into account, can deliver poor-quality images and a higher radiation dose to patients. On the other hand, there are simple
techniques that use the principles of time, distance, and shielding to help ensure the safety of both patients and workers. Radiation shielding screens and flaps are lacking in many fluoroscopy machines used in operating theatres, and radiological protection workers outside radiology and cardiology departments face specific problems. Personal dosimeters are not used by some surgeons or their use is irregular. There is a clear need for a national registry of radiation dose data for spine interventional procedures. Continuous collection and analysis of data over time from a large number of institutions will permit the establishment of national reference levels for these procedures.

12.2 Recommendations and conclusions

This thesis contributes to the development and implementation of a QA quality assurance programme for spine interventional procedures. It highlights the need for radiation dose monitoring and for a patient dose database for the establishment of national diagnostic reference levels (NDRLs) for such procedures. To the best of the authors’ knowledge this is the first study survey patient doses for spine interventional procedures in Greece. Establishment of LDRLs will allow the comparison of local clinical practice with other neurosurgery facilities nationally or internationally.

Radiation protection safety can be achieved by adopting optimal exposure techniques. When the neurosurgeon and the medical staff involved are appropriately trained and informed about dose reduction techniques, the risk for stochastic and deterministic effects can be reduced as well [528, 529]. ED has been used to quantify the detrimental effects of radiation. Its major advantage is that facilitates a comparison of the risk associated with different spatially-inhomogeneous exposures. However, it has some disadvantages including that was primarily introduced as a way to quantify risk of occupational exposures and thus cannot be used to determine individual risk, it is age and sex averaged [530-532]. The training of neurosurgeons of how to operate the fluoroscopy system with respect to patients’ size and clinical conditions could contribute to dose savings [41, 110, 111, 523,], while maintaining clinically acceptable image quality. In order to ensure patient radiation safety in the neurosurgery operating theatre, a simple and quick method to estimate patient dos during these procedures is essential, so that to set a local irradiation protocol and also so some improvements can be identified. Based on the results of this study, it is recommended that at
least KAP and FT values be recorded for each procedure. There are also other dose metrics that can be used to alert surgeons on the patient dose during the procedures [111, 533, 534].

Spine interventional procedures have the potential for high patient doses, especially for complex procedures requiring prolonged fluoroscopic exposures. In general, there was a wide variation of patient dose even for the same procedure at the same department. Without adequate dose monitoring, patient may receive higher doses than those actually needed. Furthermore, if a patient undergoing consecutive procedures neurosurgeons should keep in mind that risk for stochastic effect increases since radiation exposure is cumulative over a lifetime. Younger patients are significantly more sensitive than the older. Thus, for a given radiation dose the risk for cancer incidence or cancer mortality is higher for this group of patients, due to their longer life expectancy [535]. The results of this study have shown that MSD is far below the threshold for skin erythema. A quick and simple method for evaluation of patient doses such as utilizing a software or conversion coefficient of easily measurable quantities will help neurosurgeons to perform these procedures in compliance with as ALARA standards. Thereby maximizing the benefits of the procedure and simultaneously minimizing the risk for stochastic and deterministic effects. At this point, it should be noted the usefulness of KAP meters in dose optimization processes that the advantage of a computational method for assessing patient dose regarding the minimal interference to clinical practice.

Several parameters, such as field size and position, patient thickness and body mass index, tube voltage and filtration significantly affect the conversion coefficients. When selecting conversion coefficients to estimate ED, it should be investigated if there are large variations in those parameters between the actual investigation and the reference parameters for which the conversion coefficients were calculated. It is also important to notice that variations are observed in conversion coefficients because of the changes that have taken place to the weighting factors. To this direction, it is also important to emphasize the need for the calibration of KAP meters, as well as a periodic QC of the fluoroscopy system in order to ensure its dosimetric and imaging performance.

The need to minimize patient exposure requires that the dose be reduced to the minimum level that will generate an image with an acceptable level of noise and contrast. In order to take advantage of contrast images should be acquired using a low tube voltage exposure and a large dose rate to minimize the image noise. Increasing tube voltage decreases patient dose but also decreases contrast. Decreasing tube current decreases patient dose but also increases
image noise. Therefore, there is a set of exposure parameters that provide balance between acceptable image quality, as well as minimizing patient dose [536]. For example, this can be achieved by using copper filtration instead of thick aluminum filters, which provide the ability to reduce ED or skin dose without any significant deterioration of image quality.

Regarding the evaluation of image quality utilizing the TOR 18FG test object, it has been demonstrated that physical image quality measures for all operation modes investigated correlate with subjective assessment by human observers. This tool can be used for quick routine quality control of the imaging performance of the fluoroscopy system in order to avoid deterioration of image quality that could affect the safety and efficacy of the procedure, as well as result to increased patient dose due to additional exposures in order to identify the anatomical characteristics. However, despite the useful data provided the experimental study, in terms of both image quality and patient dose, an assessment of clinical image quality may contribute towards optimization (see section 12.3).

The basic practical hints to minimize radiation exposure during spine interventions include:

1. **Use of pulsed fluoroscopy mode.** Utilizing pulsed fluoroscopy could reduce patient dose rate up to 3.8 times.
2. **Selection of the type of fluoroscopy mode.** The use of LDF mode could reduce patient dose rate up to 2.4 times.
3. **Magnification.** The use of electronic or geometric magnification could increase patient dose rate up to 1.8 times. Thus, the use of magnification should be avoided except the clinical conditions require the opposite.
4. **Minimize beam-on time.** The fluoroscopy should be on only when new information is needed and the last image hold function should be used, in order to investigate the anatomical characteristics without need for additional exposure.
5. **Maximize FSD.** Patient should be positioned as far as possible from the X-ray source and as close as possible to the image intensifier.
6. **Vary X-ray beam direction.** This is especially important in the case of prolonged exposures, in order to avoid skin injuries if the beam is directed to the same skin area throughout the procedure.
7. **Collimation of the X-ray beam.** The X-ray field should be collimated only to the anatomical region of interest, in order to avoid irradiation of adjacent organs and
tissues. It can also reduce the dose to the most exposed area, when combined with changing projection (reduces overlapping).

8. **Training of neurosurgeons.** It is critical the operator to have specialized training in the operation of the fluoroscopy system as well as to radiological protection issues.

9. **Reference levels.** Reference levels should be established and used to evaluate dosimetric performance of the fluoroscopy equipment, and to optimize exposure protocols (FT, KAP, CD). Considerable tolerances in these values are required in order to allow for variations in patient size and complexity. The LDRLs for cervical and thoraco-lumbar interventions are 0.15 min and 0.29 min for FT values, 0.10 Gy·cm² and 0.71 Gy·cm² for KAP values, as well as 0.47 mGy and 3.24 mGy for CD values, respectively. The corresponding ALs are 0.03 min and 0.03 min, 0.01 Gy·cm² and 0.07 Gy·cm², as well as 0.05 mGy and 0.33 mGy for FT, KAP and CD values, respectively.

