ปริมาณรังสีที่เจ้าหน้าที่และผู้ป่วยได้รับจากการผ่าตัดเชื่อมกระดูกสันหลังส่วนเอวผ่านผิวหนัง โดยใช้เครื่องคอมพิวเตอร์นำวิถีชนิดลำรังสีรูปกรวย

นายจรูญโรจน์ วงษ์นิล

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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The radiation dose to staff and patient from intraoperative O-ARM system in Percutaneous Transforaminal Lumbar Interbody Fusion (TLIF) surgery

Mr. Jaroonroj Wongnil

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Medical Imaging
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จรูญโรจน์ วงษ์นิล : ปริมาณรังสีที่เจ้าหน้าที่และผู้ป่วยได้รับจากการผ่าตัดเชื่อมกระดูกสันหลังส่วนเอวผ่านผิวหนังโดยใช้เครื่องคอมพิวเตอร์นำวิถีชนิดลำรังสีรูปกรวย (The radiation dose to staff and patient from intraoperative O-ARM system in Percutaneous Transforaminal Lumbar Interbody Fusion (TLIF) surgery) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ. ดร. อัญชลี กฤษณจินดา, 49 หน้า.

เครื่องคอมพิวเตอร์นำวิถีชนิดลำรังสีรูปกรวย (เครื่องโออาร์ม, O-Arm) ช่วยในการผ่าตัด สามารถสร้างภาพแบบสองมิติและสามมิติ ปัจจุบันใช้ในการผ่าตัดมากขึ้น ทำให้ต้องตระหนักถึงปริมาณรังสีที่เจ้าหน้าที่และผู้ป่วยได้รับ วัตถุประสงค์ของการศึกษานี้เพื่อศึกษาปริมาณรังสีที่ผู้ป่วยและเจ้าหน้าที่ได้รับจากการตรวจสอบการผ่าตัดเชื่อมกระดูกสันหลังส่วนเอวผ่านผิวหนัง ทั้งการสร้างภาพแบบสองมิติและสามมิติ โดยใช้เครื่องเอกซเรย์คอมพิวเตอร์โออาร์ม

ขั้นตอนการวิจัยคือ ศึกษาปริมาณรังสีที่ผู้ป่วยได้รับโดยเก็บข้อมูลจากระบบแพคส์ ในผู้ป่วยที่ได้รับการผ่าตัดเชื่อมกระดูกสันหลังส่วนเอวผ่านผิวหนัง โดยใช้เครื่องคอมพิวเตอร์นำวิถีชนิดลำรังสีรูปกรวยจำนวน 100 ราย นำข้อมูลที่ได้มาคำนวณปริมาณรังสีที่ผู้ป่วยได้รับ ส่วนปริมาณรังสีที่เจ้าหน้าที่ได้รับจะทำการวัดการกระจายของปริมาณรังสีที่ระยะต่าง ๆจากแหล่งกำเนิดรังสี โดยใช้ข้อมูลที่ได้จากการเก็บข้อมูลจากหุ่นจำลองแทนผู้ป่วย

จากการศึกษาพบว่า ในผู้ป่วยจำนวน 100 ราย อายุเฉลี่ย 59 ปี(25 ถึง 91 ปี) การสร้างภาพแบบสองมิติ เวลาที่ใช้สร้างภาพเฉลี่ย 15.09 วินาที (5.63 ถึง 42.57 วินาที) ปริมาณรังสีที่ผู้ป่วยได้รับเฉลี่ย 1.3 มิลลิซีเวิร์ต (0.34 ถึง 4.63 มิลลิซีเวิร์ต) ในการสร้างภาพแบบสามมิติเวลาที่ใช้สร้างภาพเฉลี่ย 10.05 วินาที (7.80 ถึง 15.64 วินาที) ปริมาณรังสีที่ผู้ป่วยได้รับเฉลี่ย 10.38 มิลลิซีเวิร์ต(4.32 ถึง 27.02 มิลลิซีเวิร์ต) โดยมีจำนวนสแกน 2 ครั้ง จำนวน 53 ราย ปริมาณรังสีเฉลี่ย 8.14 มิลลิซีเวิร์ต, สแกน 3 ครั้ง จำนวน 37 ราย ปริมาณรังสีเฉลี่ย 11.72 มิลลิซีเวิร์ต และสแกน 4 ครั้ง จำนวน 10 ราย ปริมาณรังสีเฉลี่ย 16.97มิลลิซีเวิร์ต การสร้างภาพแบบสองมิติไม่มีใช้งานโปรโตคอลผู้ป่วยขนาดเล็ก โปรโตคอลขนาดกลางมีการเลือกใช้จำนวน 95 ราย โดยมีค่าปริมาณรังสีเฉลี่ย 1.27 มิลลิซีเวิร์ต (0.34 ถึง 4.63 มิลลิซีเวิร์ต) จำนวนที่เลือกโปรโตคอลผู้ป่วยขนาดใหญ่จำนวน 5 ราย มีค่าปริมาณรังสีเฉลี่ย 1.92 มิลลิซีเวิร์ต (1.47 ถึง 3.15 มิลลิซีเวิร์ต) ในการสร้างภาพแบบสามมิติไม่มีการเลือกโปรโตคอลผู้ป่วยขนาดเล็ก มีการเลือกโปรโตคอลผู้ป่วยขนาดกลาง 63 ราย โดยมีค่าปริมาณรังสีเฉลี่ย 8.15 มิลลิซีเวิร์ต (4.32 ถึง 19.59 มิลลิซีเวิร์ต) โปรโตคอลผู้ป่วยขนาดใหญ่ 34 ราย มีค่าปริมาณรังสีเฉลี่ย 13.65 มิลลิซีเวิร์ต (10.79 ถึง 21.61 มิลลิซีเวิร์ต) ในการสร้างภาพแบบสามมิติไฮเดฟฟินิชั่นโปรโตคอล มีการเลือกใช้โปรโตคอลผู้ป่วยขนาดใหญ่จำนวน 3 ราย มีค่าปริมาณรังสีเฉลี่ย 20.26 มิลลิซีเวิร์ต (13.51 ถึง 27.02 มิลลิซีเวิร์ต) ปริมาณรังสีที่นักรังสีการแพทย์ได้รับระหว่างการปฏิบัติงาน 1 เดือนจากการสร้างภาพแบบสองมิติและสามมิติมีค่า 49 และ 32 ไมโครซีเวิร์ทต่อเดือน ที่ระยะ 200 เซนติเมตรจากผู้ป่วย เจ้าหน้าที่อื่นไม่ได้อยู่ในห้องผ่าตัดขณะทำการสแกน ปริมาณรังสีสำหรับผู้ปฏิบัติงานทางรังสีกำหนดไว้ว่าไม่เกิน 4000 ไมโครซีเวิร์ทต่อเดือน, นักรังสีการแพทย์ปลอดภัยจากการปฏิบัติงาน สามารถลดปริมาณรังสีที่เจ้าหน้าที่โดยการลดเวลาและจำนวนการสแกน และอยู่ไกลจากผู้ป่วยระหว่างทำการสแกน นอกจากนี้ต้องใส่อุปกรณ์กำบังรังสีทุกครั้ง

ภาควิชา	รังสีวิทยา	ลายมือชื่อนิสิต	....
สาขาวิชา	ฉายาเวชศาสตร์	ลายมือชื่อ อ.ที่ปรึกษาหลัก	....
ปีการศึกษา	2557		

5674009930 : MAJOR MEDICAL IMAGING

KEYWORDS: O-ARM / 2D/3D MODES / TLIF SURGERY / STAFF DOSE / PATIENT DOSE / EFFECTIVE DOSE

JAROONROJ WONGNIL: The radiation dose to staff and patient from intraoperative O-ARM system in Percutaneous Transforaminal Lumbar Interbody Fusion (TLIF) surgery. ADVISOR: ASSOC. PROF. ANCHALI KRISANACHINDA, Ph.D., 49 pp.

The O-Arm system has the capability of combined two-dimensional fluoroscopy and three-dimensional computed tomography for intraoperative procedure. The increasing use of this system raises the concern of radiation exposure to staff and patients. The purpose of this study is to estimate the radiation dose delivered to staff and patient during Percutaneous TLIF surgery in 2D and 3D modes when using o-arm system.

The data from one hundred patients underwent percutaneous TLIF surgery in 2D and 3D modes using O-Arm system were recorded from PACS (Picture Archiving and Communication System) and calculated for the patient radiation dose. For staff radiation dose, the scattered dose around the O-Arm gantry were measured using CT phantom to represent patient and scan with the maximum exposure parameters.

The results showed that the average patient age was 59 (25-91) years. In 2D; the average exposure time was 15.09 (5.63-42.57) sec. The effective dose was 1.3 (0.34-4.63) mSv. In 3D; the average exposure time was 10.05 (7.80-15.64) sec. The effective dose was 10.38 (4.32-27.02) mSv. The number of scan was 2 times (53 cases), 3 times (37 cases) and 4 times (10 cases). The average effective dose from 2, 3 and 4 times scan were 8.14 mSv, 11.72 mSv and 16.97 mSv, respectively. In 2D, small size protocol was not selected. Medium size protocol was selected for 95 cases and the average effective dose was 1.27 (0.34-4.63) mSv. Large size protocol was selected for 5 cases and the average effective dose was 1.92 (1.4-3.15) mSv. In 3D, the ST3D protocol, small size protocol was not selected, medium size was selected for 63 cases and the average effective dose was 8.15 (4.32-19.59) mSv. The large size protocol was 34 cases and the average effective dose was 13.65 (10.79-21.61) mSv. In 3D, the HD3D protocol, the large size protocol selected was 3 cases and the average effective dose was 20.26 (13.51-27.02) mSv. The radiological technologist received scattered dose per month from patient in 2D and 3D of 49 and 32 μSv/month at 200 cm from patient. Other staff did not receive the scattered radiation as they were not in operating room during exposure. As the occupational dose limit is 4000 μSv/month, the radiologic technologist was safe working with O-Arm system. Cumulative dose to staff can be reduced by decreasing exposure time in 2D, reduce number of scan in 3D and stay behide the control panel during exposure. In addition the staff must wear the lead apron or using the protective barrier.

Department:	Radiology	Student's Signature	....
Field of Study:	Medical Imaging	Advisor's Signature	....
Academic Year:	2014		

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LIST OF ABBREVIATIONS AND SYMBOLS

ABBREVIATION AND SYMBOLS	TERMS
^{o}	Degree
.com	Commercial
%	Percent
Φ	Diameter
$\sum$	Sigma, Summation symbol
μ	Attenuation coefficient
μGy	MicroGray
μSv	MicroSievert
μSv/h	MicroSievert per hour
2D	Two-dimensional
3D	Three-dimensional
AAPM	American Association of Physicists in Medicine
ALARA	As Low As Reasonably Achievable
$C_{a,100}$	CT air kerma index measured free in air integrated over 100 mm
CBCT	Cone beam computed tomography
cm	Centimeter
cm^{-1}	Per centimeter
cm^{2}	Centimeter square
cm^{3}	Cubic centimeter
$C_{PMMA,100}$	CT air kerma index measured inside PMMA integrated over 100 mm
$C_{PMMA,100,C}$	CT air kerma index measured inside PMMA at center integrated over 100 mm
$C_{PMMA,100,p}$	CT air kerma index measured inside PMMA at peripheral integrated over 100 mm
Corp	Corporation
CT	Computed tomography
CTDI	CT Dose index
C_{VOL}	Volume CT air kerma index

C_w	Weighted CT air kerma index
D	Depth
DAP	Dose area product
DLP	Dose length product
D_T	Absorbed dose of tissue
E	Effective dose
E_{DAP}	Conversion co-efficient for Dose area product which is region specific normalized effective dose
E_{DLP}	Conversion co-efficient for Dose length product which is region specific normalized effective dose
et al	Et alibi, and others
Gy	Gray
$Gy.cm^2$	Gray.centimeter square
$Gy.m^2$	Gray.meter square
H	Equivalent dose
H_T	Equivalent dose of tissue T
http	Hypertext Transfer protocol
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
Inc	Incorporation
K	Air kerma
kV	Kilovoltage
kVp	Kilovoltage peak
K(z)	Air kerma along the rotation axis
l	Distance of couch moving per helical rotation
mA	Milliampere
mAs	Milliampere-second
mGy	MilliGray
mGy.cm	MilliGray.centimeter
$mGy.cm^2$	MilliGray.centimeter square
mm	Millimeter
mSv	Millisievert
$mSv.mGy^{-1}.cm^{-1}$	Millisievert per MilliGray.centimeter
$mSv.mGy^{-1}.cm^{-2}$	Millisievert per MilliGray.centimeter square

N	Number of slice
No.	Number
P	Pitch
P_{KA}	Air kerma area product
$P_{KL,CT}$	CT Air kerma-length product
PMMA	Polymethyl methacrylate
QC	Quality control
R^2	R-square
S/N	Serial number
T	Nominal thickness
USA	United States of America
W	Width
W_R	Radiation weighting factor
W_T	Tissue weighting factor
www	World wide web

CHAPTER I

INTRODUCTION

1.1. Background and Rationale

Fluoroscopy is a technique that employs X-Rays to generate real-time still images or moving images of a patient's internal body organs. It is commonly used medical technique to diagnostic and interventional procedures. The X-Rays pass through the body and an image is created on a detector, which is then transmitted to a monitor for viewing.

The real-time of fluoroscopy systems could provide anatomical information with accuracy and the performance of implant placement. The systems have been widely used for many surgical operations in operating rooms such as the spinal surgery [1]. The C-Arm radiography-fluoroscopy system with 2-dimensional (2D) display is the most widely used in intraoperative imaging during spinal surgery but this technology is limited in that it does not provide an image of the true three-dimensional (3D) anatomy of the patient and cannot be used to treat complicated cases or deformities or to perform minimally invasive surgery.

The O-Arm is an X-Ray imaging device, used for intraoperative spinal surgery. The O-Arm has been designed for surgical applications, pre-operative planning, intraoperative imaging and post-operative assessment. The principle of the system is the X-Ray source emits a cone-shaped beam directed to the area detector on the opposite site. At the same time the source and detector rotate around the patient. During the rotation a set of projections is measured and reconstructed [2]. Two imaging modes are basic fluoroscopy (2D) imaging and 3D volumetric imaging with fast 3D reconstruction displays in three orthogonal views. The main components of the O-Arm and 2D/3D images are shown in Figure 1.1.