10. **Planning and preparing the procedure.** Consideration should be given to possible clinical complications of each procedure and their impact on the patient radiation exposure and possible deterministic effects due to repetition of procedures. Previous experience with similar cases could contribute to this direction.

11. **Customizing equipment settings.** Dedicated procedures need to be customised. The demands on image quality for some procedures, projections and tools may require different dose levels. Difficult clinical conditions and heavy patients may require higher dose rate for a limited time.

12. **Image post-processing.** This may result in dose reduction at the cost of some spatial or temporal resolution, which may be acceptable in some cases.

13. **QA programme.** A comprehensive QA programme should be developed to encompass all aspects of how the patient is dealt with within the neurosurgery operating theatre. Technical operation of the equipment is tested by QC procedures. Because of the complexity of equipment, QC is time consuming and the selection of the parameters to be controlled in constancy checks and frequency are essential parts of the programme.

The experience gained by the neurosurgeon is another important factor that could contribute in the reduction of ED and ESD. In summary, this preliminary study could contribute to educational purposes in the field of radiation protection and provides a benchmark to optimize these procedures and assist to establish LDRLs and NDRLs.
neurosurgeons need to be educated and alerted on these optimization options through awareness seminars and conferences, training curricula and continuing education programs. One simple and straightforward way to reduce patient radiation dose is to reduce the frequency of using fluoroscopy for guidance during the procedure. Hendee et al report ways to avoid over-utilization of radiation [537].

In summary, this thesis successfully updated the knowledge and awareness about radiation risks to the neurosurgeons in our institution and helps them to become familiar with the operation of the fluoroscopy system as shown by the fact that they can identify the advantages and disadvantages of different operation modes used in routine clinical practice. It is also highlighted the need for continuous training and education of spine surgeons and especially for trainee surgeons by an expertised medical physicist regarding radiation protection issues. As a general conclusion, it is recommended the neurosurgery departments to implement a comprehensive radiation protection program [161]. The results of this thesis are a preliminary step towards this direction, but further work in needed both on local and national level.

12.3 Limitations and future work

The major limitation in these series of studies was that the data was representative of a single department and for a fluoroscopy system equipped with an II. No data were provided with respect to neurosurgeon and medical staff doses. Therefore, as a future work is suggested a multi-centre investigation in order to obtain data that could be used to assess patient and staff doses and to establish national DRLs for spine interventional procedures. The effort of monitoring patient doses during such procedures should also be extended to fluoroscopy systems equipped with FP detectors. A comparison can also be performed between these technologies in terms of both patient and staff dose reduction.

Regarding the clinical measurements, it is proposed that a larger number of patients should be included and distributed into more specific categories of interventions, as well as more neurosurgeons with different levels of experience to be involved, in order to have more representative results. Regarding dose calculations, an anthropomorphic phantom loaded with TLDs can be used in order to evaluate patient ESD and ED and to estimate dose conversion coefficients for KAP values. To this direction, clinical measurements using TLDs may also be performed in order to obtain direct measurements of the ESD and to estimate the
dose delivered to some radiosensitive organs (such as thyroid) that are inside the X-ray field. The influence of several additional factors (for example grade of myelopathy, neck length and diameter, waist circumference, irradiation projection) on patient dose values should also be investigated. Regarding the experimental study, the most important limitation is the usage of a PMMA phantom that does not mimic the anatomy of the neck. To this direction, it is proposed as future work additional studies using another phantom or test object or to investigate the effectiveness of antiscatter grid, especially for thinner patients. Regarding the image quality assessment, the next step is to study the low-contrast detectability and high-contrast visibility on clinical images. Such a study will further help the optimization efforts.

The results reported in this thesis, despite their limitations, can be utilised as a preliminary basis for the management of patient dose and image quality during spinal surgery procedures.
REFERENCES


References


[83]. Theocharopoulos, N., Perisinakis, K., Damilakis, J., Papadokostakis, G., Hadjipavlou, A., Gourtsoyiannis N. *Occupational exposure from common


[93]. Lange, J., Karellas, A., Street, J., Eck, J. C., Lapinsky, A., Connolly, P. J., Dipaola, C. P. Estimating the effective radiation dose imparted to patients by intraoperative


References


References


References


 References


[316]. Larsson, J. P., Persliden, J., Sandborg, M., Alm Carlsson, G. Transmission ionization chambers for measurements of air kerma integrated over beam area:


References


[524]. International Atomic Energy Agency. Radiation Protection of Patients (RPOP): Training: Training Events. Available at:
http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/2_Training Events/Doctorstraining.htm


A.1 Introduction

CALDose_X 5.0 [123] is a software tool that enables the calculation of the INAK based on the output curve of the X-ray equipment and the ESAK by multiplying the INAK with a BSF. The software uses CCs normalized to the INAK, ESAK or KAP values to assess the absorbed dose to organs and tissues as well as the effective dose for posture-specific phantoms of male and female adults. In addition, it calculates the patient’s radiological risk for cancer incidence and cancer mortality for the examination and exposure parameters defined by the user.

CALDose_X 5.0 calculates CCs for posture-specific mesh-based phantoms of male and female adults, MASH and FASH [467, 538, 539], which have organ and tissue masses based on anatomical reference data provided by the ICRP 89 [468]. By using these true to nature voxel phantoms, the CALDose_X improves earlier software tools, which were mostly based on mathematical MIRD5-type phantoms of less representative human anatomy. MASH and FASH phantoms represent an adult male patient with 73 kg weight, 176 cm height and BMI of 23.6 kg/m$^2$, as well as a female adult patient with 60 kg weight, 163 cm height and BMI of 22.6 kg/m$^2$, respectively. The patient’s age ranges between 20 and 80 years.

The phantoms were modeled in standing, as well as in the supine posture and can be used in the MC simulations of 24 X-ray examinations implementing the different projections, exposure parameters, beam qualities and field positions. The selection of the examinations and irradiation parameters was based on textbooks for X-ray practitioners and on studies performed in X-ray departments. The examinations are based on FDD, which can be selected by the user within a given interval.

The following text provides a brief description of the usage of the CALDose_X 5.0 software. More detailed information about the software, as well as MASH and FASH phantoms and skeletal dosimetry [540-544] can be found among the publications that are available on www.caldose.org.
A.2 Software user guide

Double-clicking on the CALDose_X icon shows the following cover image (Figure A.1). The "Enter" and "Exit" options are available.

![CALDose_X 5.0 cover image](image_url)

*Figure A.1 CALDose_X 5.0 cover image.*

Clicking on "Enter" button opens the graphical interface which allows the user to define the type of the X-ray examination (Figure A.2):

![Definition of the X-Ray examination](image_url)

*Figure A.2 Definition of the X-Ray examination.*

Name of the institution, room ID, patient’s name and ID are optional. Patient’s age is only required for the calculation of radiological risks. If no age is given by the user, the CALDose_X 5.0 calculates the risks for 35.0 years old adult.
Next, the selection of the patient’s sex and posture are prerequisite, in order to proceed to the “Examinations” menu. Clicking on the “Examination” button drop down a window shows the examinations available for the selected posture (Figure A.3):

![Figure A.3](image)

*Figure A.3 Definition of patient data, sex, posture and view of available X-ray examinations.*

After selecting the examination and projection, the FDD, the charge (mAs), the tube potential (kV) and the field position should be determined. The mAs values need to be defined only for absolute organ absorbed dose calculation, while three field positions are available, the standard field position as well as the standard filed +/- 2cm up and down (Figure A.4).