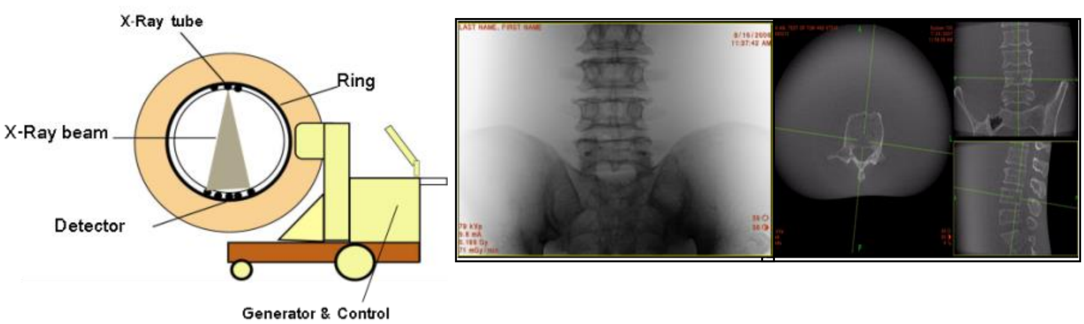

Figure 1.1: Left; The components of O-Arm. Right: The 2D and 3D images[3].

The O-Arm main components consist of;

The gantry contains an inner ring with a rotor unit that includes X-Ray tube and detector.

The Cabinet has energy storage unit containing the battery power supply and control unit to motorize mechanics assembly.

The imaging mode consists of;

The 2D mode allows real-time X-Ray viewing of the patient with high temporal resolution.

The 3D mode takes a sequence of pulsed X-Ray exposures throughout a 360 degree rotation.

The operation of lumbar spine[4]

The treatment will first start with the cause of the back pain, and finding the best way to lessen pain for the patient. In general, treatment consists of 2 main options.

Conservative treatment:

- Supportive treatment: Medication, physical therapy, and resting, except cases with specific indication of an alternative treatment.
- Spinal intervention: Aims to relieve or find the cause of pain. This procedure is suitable for the patients who have had unsuccessful results from other conservative treatments, or those whose pain is caused by a disturbed nerve.

Spine surgery:

Surgery is considered if the patients cannot control urinating, has leg weakness, cannot walk or has had unsuccessful results from other treatments. There are many procedures depending on the patient's condition and the indication of the surgery.

Table 1.1: The operation of lumbar spine; Treatment options.

Conditions	Treatment options			Machine
	Spinal intervention	Conventional surgery	Minimally invasive surgery	
Herniated disc Spinal stenosis	Epidural steroid injection	Microscopic discectomy	Endoscopic discectomy	C-Arm
Spondylolisthesis	Epidural steroid injection	Spinal fusion	Percutaneous TLIF	O-Arm
Osteoporotic compression fracture	-	-	Balloon kyphoplasty	C-Arm

Percutaneous Transforaminal Lumbar Interbody Fusion (TLIF) [4]

The Percutaneous Transforaminal Lumbar Interbody Fusion (TLIF) is a procedure that involves removing an intervertebral disc from between two vertebrae and fusing them together through key-hole incision in the back. The O-Arm will be used to create 2D and 3D images prior to the surgery. Screws will be placed through keyhole skin incisions. Patients will have much less pain after surgery, loss less blood during surgery and get back to normal life much faster.

The O-Arm is an imaging system that makes a new level in lumbar operation. In addition, the radiation dose has become an increasingly important issue in patient and operator.

1.2. Objective

To study the radiation dose delivered to patients and staffs during Percutaneous TLIF surgery in 2D and 3D modes when using O-Arm system.

1.3. Definition

- Staff radiation dose: Staff radiation dose (μSv) is all exposure incurred by work in the course of their work relates to scatter radiation.
- Absorbed dose: Absorbed dose (mGy) is a measure of the amount of energy from an ionizing radiation deposited in a medium
- Patient dose: Patient dose is the dose applied to a patient exposed to radiation taking into account the specific organs and areas of the body that are exposed.
- Patient size: Patient size is the default parameter on control panel of O-Arm selected by operator. There are 3 sizes, small, average and large as related to radiation dose.

CHAPTER II

REVIEW OF RELATED LITERATURE

2.1. Theory

2.1.1. Principle of O-Arm imaging system

The O-Arm imaging system is a mobile X-Ray system with a generally O-shaped gantry ring. The system designed for 2D fluoroscopic use and 3D imaging and is intended to be used where a surgeon benefits from information of anatomic structures and objects with high X-Ray attenuation such as bony anatomy and metallic objects. The O-Arm imaging system could produce a 3D volume image like a CT scanner, but it uses Cone-Beam CT (CBCT) imaging, rather than fan-beam imaging (figure 2.1). In a typical CT scanner, as the patient moves through the gantry, the scanner takes a number of cross-sectional radiographic "slice" images, using fan-beam technology[5]. These images are then stacked up and computer-aided tomography algorithms are used to create a three dimensional volume image of the patent. In contrast, with the O-Arm System, there is no movement of the patient relative to the gantry. The O-Arm system does not take cross-sectional slice images, but rather captures the entire anatomical area in each image taken as the X-Ray tube and detector rotate 360 degrees around the patient. A different type of computer algorithm is then used to recreate the 3D volume image. The O-Arm imaging system is compatible with certain Image guided surgery systems.

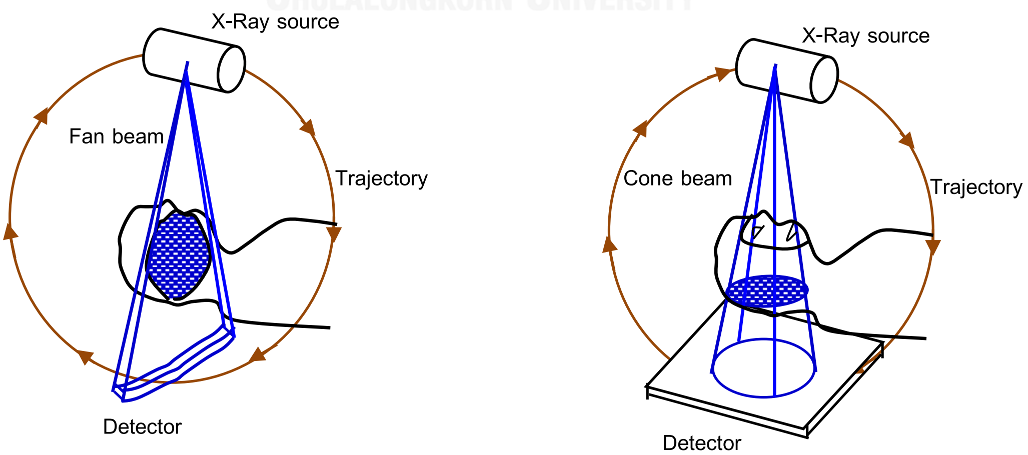

Figure 2.1: Diagrams show geometry of (Left) ; Fan beam imaging.(Right): Cone beam imaging.

The O-Arm and C-Arm: the O-Arm in 3D mode takes multiple 2D images of the full patient volume as the tube and detector move 360 degrees around the patient, and then reconstructs the 3D anatomy from them. During this process, the O-Arm gantry remains stable in one position. Although some C-arms are capable of taking 3D Images by rotation of the gantry during imaging, due to mechanical and sterility constraints, there are no currently C-Arm able to capture fluoroscopic images throughout a full 360 degrees.

2.1.2. Image acquisition

The O-Arm imaging system has two main acquisition modes that produce 2D fluoroscopy mode and 3D mode:

2.1.2.1. 2D Fluoroscopy Mode

This acquisition mode uses pulsed X-Rays at up to 30 frames per second to produce high resolution, real time images. The default is standard fluoroscopy and another mode is high level fluoroscopy (HLF).