![Figure A.4](image)

*Figure A.4 Selection of Cervical Spine examination, RLAT projection, FDD = 100 cm, 10 mAs and 65 kV for standard field position.*
Then, select the output curve to calculate the INAK. CALDose_X 5.0 provides the ability to choose the theoretical output curve for 2.5 mm Al filtration or to add the output curve of another X-ray system into the table (Figure A.5).

Figure A.5 Selection of the theoretical output curve for 2.5 mm Al filtration provided by the CALDose_X 5.0.

Based on the output curve, the CALDose_X 5.0 calculates the INAK and ESAK using the BSF for the selected examination and exposure parameters (Figure A.6).

Figure A.6 Theoretical output curve, INAK, ESAK and the BSF values.

Clicking on “Show Image” button, a visualization of the X-ray field for the selected examination pops up (Figure A.7). Right-clicking provides the ability to save and/or print the visualization.
Figure A.7 Visualization of the selected Cervical Spine RLAT examination.

Clicking on “Calculate Dose” button, a small window pops up for selecting the output mode of the calculations (organ/tissue absorbed doses or CCs), as well as the normalization quantity (INAK, ESAK, KAP) (Figure A.8). The INAK and ESAK values are filled automatically if the option ‘Yes’ is selected for ‘Calculate INAK?’ in Figure A.6. Otherwise INAK and ESAK values have to be filled into the corresponding fields shown in Figure A.8. In case of using the KAP, the user has to fill in a value for the KAP.

Figure A.8 Selection of the output mode for calculations and normalization quantity: organ and tissue absorbed doses based on ESAK values.

Clicking on “Calculate Organ and Tissue Absorbed Doses” button produces the Table A.1, which shows the results for the selected examination and exposure parameters. Organ
and tissue absorbed doses are given in mGy and the statistical error in %. Absorbed doses with a statistical error greater than 10% are not shown in the table. The “weighted MASH dose” represents the male contribution to the effective dose. The quantity “weighted FASH dose” is given in the result tables for females. The effective dose is the arithmetic mean of the two sex-specific contributions.

**Table A.1 CALDose_X 5.0 organ and tissue absorbed doses, as well as associated cancer risks for the selected examination.**

<table>
<thead>
<tr>
<th>INSTITUTION:</th>
<th>PGNP</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROOM:</td>
<td>NEUROSURGERY</td>
</tr>
<tr>
<td>X-RAY TUBE (Filter: 2.5 mm Al):</td>
<td>Rendimento Teórico/Theoretical Output</td>
</tr>
<tr>
<td>ADULT PATIENT:</td>
<td>Male Standing</td>
</tr>
<tr>
<td>Name:</td>
<td>PATIENT</td>
</tr>
<tr>
<td>ID:</td>
<td>1</td>
</tr>
<tr>
<td>Calculation date:</td>
<td>30/01/2017</td>
</tr>
</tbody>
</table>

EXPOSURE CONDITIONS
MASH3STA: CERVICAL SPINE, RIGHT LATERAL (RLAT)
IMAGE ON LEFT SIDE OF THE BODY
65 kVcp 2.5 mm Al 17 Deg Tungsten IPEM/SR78
MEAN SPECTRAL ENERGY: 37.3 keV  ABSORBED FRACTION: 0.50
SOURCE-TO-DETECTOR (FILM): 100 cm
SOURCE-TO-SKIN: 83.0 cm
FIELD SIZE IN DETECTOR PLANE: 18 cm x 24 cm
FIELD POSITION: STANDARD  POSTURE: STANDING
MALE ADULT (ICRP89)
BODY MASS: 73.0 KG, STANDING HEIGHT: 176.0 CM
CHARGE: 10 mAs

ORGAN/TISSUE ABSORBED DOES

<table>
<thead>
<tr>
<th>ORGAN/TISSUE</th>
<th>mGy</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESAK</td>
<td>1.270</td>
<td>0.00</td>
</tr>
<tr>
<td>BRAIN</td>
<td>0.020</td>
<td>0.83</td>
</tr>
<tr>
<td>ORAL MUCOSA</td>
<td>0.128</td>
<td>1.01</td>
</tr>
<tr>
<td>LUNGS</td>
<td>0.008</td>
<td>1.02</td>
</tr>
<tr>
<td>OESOPHAGUS</td>
<td>0.017</td>
<td>2.74</td>
</tr>
<tr>
<td>EYES</td>
<td>0.003</td>
<td>9.87</td>
</tr>
<tr>
<td>SKIN ENTRANCE 7.2cm X 7.2cm</td>
<td>1.279</td>
<td>1.00</td>
</tr>
<tr>
<td>SALIVARY GLANDS</td>
<td>0.264</td>
<td>0.84</td>
</tr>
<tr>
<td>THYMUS</td>
<td>0.003</td>
<td>8.66</td>
</tr>
<tr>
<td>THYROID</td>
<td>0.208</td>
<td>1.28</td>
</tr>
<tr>
<td>EXTRATHORARCCIC AIRWAYS</td>
<td>0.128</td>
<td>0.92</td>
</tr>
<tr>
<td>HEART WALL</td>
<td>0.003</td>
<td>2.88</td>
</tr>
<tr>
<td>LYMPHATIC NODES</td>
<td>0.020</td>
<td>1.07</td>
</tr>
<tr>
<td>SKELETON AVERAGE</td>
<td>0.063</td>
<td>0.71</td>
</tr>
<tr>
<td>MAXIMUM RBM ABSORBED DOSE</td>
<td>0.169</td>
<td>0.92</td>
</tr>
<tr>
<td>MAXIMUM BSC ABSORBED DOSE</td>
<td>0.220</td>
<td>1.52</td>
</tr>
<tr>
<td>WEIGHTED MASH DOSE</td>
<td>0.018</td>
<td>1.64</td>
</tr>
</tbody>
</table>

RISK OF CANCER INCIDENCE 0.155 CASES PER 100000
RISK OF CANCER MORTALITY 0.13 CASES PER 100000
Figure A.9 shows the selection of the option for CCs normalized to ESAK values for the selected examination and exposure parameters. The results are shown in Table A.2. CALDose_X 5.0 also emits CCs for the radiological risks at the end of the table. If no age was given by the user, it emits CCs for radiological risks for adults of 35 years of age.

Figure A.9 Selection of the output mode for calculations and normalization quantity: organ and tissue absorbed doses CCs based on ESAK values.