The 2D mode is normally used to find the angles of the patient's anatomy that the surgeon wants to refer to during the operation. The 2D mode is used as a standard fluoroscopy tool, and to take scout images prior to surgery.

Taking AP Images: the X-Ray source and detector should be reversed 180° and the position of the source to be on the bottom in order to reduce the scatter effect.

Taking Lateral Images: all operating personnel should be on the opposite side from the X-Ray source to minimize the effect of X-Ray absorption resulting from the scatter effect.

2.1.2.2. 3D Cone Beam CT Mode

In 3D acquisition modes, a series of pulsed X-Ray exposures is created throughout a complete 360-degree rotation of the gantry rotor. The system stores these exposures and uses a reconstruction algorithm to develop a 3-dimensional image of the patient's anatomy from them. The image is displayed on the monitor screen as a high resolution display in the axial, coronal, and sagittal planes [6].

Standard 3D mode: the parameters are automatically set to 100 mA, 10 millisecond pulse width per exposure at 120 kVp. These parameters could be modified according to patient's anatomy.

High Definition 3D (HD3D) mode: the parameter provides improved image quality over that of regular 3D. The rotor spins at 15 degrees per second, while acquiring images at a rate of 30 frames per second, thus capturing approximately 740 projections.

Enhanced 3D Mode: this mode is designed to optimize image resolution for cranial anatomy. It has the same spin velocity and frame rate as HD3D mode, but different kVp and mA settings and a different reconstruction algorithm. It is designed for cranial images only.

The patient size for 2D mode and 3D Cone beam CT mode is the default parameter on control panel of O-Arm selected by operator. There are 3 sizes, small, average and large as related to radiation dose.

2.1.3. Quantities for dosimetry

2.1.3.1. CT air kerma index

The CT air kerma index, $C_{a,100}$, measured free in air for a single rotation of a CT scanner is the quotient of the integral of the air kerma along a line parallel to the axis of rotation of the scanner over a detector active length of 100 mm and the nominal slice thickness, T [6]. The integration range is positioned symmetrically about the volume scanned, thus:

$$C_{a,100} = \frac{1}{T}\int_{-50}^{+50} K(z)dz$$

where K(z) is air kerma (Gy) along the rotation axis and T is nominal thickness (mm).

For a multislice scanner with N simultaneously acquired slices of nominal thickness T (nominal width of irradiated beam NT), $C_{a,100}$ becomes:

$$C_{a,100} = \frac{1}{NT}\int_{-50}^{+50} K(z)dz$$

where N is number of slices.

The CT air kerma index is also measured inside PMMA head and body phantoms and is defined similarly to $C_{a,100.}$ The notation use is $C_{PMMA,100}$.

The weighted CT air kerma index, C_W, combines values of $C_{PMMA,100}$ measured at the centre and periphery of a standard CT dosimetry phantom. It is given by:

$$C_w = \frac{1}{3}(C_{PMMA,100,C} + 2C_{PMMA,100,P})$$

The quantity $C_{PMMA,100,c}$ is measured at the centre of the standard CT dosimetry phantom and $C_{PMMA,100,p}$ is the average of values measured at four positions around the periphery of the same phantom.

A further quantity, C_{VOL}, takes into account the helical pitch or axial scan spacing thus:

$$C_{VOL} = C_W \frac{NT}{l} = \frac{C_W}{p}$$

Where l is the distance moved by the patient couch per helical rotation and p is pitch defines as total distance of couch moving divided by number of slices and nominal thickness.

In CBCT; X-Ray source emitted a cone shape beam directed to the detector around patient in one rotation while the patient and couch are not moving. Thus the pitch is equal to 1.

2.1.3.2. CT air kerma-length product

CT air kerma-length product or CT Dose-length product (DLP) determined for the standard CT dosimetry phantom and a complete CT examination, $P_{KL,CT}$,(mGy.cm) is calculated using the following equation:

$$P_{KL,CT} = \sum_j C_{VOL} l$$

where j represents each serial or helical scan sequence forming part of the examination and l is scan length. DLP characterizes exposure for a complete examination in relation to linear integration of the dose to the standard head or body CT dosimetry phantom on the basis of absorbed dose to air.

In CBCT; scan length is equal to height of field size.

2.1.3.3. Effective dose

Effective dose is a quantity used as indicator of overall patient dose that related to detriment arising from stochastic effects. It was defined by International Commission on Radiological Protection Publication 60 (ICRP 60) (1991). It is the sum over all the organs and tissues of the body of the product of the equivalent dose, H_T, to the organ or tissue and a tissue weighting factor, $W_{T.}$ for that organ of tissue (ICRP Publication 103) [7],[8].

Effective dose is obtained by multiplying the equivalent dose (mSv) by tissue weighting factor to allow comparison with other types of radiological examination. There is sometimes a need to assess effective dose for CT procedures.

Alternatively, broad estimates of effective dose (E) may be derived from values of DLP for an examination using appropriately normalized coefficients:

$$E = DLP \times E_{DLP}$$

where E is effective dose unit in mSv, DLP is dose length product unit in mGy.cm and E_{DLP} is the region specific normalized effective dose unit in $mSv.mGy^{-1}.cm^{-1}$, general values of E_{DLP} appropriate to different anatomical regions of the patient such as 0.015 $mSv.mGy^{-1}.cm^{-1}$ for abdomen [9] (ICRP Publication 103).

2.1.3.4. Air kerma area product

The air kerma–area product, P_{KA}, or Dose Area Product (DAP) is the integral of the air kerma over the area of the X-Ray beam in a plane perpendicular to the beam axis. Thus:

$$P_{KA} = \int_A K(x, y)\,dxdy$$

The unit of air kerma area product is $Gy.m^2$ or $Gy.cm^2$. The air kerma–area product has the useful property that it is approximately invariant with distance from the X-Ray source. The planes of measurement and calculation are not so close to the patient or phantom that there is a significant contribution from backscattered radiation.

2.2. Review of Related Literature

Seok PM et al [1] reported their study in Radiation Protection Dosimetry 2011. An anthropomorphic thorax phantom (RS-111) consists of tissue-equivalent materials for bone and soft tissues in the human torso. The radiation doses in orthopedic surgical procedure using C-arm and O-Arm systems in their 2D fluoroscopy modes was simulated and the radiation doses to susceptible organs to which operators can be exposed were investigated. The results showed that the O-Arm delivered higher doses, 2.3 times of the C-Arm, to the sensitive organs of the operator in all configurations. Thus, the operators need to pay more attention to managing radiation exposure, especially when using the O-Arm system.

Schafer S et al [10] assessed image quality, radiation dose when using Mobile C-Arm cone-beam CT (CBCT) integration with interventional guidance for spine surgery. A flat-panel detector based mobile isocentric C-arm for cone-beam CT (CBCT) has been developed to allow intraoperative 3D imaging with sub-millimeter spatial resolution and soft-tissue visibility. Image quality and radiation dose were evaluated in spinal surgery, commonly relying on lower-performance image intensifier based mobile C-arms. Scan protocols were developed for task specific imaging at minimum dose and integration of the imaging system with a surgical guidance system demonstrated in pre-clinical studies of minimally invasive spine surgery. Image quality was assessed using tissue-equivalent inserts in chest and abdomen phantoms to evaluate bone and soft tissue contrast-to-noise ratio as a function of dose, and task-specific protocols were defined. Task-specific protocols provide an important basis for minimizing radiation dose. Image quality for surgical guidance was identified in bone protocols at techniques 1.81 mGy for thoracic spine and 3.16 mGy for lumbar spine. In soft tissue protocols was selected at techniques 4.26 mGy and 10.6 mGy for thoracic spine and lumbar spine, respectively.