The software provides the options to save and/or print the results. In order to save the results in an Excel table one has to apply the following procedure:

(a) Save the results (Table A.1 or A.2) as a .txt file.
(b) Copy the table from the .txt file, open Excel and paste the table into Excel.
(c) Below the Excel table, which usually appears in disarray, is a small icon offering paste options.
(d) Select the option “use txt import wizard”.
(e) Select “fixed width” and click on “next” and if requested click again on “next” until the data appear correctly aligned.
(f) Add new columns of data as required.
Table A.2 CALDose_X 5.0 conversion coefficients between organ and tissue absorbed doses and ESAK for the selected examination and exposure parameters.

INSTITUTION: PGNP
ROOM: NEUROSURGERY
ADULT PATIENT: Male Standing Age: 50 years
Calculation date: 30/01/2017 CALDose_X_5.0

EXPOSURE CONDITIONS
MASH3STA: CERVICAL SPINE, RIGHT LATERAL (RLAT)
IMAGE ON LEFT SIDE OF THE BODY
65 kVcp 2.5 mm Al 17 Deg Tungsten IPEM/SR78
MEAN SPECTRAL ENERGY: 37.3 keV ABSORBED FRACTION: 0.50
SOURCE-TO-DETECTOR (FILM): 100 cm
SOURCE-TO-SKIN: 83.0 cm
FIELD SIZE IN DETECTOR PLANE: 18 cm x 24 cm
FIELD POSITION: STANDARD POSTURE: STANDING
MALE ADULT (ICRP89)
BODY MASS: 73.0 KG, STANDING HEIGHT: 176.0 CM

ABSORBED DOSE PER ENTRANCE SURFACE AIR KERMA

<table>
<thead>
<tr>
<th>ORGAN/TISSUE</th>
<th>Gy/Gy</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESAK/ESAK</td>
<td>1.000</td>
<td>0.00</td>
</tr>
<tr>
<td>BRAIN</td>
<td>0.016</td>
<td>0.83</td>
</tr>
<tr>
<td>ORAL MUCOSA</td>
<td>0.101</td>
<td>1.01</td>
</tr>
<tr>
<td>LUNGS</td>
<td>0.006</td>
<td>1.02</td>
</tr>
<tr>
<td>OESOPHAGUS</td>
<td>0.013</td>
<td>2.74</td>
</tr>
<tr>
<td>EYES</td>
<td>0.002</td>
<td>9.87</td>
</tr>
<tr>
<td>SKIN ENTRANCE 7.2cm X 7.2cm</td>
<td>1.007</td>
<td>1.00</td>
</tr>
<tr>
<td>SALIVARY GLANDS</td>
<td>0.208</td>
<td>0.84</td>
</tr>
<tr>
<td>THYMUS</td>
<td>0.002</td>
<td>8.66</td>
</tr>
<tr>
<td>THYROID</td>
<td>0.164</td>
<td>1.28</td>
</tr>
<tr>
<td>EXTRATHORACIC AIRWAYS</td>
<td>0.101</td>
<td>0.92</td>
</tr>
<tr>
<td>HEART WALL</td>
<td>0.002</td>
<td>2.88</td>
</tr>
<tr>
<td>LYMPHATIC NODES</td>
<td>0.016</td>
<td>1.07</td>
</tr>
<tr>
<td>SKELETON AVERAGE</td>
<td>0.050</td>
<td>0.71</td>
</tr>
<tr>
<td>MAXIMUM RBM ABSORBED DOSE</td>
<td>0.133</td>
<td>0.92</td>
</tr>
<tr>
<td>MAXIMUM BSC ABSORBED DOSE</td>
<td>0.173</td>
<td>1.52</td>
</tr>
<tr>
<td>WEIGHTED MASH DOSE</td>
<td>0.014</td>
<td>1.64</td>
</tr>
</tbody>
</table>

RISK OF CANCER INCIDENCE: 0.121 CASES PER 100000/ESAK(mGy)
RISK OF CANCER MORTALITY: 0.102 CASES PER 100000/ESAK(mGy)
APPENDIX B

SPINAL SURGERY BASIC INSTRUMENTATION

B.1 Introduction

The surgeon’s approach to the spine determines the type of the instruments that will be used. According to the indications (see chapter 2) three approaches are possible: anterior, posterior and lateral. The anterior approach to the thoracic and lumbar spine demands the manipulation of the vessels and organs out of the way, in order to operate on the spine. These vessels and organs are not in the path in the case of posterior or lateral approaches. An anterior approach requires additional retractors and vascular clamps that are not needed during posterior or lateral procedures, while the lateral approach also uses minimally invasive instruments. Although spinal instrumentation and implants have been developed during the years, the basic instruments required for spine surgery is common to spine sets throughout the world.

The following text provides an overview of the basic instrumentation utilized during cervical spinal surgery procedures (see chapter 2).

B.2 Overview of basic spinal instruments

The basic instruments can be broadly classified into five categories, and each plays a very important and specific role in order to achieve successful surgical procedures. These categories are: retractors, periosteal elevators, rongeurs, nerve hooks, and curettes. The size of the instruments differs according to the location of the surgery, since the size of the vertebra increases, as they progress from the cervical to the lumbar spine.
B.2.1 Retractors

To expose the spine, an electrocautery pencil, knife handle, elevator, and self-retaining retractor are required. The type of retractor depends on the depth of the incision. For all spine surgeries, Weitlaner retractors (Figure B.1) of various lengths are primarily used to establish retraction of the skin and muscle. As the wound becomes deeper and lengthens, the Derrico retractor (Figure B.2) or Adson Cerebella retractor (Figure B.3) may be used. The body of the Derrico retractor is larger to facilitate a longer incision.

Figure B.1 Weitlaner retractor.

Figure B.2 Derrico retractor.

Figure B.3 Adson Cerebellar retractor.
The hand-held Meyerding retractor (Figure B.4) or Taylor retractor (Figure B.5) are usually used when acquiring bone from the iliac crest for spinal fusion.

**Figure B.4 Hand-held Meyerding retractor.**

**Figure B.5 Taylor retractor.**

The Derrico nerve root retractor (Figure B.6, bottom) or Caspar nerve root retractor (Figure B.6, top), can be used for fine work near the disk, along with the Micro Williams retractors (Figure B.7), which have deep and narrow blades. The nerve root retractors have a curved design in order to allow their placement deep in the wound to retract a nerve root while leaning out of the surgeon’s optical path so that the surgical field can be easily seen. The person’s hand holding the retractor should be out of the midline view of the spine, so the nerve can be retracted to the side, while the surgeon works around it.
B.2.2 Elevators

The Hoen Sedilot elevators (Figure B.8) and Cobb elevators (Figure B.9) are commonly used in spine surgery. The Cobb elevator is available with various lengths of handles and sizes of paddles, in proportion to the level of the spine to be treated. It can be used along with a surgical sponge to elevate and push the muscle away from the bone in order to permit visualization of the spine. More dissection is required if spinal implants and fusion are
intended to be performed. When more fine work is needed, the Penfield 4 elevator (Figure B.10) is used.

![Hoeng Sedilot elevator](image)

*Figure B.8 Hoen Sedilot elevator.*

![Cobb elevator](image)

*Figure B.9 Cobb elevator.*

![Penfield 4 elevator](image)

*Figure B.10 Penfield 4 elevator.*

### B.2.3 Rongeurs

The Stille-Luer Horsley rongeur (Figure B.11), Leksell rongeur (Figure B.12), and Duckbill rongeur (Figure B.13) are used to remove the spinous process. The Stille-Luer Horsley and Leksell rongeurs point straight from the handle, while the duckbill rongeur
points to the side. The Stille-Luer Horsley rongeur provides a fixed 10 mm bite to remove bone, while the Leksell and Duckbill rongeurs are available in varying widths.

Figure B.11 Stille-Luer Horsley rongeur.

Figure B.12 Leksell rongeur.

Figure B.13 Duckbill rongeur.
The Kerrison rongeur (Figure B.14) is used to remove bone from smaller areas of the spine. Its main features include:

- Variable jaw widths, including 1, 2, 3, 4, and 5 mm.
- Two jaw slopes (40° and 90°).
- Can be used for up or down biting.

![Figure B.14 Kerrison rongeur.](image)

Pituitary rongeurs (Figure B.15) are used to remove the disc and tissue in small spaces. Their main features include:

- Can be used for straight, up, and down biting.
- Several jaw widths, including 2, 3, and 4 mm.
- Proper length of axis to facilitate spinal procedures.

![Figure B.15 Pituitary rongeur.](image)
Some rongeurs, such as the Casper pituitary rongeur (Figure B.16), have serrated jaws to help remove disc and tissue. Microdisectomy procedures require the use of a microscope, as well as three rongeurs to remove the disc tissue: the micro straight pituitary rongeur (Figure B.17), the Peapod pituitary rongeur (Figure B.18), and the Micro Williams pituitary rongeur (Figure B.19).

Figure B.16 Caspar serrated pituitary rongeur.

Figure B.17 Micro straight pituitary rongeur.

Figure B.18 Peapod pituitary rongeur.
B.2.4 Nerve hooks

Nerve hooks are used to explore areas around the sensitive nerves localized in the spine. Three nerve hooks should be part of basic set of instruments used in spinal surgeries. These include the Dandy blunt nerve hook (Figure B.20), which is short and blunt designed, the Cushing Gasserian blunt nerve hook (Figure B.21), which is longer in length, and the Weary Black nerve hook (Figure B.22), which is thinner and has more sharp design. When operating under a microscope, the Malis (micro) nerve hook (Figure B.23), which is smaller in size, may be required.

Figure B.19 Micro Williams pituitary rongeur.

Figure B.20 Dandy blunt nerve hook.

Figure B.21 Cushing Gasserian nerve hook.
Appendix B

Figure B.22 Weary Black nerve hook.

Figure B.23 Malis (micro) nerve hook.

B.2.5 Curettes

Curettes are used to remove bone. They are available with various sizes of cups, which can be periodically sharpened to improve their performance, but with caution to retain their size specifications. After multiple sharpenings, the depth of the cup will be compromised and, the instrument may not meet the surgeon’s expectations.

Curettes can be straight (Figure B.24) or angled (Figure B.25). The Epstein curette with a reverse-angled cutting cup (Figure B.26) is commonly requested for microdiscectomy surgeries.

The variety of spinal implants constitutes a challenge for surgeons because there are implant systems designed for each level of the spine. Each system may involve different screws, hooks, plates, and rods to stabilize the spine.

Figure B.24 Angled curette.
Figure B.25 Straight curette.

Figure B.26 Epstein curette.
APPENDIX C

CALIBRATION OF KAP METER

C.1 Introduction

The built-in KAP meter is mounted on the X-ray tube housing, so that the sensitive volume of the chamber cover the entire X-ray beam, including both focal and extrafocal radiation, as well as the penumbra regions. The KAP of an x-ray beam is the surface integral of air kerma over the area of the entire beam in a plane perpendicular to the beam central axis [277]. In ideal beams, the KAP is independent with the distance from the X-ray source and a geometry independent calibration coefficient can be estimated [296]. In clinical practice, the extra-focal and scattered radiation, as well as attenuation in air affects the KAP values, resulting in dependence on the plane and area of integration [316, 373, 545].

Modern X-ray systems are often equipped with integrated KAP meters either chamber or devices which determine the KAP on the basis of exposure parameters (tube current and voltage) and the setting of the diaphragm. It is important to calibrate the KAP meters are for all relevant clinical conditions in which the systems are used, in order to achieve adequate accuracy of patient dose measurements. They must be calibrated in situ for the same X-ray system and irradiation geometry as used with patients, in order to take into account the equipment-specific effects of extra-focal and stray radiation [277]. The calibration coefficient of a typical KAP meter significantly depends on the energy dependence of these chambers, due to their materials and design [315, 316, 373, 525, 526, 545]. Within range of radiation qualities occur in diagnostic and interventional radiology, the calibration coefficients of a KAP meter may vary by 20-30%. Consequently, the energy dependence should be considered in their calibration [526]. Uncertainties of 7% or lower (k=2) are recommended for air kerma and KAP measurements, while an uncertainty of 5% (k=2) of the calibration coefficient should not be exceeded [277, 296]. According to the international standard IEC 60580 [317], a combined standard uncertainty of 25% (k=2) in KAP measurements should not be exceeded under specified conditions, but under more strictly limited conditions the uncertainty may be reduced.
KAP reference values are usually determined by approximating the surface integral by the product of the nominal area A of the x-ray field and the air kerma measured in the centre of the field (beam area method) [277, 296, 316, 368, 373]. However, non-uniformity of the X-ray field may cause inaccuracy in this method. Other important sources of uncertainty are the measurements of field size and the location of the planes of air kerma and field size determination [316, 373, 525, 545]. The dependence of calibration coefficients on the non-uniformities of the x-ray beam results in problems for in situ calibrations when using the beam area method at clinical x-ray systems. To overcome this problem, field sizes of about 10×10 cm² have been recommended for calibration, but a standardized calibration geometry is needed in order to provide single-valued calibration coefficients [277, 296, 368].

The accuracy of calibration can be improved by measuring directly the reference KAP value using KAP chambers, thus avoiding the problems arising from the non-uniformities of the x-ray field. The extra-focal and stray radiations depend on the distance and equipment. Therefore, in order to provide a calibration independent of individual x-ray systems, the reference KAP value should be determined at the position of the chamber. This does not guarantee the accuracy of measurements with patients, since the KAP values and calibration coefficients are not the same at the chamber and at other distances. In the tandem calibration method [525], the clinical KAP meter is used in its clinical position and the reference value is measured simultaneously at a distance with a reference KAP meter, estimating the KAP value at the entrance plane of a virtual patient. This method is suitable for in situ calibration of clinical KAP meters, avoiding the most important limitations of the beam area method [277, 296, 316, 368, 373].

When calibrating the clinical KAP meter, measurements should be performed with the reference dosimeter and the KAP meter simultaneously. The KAP values should be determined for the X-ray beam transmitted through the chamber and directed to the patient. A KAP chamber typically attenuates the air kerma by 15-20% [296]. In an under couch X-ray tube, the attenuation in the patient couch has to be regarded and in situ calibration has to be carried out separately for under couch and over couch X-ray tubes [296].