Lange J. et al [11] estimated the radiation dose imparted to patients during typical thoracolumbar spinal surgical scenarios. Thermoluminescence dosimeters were placed in a linear array on a foam-plastic thoracolumbar spine model centered above the radiation source for O-Arm presets of lumbar scans for small or large patients. Air dosimeter measurements were converted to skin surface measurements, using published conversion factors. Dose-length product was calculated from these values. Effective dose was estimated using published effective dose to dose-length product conversion factors. Calculated dosages for many full-length procedures using the small-patient setting fell within the range of published effective doses of abdominal CT scans at 1–31 mSv. Calculated dosages for many full-length procedures using the large-patient setting fell within the range of published effective doses of abdominal CT scans when the number of scans did not exceed 3.

Hart R et al [12] compared a computer-assisted navigation with a conventional procedure in order to assess if it is possible to reduce radiation exposure while preserving the accuracy of screw placement. The first "conventional" group consisted of 30 patients, with an average of 1.9 segments of the lumbar spine stabilized. Screws were inserted transpedicularly under image intensifier guidance. In the second "navigated" group of 30 patients, stabilization of 1.8 segments was performed on average. A CT-free fluoroscopic 2D spinal navigation system (Vector Vision, Brain LAB, Germany) was used intra-operatively. It combines image-guided surgery with C-arm fluoroscopy. Navigation allows us to keep the same accuracy of pedicle screw placement while reducing radiation exposure. The mean duration of data registration was 6.0 minutes (range, 3 to 11 minutes). In multiple-level vertebral instrumentations this reduction is more pronounced.

From literature review, the phantoms were used in most studies to estimate radiation dose to staff and patient from O-Arm system. This study is the first in Thailand to assess the staff and patient radiation dose from O-Arm system in 2D and 3D modes.

CHAPTER III
RESEARCH METHODOLOGY

3.1. Research Design

This study is an observational descriptive design.

3.2. Research Design Model

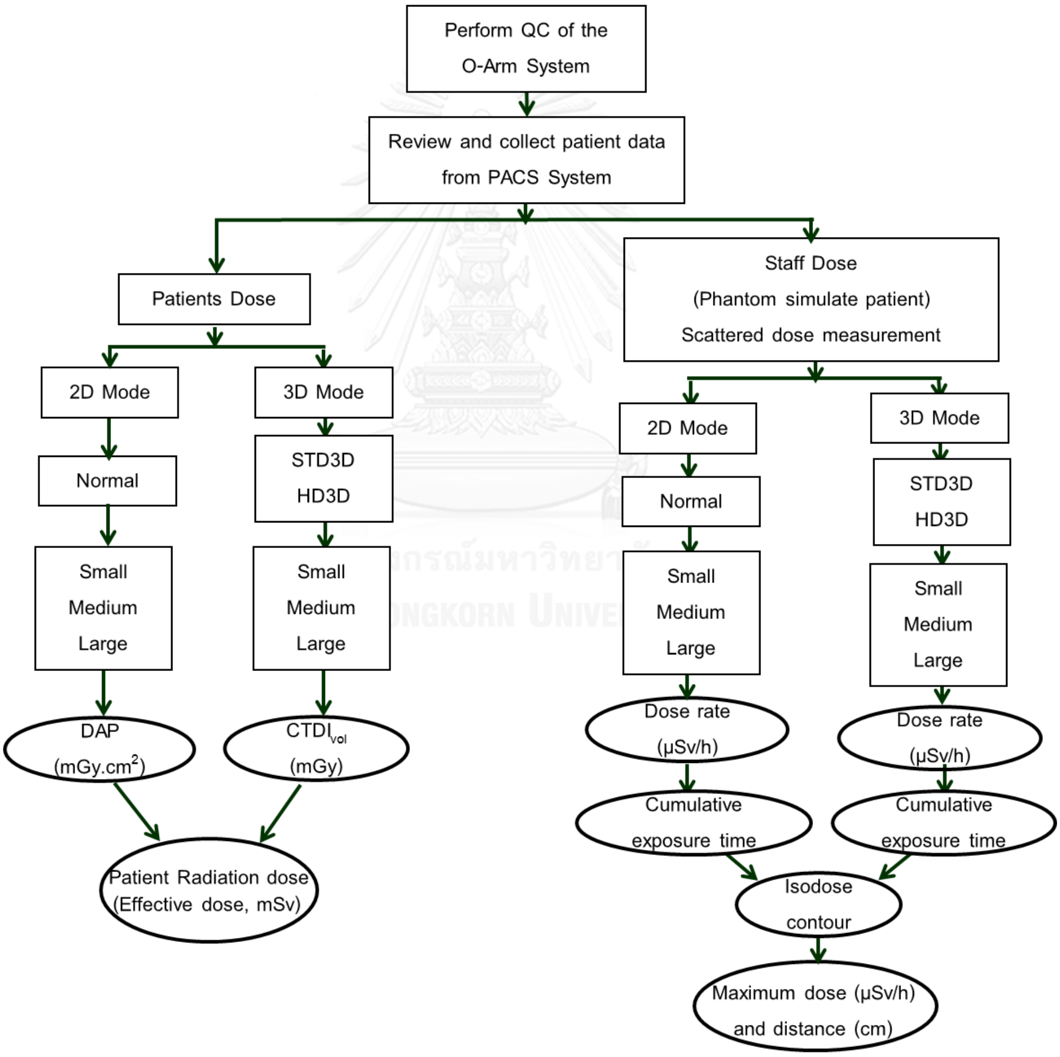

Figure 3.1: Research design model.

3.3. Conceptual Framework

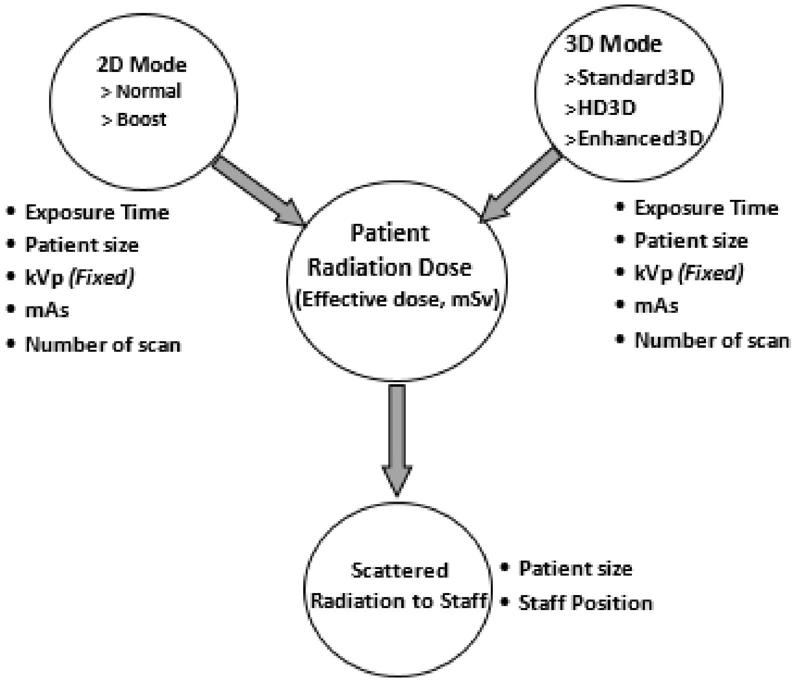

Figure 3. 2: Conceptual Framework.