The following text provides an overview of the methods that can be utilized for the calibration of the clinical KAP meters. Within the framework of this thesis, the beam area method was used, which is based on the measurement of the air kerma by a diagnostic dosimeter as well as the beam area on the plane of the measurement [277, 296, 368]. Another method uses a reference KAP meter already calibrated at a SSDL (IAEA method
Appendix C

More information about these methods, their advantages and disadvantages, as well as sources of uncertainties are available in the literature [277, 296, 316, 317, 325, 368, 373, 465, 525, 526, 527, 545-549].

C.2 Methods of KAP meter calibration

C.2.1 Calibration using diagnostic dosimeter (Beam area method)

The KAP is determined as the product of the air kerma on the central axis of the X-ray beam and the nominal beam area measured (or corrected) at the same distance. For all clinically relevant radiation qualities, the clinical (field) KAP meter is exposed for a specific, fixed field size simultaneously with a reference class diagnostic dosimeter (usually an ionisation chamber) positioned at a proper distance from the KAP meter (≥ 30 cm), in order to avoid additional scattering. A beam area of approximately 10×10 cm$^2$ at the plane of the measurement is recommended [296].

C.2.1.1 Over couch geometry

The calibration procedure for over couch installation (Figure C.1(a)) includes the following steps [296]:

1. Mount the clinical KAP meter on the X-ray tube housing and connect it to a calibrated electrometer. In case of installations that are equipped with an integrated KAP meter, use this device.
2. Position the detector of the calibrated diagnostic dosimeter on the central axis of the X-ray beam and 20 cm above the couch, to avoid the influence of backscattered radiation. A block of Styrofoam can be used to support the detector.
3. The X-ray beam should be collimated, such that the exposed area at the position of the detector is approximately 10 × 10 cm$^2$.
4. Expose the detector and the KAP meter using all clinically relevant combinations of tube voltage and total filtration (beam quality $Q$).
5. Record measures from the KAP meter, $M^KAP_Q$, and the reference dosimeter, $M^{ref}_Q$. 

335
For direct films:

6. Remove the reference detector and place a direct film perpendicular to the central axis of the X-ray beam at the position of the reference detector.
7. Expose the film. The maximum OD must not exceed 0.5, so that it is clearly lower than the maximum film blackening.
8. Develop the film and determine the nominal beam area ($A_{\text{nom}}$). This area is defined within 50% of the maximum OD. This can be achieved by using a densitometer and a ruler or the eye and a ruler (x-ray field dimensions are measured from midways of the penumbra).

For computed radiography cassette:

6. Remove the reference detector and place a computed radiography cassette perpendicular to the central axis the X-ray beam at the position of the reference detector.
7. Expose the cassette.
8. Produce a ‘soft’ copy image and determine the nominal beam area, $A_{\text{nom}}$, as the area within 50% of the maximum pixel value. A scale may be useful in the digital image to check the magnification.

![Diagram](image)

**Figure C.1** Set-up for calibration of KAP meter using diagnostic dosimeter: (a) over couch installation, (b) under couch installation [296].
The calibration coefficient \( N_{K\alpha, Q} \) is estimated from the readings \( M_{Q}^{K\alpha P} \) and \( M_{Q}^{ref} \) (corrected for air density) of the clinical KAP meter and the reference dosimeter, respectively, as well as the measured nominal beam area \( A_{nom} \) using the equation:

\[
N_{K\alpha, Q} = \frac{M_{Q}^{ref}}{M_{Q}^{K\alpha P}} N_{K\alpha, Q_0}^{ref} k_{Q_0}^{ref} A_{nom}
\]  

(C.1)

where \( N_{K\alpha, Q_0}^{ref} \) is the calibration coefficient of the reference dosimeter acquired at a beam quality \( Q_0 \) and \( k_{Q_0}^{ref} \) the correction factor for the different response between beam qualities \( Q_0 \) and \( Q \).

### C.2.1.2 Under couch geometry

The KAP value should indicate the radiation incident on the patient and, therefore, take into account the attenuation in the couch, as well as the radiation scattered from the couch that may reach the patient. The couch may attenuate KAP by about 15-30% [296]. For under couch calibration of a clinical KAP meter, the detector should be placed on the table top, in order to take into account the beam attenuation and scattering by the table. The entry window of the KAP meter should be positioned towards the X-ray focus. The calibration setup is shown in Figure C.1(b). Steps 3-8 as described above are also followed for the calibration of under couch installations. The calibration coefficient \( N_{K\alpha, Q} \) was then calculated using the equation C.1.

### C.2.2 Calibration using a reference KAP meter

A reference KAP meter can alternatively be used for the calibration of clinical KAP meters. It should be calibrated for the radiation incident on the KAP chamber. In the case that it is calibrated for transmitted radiation, the correction factor correcting for the attenuation in the KAP chamber should be provided by the SSDL. A difference of approximately 10-15% may occur in the calibration factors between incident and transmitted radiation beams. The calibration of the reference KAP meter is recommended for a range of beam qualities characterized by their HVL values [277, 296, 526]. Standard RQR radiation qualities [548, 549] are generally used for calibration in laboratories [277, 296], although they do not cover the whole range of radiation qualities used in diagnostic x-ray.
examinations. Interpolation between two points is recommended in order to obtain the calibration coefficient for the beam qualities available in clinical practice. However, an extrapolation beyond the HVL range provided in the calibration certificate is not recommended.

Interpolation between two calibration points for the reference KAP meter can be employed for a total filtration of up to 3 mm Al, independently of the X-ray tube voltage. For X-ray beams with higher filtrations, both HVL and the tube voltage values may be required to perform the interpolation [296, 526].

C.2.2.1 Over and under couch geometry (IAEA method)

The calibration set-up for both over couch and under couch installations is presented in Figure C.2. It is the same as in the beam area method besides that the diagnostic dosimeter is now replaced by the reference KAP meter. The calibration procedure described for the beam area method is followed.

![Figure C.2](image)

**Figure C.2** Set-up for calibration of KAP meter using reference KAP meter, according to IAEA method: (a) over couch installation, (b) under couch installation [296].

The calibration coefficient $N_{p_{x},Q}$ is calculated from the readings $M_{Q}^{KAP}$ and $M_{Q}^{KAP,\text{ref}}$ (corrected for air density) of the clinical KAP meter and the reference KAP meter, respectively, using equation:
where $N_{P_kQ_0}^{ref}$ is the calibration coefficient of the reference KAP meter acquired at a beam quality $Q_0$ and $k_{Q_0}^{ref}$ the correction factor for the different response between beam qualities $Q_0$ and $Q$.

### C.2.2.2 Tandem calibration method

In this method, the clinical KAP meter is calibrated using a reference KAP meter. The chambers are irradiated simultaneously. The clinical KAP chamber is used in the same x-ray unit, position and geometry as in the measurements with patients, and the reference KAP chamber is placed at a longer distance corresponding to the entrance surface of a virtual patient. The distance between the chambers should be large enough to reduce scattering from one to the other, but simultaneously the field size at the reference chamber should be kept small so that the entire beam will hit the chamber [525].