3.4. Keywords

- Cone beam computed tomography
- CBCT
- 2D mode
- 3D mode
- Dosimetry

3.5. Research Questions

- What are the ranges of radiation dose delivered to patients during Percutaneous TLIF surgery in 2D and 3D modes?

- What are the maximum scattered doses to staff and what is the distance from radiation source during Percutaneous TLIF surgery in 2D and 3D modes?

3.6. Materials

3.6.1. Medtronic O-Arm System and Dose Area Product (DAP)

Figure 3.3: Left; The Image Acquisition System and Mobile View Station. Right; DAP meter (VacuTec, Dresden, Germany) placed on the inner surface of the O-Arm ring and attached to the X-Ray tube.

Manufacturer:	Medtronic
Model:	O-Arm
X-Ray Tube:	Varian A132 rotating anode
Tube voltage:	40 – 125 kVp
Tube current:	10-320 mA
Exposure time:	0.001 – 10 sec
Focal spots:	0.6mm and 1.2mm
2D:	Pulsed fluoroscopy at 30 frames per second.
Standard 3D:	~13 seconds to acquire data over 360^0
High Definition 3D:	< 25 seconds to acquire data over 360°
3D Imaging Volume:	Cylindrical Volume; 15cm (high) x 20cm (diameter)
X-Ray Detector:	Amorphous silicon digital X-Ray detector
DAP meter:	VacuTec, Dresden, Germany

3.6.2. QC materials

3.6.2.1. 2D mode

3.6.2.1.1. Unfors RaySafe Xi R/F Platinum dosimeter (S/N:174303)

The R/F dosimeter measures maximum air kerma rate (AKR) and exposure rate. (Figure 3.4)

Figure 3.4: Unfors RaySafe Xi R/F Platinum dosimeter[13]

3.6.2.1.2. Copper sheets; 0.5 mm. and 1 mm. thickness for 2D calibration to drive kVp during Fluoroscopy calibration. (Figure 3.5)

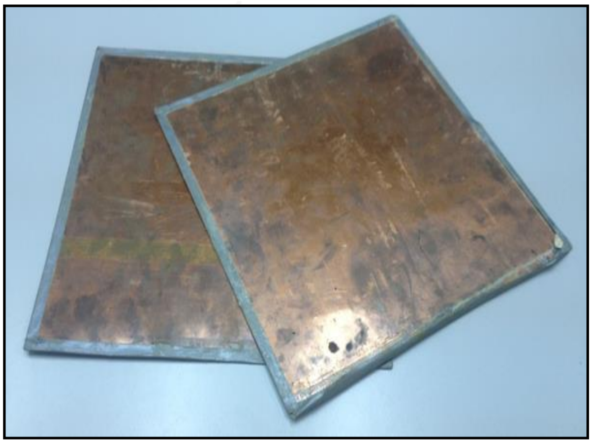

Figure 3.5: Cu sheets; 0.5 mm. and 1 mm. thickness (30x30 cm)

3.6.2.2. 3D mode

3.6.2.2.1. Pencil ionization chamber, 10 cm. active length, Unfors (S/N:175667) as in figure 3.6

CT dose will be measured in $CTDI_{vol}$ and dose length product (DLP).

Figure 3.6: Pencil ionization chamber with readout device

3.6.2.2.2. PMMA BODY Phantom 32 cm. diameter, 15 cm thick, (S/N: 0063)

The PMMA BODY Phantom for cone beam CT Calibration. (Figure 3.7)

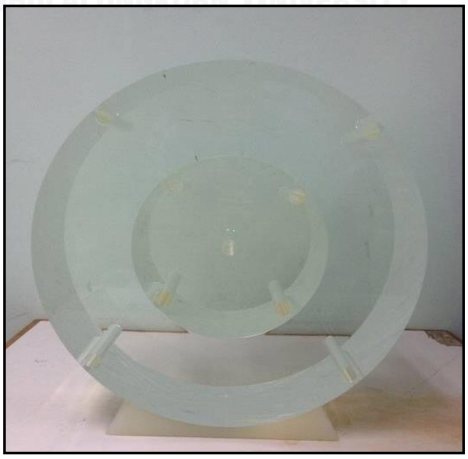

Figure 3.7: CT cylindrical phantom.

3.6.2.3. Pancake chamber, 180 cm^3 active volume, Unfors (S/N:174391) as shown in figure 3.8 for scattered radiation measurement received by staff.

Figure 3.8: Pancake dosimeter with readout device for scattered dose received by staff.

3.7. Methods

3.7.1. Perform the QC of the O-Arm system on radiation output measurement in 2D and 3D modes according to manufacturer's guideline to verify the radiation dose from manual.

- 2D mode, measure maximum air kerma rate (AKR) unit in mGy/min and exposure rate unit in R/min.
- 3D mode, measure CT dose index (CTDI, mGy) and dose length product (DLP, mGy cm).

3.7.2. Collect patient radiation dose from monitor/PACS (Picture Archiving and Communication System)

- 2D Fluoroscopy, record DAP in $mGy.cm^2$ and absorbed dose in mGy.
- 3D collect $CTDI_{vol}$, record in mGy and DLP unit in mGy.cm

The effective dose, mSv calculated by the following equation;

2D; $$E = DAP \times E_{DAP} \quad (1)$$

where E is effective dose in mSv.

E_{DAP} is conversion co-efficient, 0.00021 mSv.mGy^{-1}.cm^{-2} [7]

3D; $$E = DLP \times E_{DLP} \quad (2)$$

where E is effective dose in mSv.

E_{DLP} is conversion co-efficient, 0.015 mSv.mGy^{-1}.cm^{-1} for abdomen. [7]

3.7.3. Evaluate staff radiation dose.

- Record parameter preset and exposure technical data from PACS.
- Place the CT PMMA cylindrical phantom on Jackson couch to simulate the patient.
- Set the maximum exposure parameters as possible.
- Use pancake chamber to measure scattered dose in μSv/h around the
- O-Arm gantry and CT PMMA phantom in every 50–200 cm. along a horizontal plane at iso-center height. (Figure 3.9)
- Draw the iso-dose contour around the X-Ray source in the operating room.
- Compare scattered dose with other references and the International Commission on Radiological Protection guidelines.

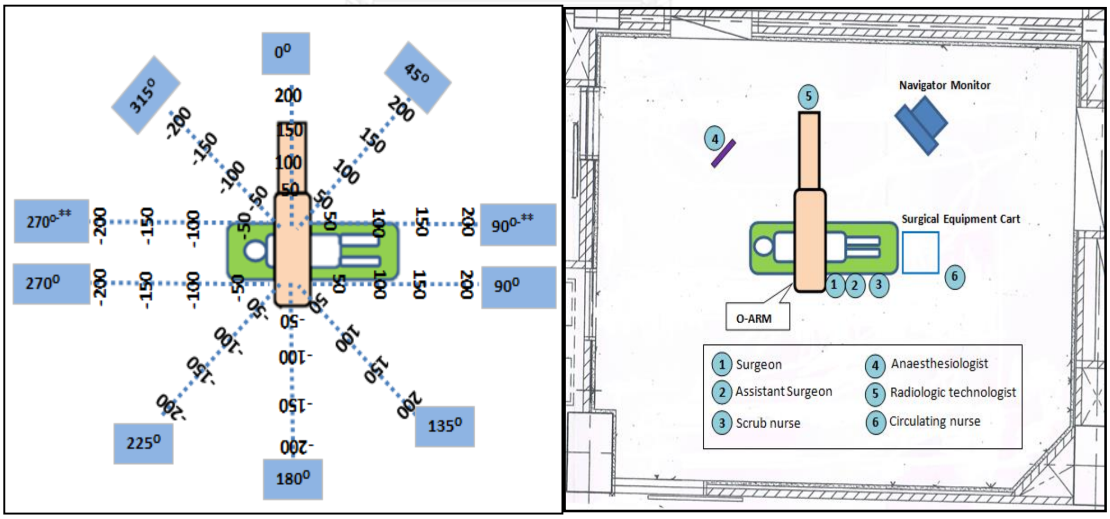

Figure 3.9: Left; Staff dose measurement around O-Arm gantry. Right: Staff position 1-6 during procedures.

3.8. Sample size determination

1. Target population:

All patients who were requested Percutaneous TLIF surgery using O-Arm system in 2D and 3D modes at Radiology department, Bumrungrad International Hospital from October 2013 to July 2014.

2. Sample size estimation:

(1) The data is consecutive collection.

(2) The sample population is independent, retrospective data

The sample size will be determined using formula as following:

$n = (Z_{\alpha/2})^2 \sigma^2 / d^2$ by; $Z_{\alpha/2} = 1.96$

$= (1.96)^2 (5.10)^2 / (1^2)$ σ = Standard deviation (5.10)

$= 99.92$ σ^2 = Variance of data (26.01)

= 100 cases d = Acceptable error (1 mGy)

The data will be collected retrospectively after the ethical consideration approved.

3.9. Statistical Analysis

Arithmetic Mean, Maximum, Minimum and range ($CTDI_{vol}$, DAP, DLP, E).

3.10. Outcome measurement

Radiation dose

- $CTDI_{vol}$: mGy
- DAP : $mGy.cm^2$
- DLP : mGy.cm
- Effective dose rate: μSv/h

3.11. Expected Benefit

The result from this study will show the average and range of patient and staff doses received from the TLIF procedures. The appropriate exposure parameters should be used to avoid the radiation injury the patient and staff would receive. The appropriate staff position is obtained for the radiation safety during the procedures.

3.12. Ethical consideration

Although the patient data will be collected from the monitor/PACS system of the hospital, not direct contacts to patients, the staff dose is determined by using CT phantom, the research proposal had been submitted and approved by Ethic Committee of Faculty of Medicine, Chulalongkorn University. The process at Bumrungrad International Hospital is in progress.

CHAPTER IV
RESULTS

4.1. Quality control of the O-Arm system

The results of quality control of the O-Arm systems were within acceptable range of IAEA and Manufacturer [14]. They are shown in Appendix B.

Radiation output measurement in 2D: the maximum Air Kerma Rate (AKR) in mGy/min and R/min at normal and boost modes were acceptable when compared with the criteria from IAEA as shown in table 4.1, [15], [16]

Table 4.1: Maximum Air Kerma Rate

Protocol	kVp	mA	Maximum Air Kerma Rate			
			(mGy/min)		(R/min)	
			Measurement	Criteria	Measurement	Criteria
Normal Fluoro	118	12.0	86.3	< 88	9.8	< 10
High Level Fluoro	122	22.0	168.0	< 180	19.1	< 20

Radiation output measurement in 3D: the $CTDI_{vol}$ and DLP, the percent difference of $CTDI_{vol}$ and DLP between measurement/displayed, measurement/manufacturer values and displayed and manufacturer values ranged from 0.01 to 13.45. They are shown in Appendix B.

4.2. Patient Radiation Dose

The patient data was recorded from monitor/PACS. 100 patients consist of 24 nations, Thai 39 cases, Myanmar 13 cases, USA 6 cases, Australia 6 cases, Oman 6 cases and the rest 30 cases are several nations. There are 45 female and 55 male underwent intraoperative O-Arm system in Percutaneous TLIF surgery in 2D and 3D modes. The average age was 59 years, range 25 to 91 years.

The results on patient radiation dose in 2D mode were shown in Table 4.2 of average DAP value and the effective dose with ranges. In order to calculate the effective dose, DAP value was multiplied by conversion co-efficient, 0.00021 $mSv.mGy^{-1}.cm^{-2}$.

Table 4.2: Patient data and radiation dose in 2D Mode

Data	2D Mode				
	Age (Yrs.)	Body weight (kg)	Exposure time (Sec)	DAP ($mGy.cm^2$)	Effective Dose (mSv)
Average	59	75.57	15.09	6,213.26	1.30
Min	25	45.70	5.63	1,595.80	0.34
Max	91	139.10	42.57	22,033.11	4.63

Table 4.3 shows the average $CTDI_{vol}$, DLP and effective dose with ranges in 3D mode. The effective dose was calculated by DLP multiplied by conversion co-efficient, 0.015 $mSv.mGy^{-1}.cm^{-1}$.

Table 4.3: Patient data and radiation dose in 3D Mode

Data	3D Mode					
	Age (Yrs.)	Body weight (kg)	Exposure time (Sec)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	Effective Dose (mSv)
Average	59	75.57	10.05	43.27	692.06	10.38
Min	25	45.70	7.80	18.00	287.79	4.32
Max	91	139.10	15.64	112.60	1,801.00	27.02

Among 100 cases, case number 99 and 9 obtained minimal and maximal effective doses as shown in Table 4.4 of 2D and Table 4.5 of 3D modes. The minimum and maximum total effective dose from 2D and 3D mode were 4.66 and 28.74 mSv, respectively.

Table 4.4: The minimum effective dose of case number 99 and maximum in case number 9 in 2D mode.

Case No.	2D Mode					
	Age (Yrs.)	Body weight (kg)	Exposure time (Sec)	Exposure (mGy)	DAP ($mGycm^2$)	Effective Dose (mSv)
99	50	48.80	6.43	7.10	1,595.8	0.34
9	61	96.90	19.90	36.25	8,205.4	1.72

Table 4.5: The minimum effective dose of case number 99 and maximum in case number 9 in 3D mode.

Case No.	3D Mode						
	Age (Yrs.)	No. of Scan	mAs	Exposure time (Sec)	$CTDI_{vol}$ (mGy)	DLP (mGycm)	Effective Dose (mSv)
99	50	2	250.24	7.82	18.02	288.16	4.32
9	61	4	1,564.00	15.64	112.60	1,801.00	27.02

The number of scans and effective dose (mSv) with range were shown in Table 4.6.

Table 4.6: Number of scans and average with range of effective dose (mSv) in 3D mode.

No. of scan	Effective dose (mSv)
2 Scans	8.14 (4.32-13.51)
3 Scans	11.72 (6.01-20.26)
4 Scans	16.97 (11.51-27.02)

The radiation dose imparted during various types of level fusion is given in Table 4.7

Table 4.7: Number of scans and radiation dose imparted associated with TLIF procedures.