![Figure C.3 Set-up for calibration of KAP meter using tandem method.](image-url)

The proportion of scattered radiation hitting the reference chamber in the calibration is not the same as that hitting the patient in practice. From this point of view, an uncertainty is introduced into the reference KAP value, giving rise to an additional uncertainty in the
calibration of field KAP meters. In addition, the area of the reference KAP chamber must be essentially larger than the nominal x-ray field in the plane of the chamber, to include the regions of penumbra. The calibration geometry could be standardized by the position and area of the reference KAP meter, in order to define reasonable field sizes at typical patient distances. In under couch geometry, the reference KAP chamber can be placed above the patient couch and close to the table top so that radiation scattered from the table is included in the reference KAP value.

The calibration coefficient $N_{\text{clin}}$ of the clinical KAP meter is calculated as the ratio of the reference KAP value $P_{KA}^{\text{ref}}$ and the reading $M_{\text{clin}}$ of the clinical meter:

$$N_{\text{clin}} = \frac{P_{KA}^{\text{ref}}}{M_{\text{clin}}}$$  \hspace{1cm} (C.3)

where the reference KAP value $P_{KA}^{\text{ref}}$ is determined with the reference KAP meter as the product of its reading $M_{\text{ref}}$ and calibration coefficient $N_{\text{ref}}$ for the incident radiation:

$$P_{KA}^{\text{ref}} = N_{\text{ref}} \times M_{\text{ref}}$$  \hspace{1cm} (C.4)

For the calibration coefficient $N_{\text{ref}}$ of the reference KAP meter, the total filtration of the x-ray system and the filtration caused by the field KAP meter must be included, as well as the filtration of the patient couch in the case of under-couch geometry. The calibration should cover all clinically relevant radiation qualities, because the response of typical KAP meters depends rather strongly on the energy distribution of the x-ray beam.
SUMMARY

In recent years, an increasing number of fluoroscopically guided procedures has been introduced into the field of spine surgery. However, the use of fluoroscopy by neurosurgeons outside the imaging department, where in most cases lacking of appropriate training and awareness in radiological protection issues, resulting in increased radiation risks to both patients and medical staff. Thus, patient and staff dose monitoring, its optimization, as well as the implementation of a quality assurance programme becomes essential for all spine interventional procedures.

In the framework of this thesis, an evaluation and optimization of patient dose and image quality in fluoroscopically guided cervical discectomy and fusion procedures is performed. The patient’s dose evaluated utilizing the dosimetric quantities recorded from the dosimetric report of the fluoroscopy system (fluoroscopy time, kerma-area-product (KAP), cumulative dose (CD)), while the correlation of the KAP and CD values with fluoroscopy time is also studied. The KAP values, the exposure parameters (tube voltage, tube current, tube output), as well as irradiation geometry parameters (projection, field size, focus-to-detector distance, focus-to-skin-distance) were used as ‘‘input’’ in CALDoseX 5.0 software, based on Monte Carlo simulation, to estimate the patient entrance surface dose (ESD), effective dose (ED) and thyroid absorbed dose. As part of this thesis, conversion coefficients were also estimated based on KAP values, in order to estimate mean organ absorbed doses during such procedures. The factors taken into consideration in dose assessment are the patient’s gender and body mass index, the type of fusion (single or multiple levels), the surgical approach, as well as neurosurgeon experience. In addition, comparison of the results with corresponding dosimetric studies from the literature is carried out.

In order to optimize the procedure, both in terms of patient dose and image quality, an experimental study is carried out utilizing a PMMA phantom and the TOR 18FG test object to simulate the patient, under clinical exposure conditions. The effect of all the parameters selected by the operator of the fluoroscopy system (fluoroscopy mode: continuous or pulsed, low or high dose fluoroscopy, electronic or geometric magnification), as well as the patient’s size is studied, in terms of ESD to the patient and image intensifier. The corresponding images obtained from all irradiation combinations were subjectively evaluated by observers in terms of detectability and discriminability of specific low-contrast and high-contrast objects respectively, as well as utilizing physical image quality metrics (signal-to-noise ratio...
Summary

(SNR), contrast-to-noise ratio (CNR), high-contrast spatial resolution (HCSR)). A figure of merit (FOM) was also introduced, combining the dosimetric and imaging performance of the fluoroscopy system, in order to select the optimal settings of the fluoroscopy system with respect to patients’ size to be treated. Additionally, a series of practical guidance is provided towards further optimization of the radiological protection during these procedures.

Furthermore, within the framework of the development and implementation of a quality assurance and radiation protection programme for neurosurgical procedures in spine, local diagnostic reference levels (LDRLs) and action levels (ALs) are estimated for cervical discectomy and fusion, as well as for thoraco-lumbar discectomy and fusion procedures. A preliminary evaluation for ESD, ED and gonadal dose received by the patients undergoing interventions in thoracic and/or lumbar spine was also performed, using appropriate conversion coefficients based on KAP values. The reference levels were calculated as the 75th and 10th percentile respectively, for fluoroscopy time, KAP and CD values utilizing three methods (for the total sample of patients, with size correction method and weight banding method) and compared between them and with corresponding values from the literature. The distribution histograms of KAP and CD values were also studied and the dose values were correlated with fluoroscopy time. The influence of several anatomical, clinical and technical factors affecting procedure complexity, on the reference dose values was investigated. The factors investigated are the patient’s age and gender, the body mass index, the type of fusion (single or multiple levels), the surgical approach and treated levels, the type of implants (cages and/or rod, screws), as well as the neurosurgeon experience.

Finally, the limitations of this thesis are reported and topics for future work are proposed that could further contribute towards awareness, training and establishment of radiation protection culture by the neurosurgeons and all those involved in minimally invasive spine surgery.
ΠΕΡΙΛΗΨΗ

Τα επεμβάσεις έχει εισαχθεί στον τομέα της χειρουργικής της σπονδυλικής στήλης. Ωστόσο, η χρήση ακτινοσκόπησης από νευροχειρουργούς, όπως και η περισσότερες περιπτώσεις έχουν ελλιπή εκπαίδευση και ενημέρωση σε θέματα ακτινοπροστασίας, έχει ως αποτέλεσμα την αύξηση των κινδύνων από την ακτινοβολία τόσο για τους ασθενείς όσο και για το προσωπικό. Έτσι, η παρακολούθηση της δόσης του ασθενούς και του προσωπικού, η βελτιστοποίησή της καθώς και η εφαρμογή ενός προγράμματος διασφάλισης ποιότητας γίνεται απαραίτητη σε όλες τις επεμβατικές διαδικασίες της σπονδυλικής στήλης.

Στα πλαίσια της διατριβής, πραγματοποιήθηκε αξιολόγηση και βελτιστοποίηση της δόσης ασθενούς και της ποιότητας εικόνας στην ακτινοσκοπική καθοδηγούμενη αυγενική δίσκεκτομή και σπονδυλοδεσία. Η δόση του ασθενούς αξιολογήθηκε χρησιμοποιώντας τις παραμέτρους δόσης που καταγράφηκαν από τη δοσιμετρική αναφορά του ακτινοσκοπικού συστήματος (χρόνος ακτινοσκόπησης, γινόμενο kerma-επιφάνειας (KAP), συσσωρευτική δόση (CD)), ενώ μελετήθηκε και η συσχέτιση των τιμών του KAP και της CD με τον χρόνο ακτινοσκόπησης. Οι τιμές του KAP, οι παράμετροι έκθεσης (υψηλή τάση, ρεύμα λυχνίας, παροχή λυχνίας) καθώς και η γεωμετρία ακτινοβόλησης (προβολή, μέγεθος πεδίου ακτινοβόλησης, απόσταση εστίας-ανιχνευτή και εστίας-δέρματος) χρησιμοποιήθηκαν ως ‘‘είσοδος’’ στο λογισμικό CALDoseX 5.0 που βασίζεται σε προσομοίωση Monte Carlo, για τον υπολογισμό της δόσης εισόδου (ESD) και της ενεργού δόσης (ED) στον ασθενή, καθώς και της δόσης που λαμβάνει ο θυρεοειδής αδένας. Ως μέρος της διατριβής, υπολογίστηκαν επίσης και συντελεστές μετατροπής που βασίζονται στην τιμή του KAP, για τον υπολογισμό της μέσης δόσης του συνόλου των οργάνων κατά τις επεμβάσεις αυτές. Οι παράγοντες που λαμβάνονται υπόψη είναι το φύλο του ασθενούς, ο σωματοτύπος του, ο τύπος της σπονδυλοδεσίας (ενός ή πολλαπλών επιπέδων), η προσπέλαση καθώς και η εμπειρία του νευροχειρουργού. Επίσης, πραγματοποιήθηκε σύγκριση των αποτελεσμάτων με αντίστοιχες δοσιμετρικές μελέτες από τη διεθνή βιβλιογραφία.

Προκειμένου να βελτιστοποιηθεί η διαδικασία της επέμβασης, τόσο ως προς τη δόση που λαμβάνει ο ασθενής όσο και ως προς την ποιότητα εικόνας πραγματοποιήθηκε πειραματική μελέτη με τη χρήση ομοιόμορφου από PMMA και του ‘‘εργαλείου ελέγχου’’ TOR 18FG για την προσομοίωση του ασθενούς, υπό τις κλινικές συνθήκες ακτινοβόλησης. Μελετήθηκε η επίδραση όλων των παραμέτρων που επιλέγονται από τον χειριστή του ακτινοσκοπικού.
συστήματος (είδος ακτινοσκόπησης: συνεχής ή παλμική, χαμηλής ή υψηλής δόσης, ηλεκτρονική ή γεωμετρική μεγέθυνση) καθώς και του μεγέθους του ασθενούς, ως προς τη δόση εισόδου στον ασθενή και στον αιχμετήτορα εικόνας. Οι εικόνες που προέκυψαν από όλους τους συνδυασμούς ακτινοβόλησης αξιολογήθηκαν τόσο από παρατηρήσεις ως προς την ανιχνευσιμότητα και διακρισιμότητα αντικειμένων χαμηλής και υψηλής αντίθεσης αντιστοίχως, όσο και με φυσικούς δείκτες ποιότητας εικόνας (λόγος σήματος προς θόρυβο (SNR), λόγος αντίθεσης προς θόρυβο (CNR), διακριτική ικανότητα υψηλής αντίθεσης (HCSR)). Επίσης, σχεδίασε και ένα συνολικός δείκτης ποιότητας (FOM), ως συνδυασμός της δοσιμετρικής και απεικονιστικής απόδοσης του ακτινοσκοπικού συστήματος, ώστε να επιλέγεται ο βέλτιστος τρόπος λειτουργίας του σε συνάρτηση με το μέγεθος του ασθενούς.

Επιπρόσθετα, δίνονται και πρακτικές οδηγίες για την περαιτέρω βελτιστοποίηση της ακτινοπροστασίας κατά τις επεμβάσεις αυτές.

Επιπλέον, στα πλαίσια της διαδικασίας ανάπτυξης και εφαρμογής προγράμματος διαφάνειας ποιότητας και ακτινοπροστασίας για τις νευροχειρουργικές επεμβάσεις στη σπονδυλική στήλη, υπολογίστηκαν τοπικά διαγνωστικά επίπεδα αναφοράς (LDRs) και επίπεδα δράσης (ALs) τόσο για τις επεμβάσεις ανεξαρτήτως δισκηχιωμένης και σπονδυλοδεσίας όσο και θωρακικής-οσφυικής δισκηχιωμένης και σπονδυλοδεσίας. Πραγματοποιήθηκε επίσης, προκαταρκτικός υπολογισμός της ESD, ED και της δόσης στους γονάδες των ασθενών που συμμετείχαν σε επεμβάσεις θωρακικής και οσφυικής μοίρας, χρησιμοποιώντας κατάλληλους συντελεστές μετατροπής των τιμών του KAP. Τα επίπεδα αναφοράς υπολογίστηκαν ως το 75% και 10% αντιστοίχως, για τις τιμές του χρόνου ακτινοσκόπησης, του KAP και της CD, με τρεις μεθόδους (για τον συνολικό αριθμό ασθενών, με τη μέθοδο της διόρθωσης μεγέθους και τη μέθοδο ζώνης βάρους) και συγκρίθηκαν μεταξύ τους και με αντίστοιχες τιμές από τη διεθνή βιβλιογραφία. Μελετήθηκαν οι αστιγματικές της κατανομής των τιμών του KAP και της CD και συσχέτισθηκαν οι τιμές δόσης με τον χρόνο ακτινοσκόπησης. Επίσης, αξιολογήθηκε η επίδραση στα επίπεδα αναφοράς διάφορων ανατομικών, κλινικών και τεχνικών παραμέτρων που επηρεάζουν την πολυπλοκότητα της κάθε επέμβασης. Οι παράμετροι που μελετήθηκαν είναι η ηλικία και το φύλο του ασθενούς, ο σωματοτύπος του, ο τόπος της σπονδυλοδεσίας (ενός ή πολλαπλών επιπέδων), η προστάτευση και τα επίπεδα της επέμβασης, το είδος των εμφυτευμάτων (κλωβόδιος ή/και πλάκες, ράβδοι, βίδες), καθώς και η εμπειρία του νευροχειρουργού.

Τέλος, αναλύονται οι περιορισμοί της διατριβής και προτείνονται θέματα μελλοντικής μελέτης που θα συμβάλλουν στην προσπάθεια ενημέρωσης, εκπαίδευσης και απόκτησης
κουλτούρας ακτινοπροστασίας από τους νευροχειρουργούς και όλους τους εμπλεκόμενους στις ελάχιστα επεμβατικές τεχνικές της σπονδυλικής στήλης.