Level Fusion	No. Scans	STD3D		STD3D-L		HD3D-L	
		Number of cases	Effective dose (mSv)	Number of cases	Effective dose (mSv)	Number of cases	Effective dose (mSv)
1	2	32	6.56 (4.32-10.13)	17	10.80 (10.79-10.81)	1	13.51
	3	15	8.94 (6.48-10.13)	5	16.21	1	20.26
	4	-	-	1	21.61	1	27.02
2	2	2	6.75 (6.75-6.75)	1	10.81	-	-
	3	7	8.50 (6.01-10.13))	8	16.40 (16.20-17.56)	-	-
	4	6	14.26 (11.51-19.59)	2	17.76 (17.27-18.25)	-	-
3	2	-	-	-	-	-	-
	3	1	11.16		-	-	-
	4	-	-		-	-	-

The patient size (medium and large) and effective dose with range in 2D and 3D mode were shown in Table 4.8.

Table 4.8: Number of medium and large in range of effective dose (mSv) in 2D and 3D modes.

Patient Size	2D Mode Number, (Effective dose; mSv)	3D Mode Number, (Effective dose; mSv)	
	Normal Flu	STD3D	HD3D
Medium	Number of patients 95 1.27 (0.34-4.63)	Number of patients 63, 8.15 (4.32-19.59)	N/A
Large	Number of patients 5 1.92 (1.47-3.15)	Number of patients 34 13.65 (10.79-21.61)	Number of patients 3 20.26 (13.51-27.02)

4.3. Staff Radiation Dose

The scattered dose rate in μSv/h around the O-Arm gantry at 50 – 200 cm. were shown in Table 4.9, 4.10 and 4.11.

Table 4.9: The scattered dose in Antero-posterior view (AP) view in 2D mode.

2D--AP	Scattered dose in μSv/hr									
Distance(cm)	0°	45°	90°-**	90°	135°	180°	225°	270°-**	270°	315°
50	N/A	41,250	38,420	38,060	42,700	N/A	30,450	23,950	33,180	28,340
100	158	12,430	11,320	11,880	11,420	4,056	8,928	9,686	9,712	9,763
150	109	5,308	5,152	4,938	5,607	2,436	4,502	4,094	2,323	4,393
200	77	2,930	1,736	2,627	3,081	1,528	2,631	2,036	644	2,314

Table 4.10: The scattered dose rate in Lateral view (LAT) view in 2D mode.

2D--LAT	Scattered dose in μSv/hr									
Distance(cm)	0°	45°	90°-**	90°	135°	180°	225°	270°-**	270°	315°
50	N/A	36,130	28,590	31,310	62,430	N/A	43,110	24,900	29,670	21,140
100	245	11,270	11,900	12,040	17,400	760	13,820	9,740	10,280	7,759
150	130	5,192	5,601	5,630	8,433	516	6,383	3,978	4,026	3,929
200	85	2,965	2,817	2,922	4,174	322	3,390	2,070	1,782	2,192

Table 4.11: The scattered dose rate in 3D mode.

3D	Scattered dose in μSv/hr									
Distance(cm)	0°	45°	90°-**	90°	135°	180°	225°	270°-**	270°	315°
50	N/A	65,570	49,150	53,110	69,820	N/A	65,180	53,500	58,610	66,100
100	11,300	21,440	15,620	15,310	19,480	14,270	19,660	15,320	13,530	21,120
150	130	9,320	7,120	6,640	9,510	4,990	8,120	6,560	5,560	9,560
200	110	5,180	3,480	3,590	3,650	2,710	4,730	3,260	3,050	5,360

The total staff radiation dose rate (mSv/h) in AP, Lateral and 3D in air at staff position 1-6 during procedures were shown in Table 4.12 and Figure 4.1.

Table 4.12: Staff radiation dose rate (AP, Lateral and 3D) at position 1-6

Staff position	Total Exposure Rate (mSv/h)
1	174.95
2	39.23
3	61.65
4	30.69
5	0.28
6	8.04

During exposure, surgeon (position 1), assistant surgeon (position 2), scrub nurse (position 3), anesthesiologist (position 4) and circulating nurse (position 5) are outside operating room. Only radiological technologist (position 5) is available in the operating room as shown in figure 4.1.

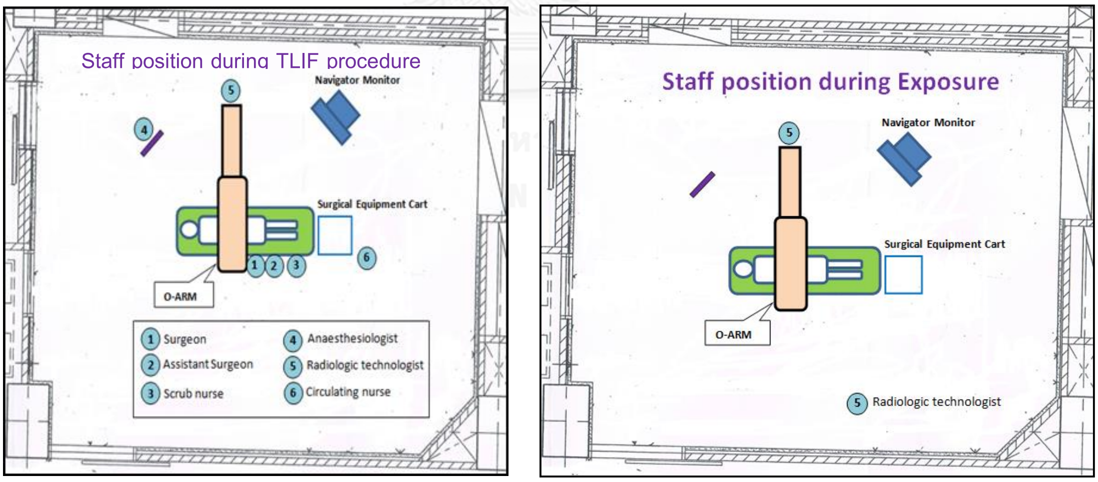

Figure 4.1: Staff position during exposure.

The radiologic technologist operate the system in operating room with total maximum exposure time was 67 sec per case. One radiologic technologist operates 2 day/week. (2cases/day). The maximum scattered dose received by radiologic technologist was 81 μSv/month at 200 cm. from patient. The dose is much lesser than the monthly limit of 4,000 μSv.

The exposure rate (mSv/h) measured around the X-Ray source in the operating room was shown in figure 4.2. and isodose contour from exposure rate (technique: 120 kVp, 100 mA, 4 Sec) shown in figure 4.3.

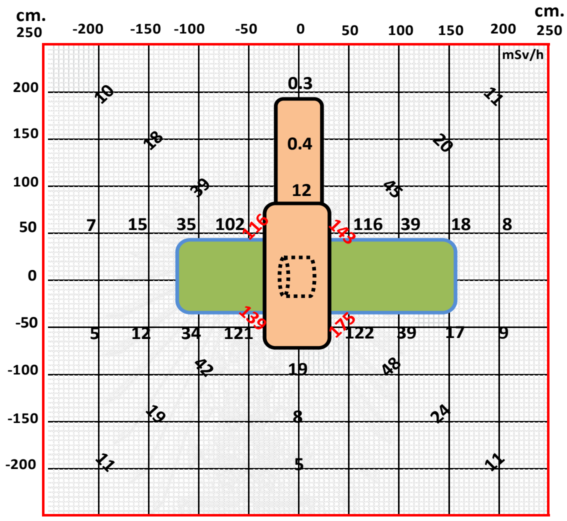

Figure 4.2: Left; Exposure rate (mSv/h) measured from scatter radiation.

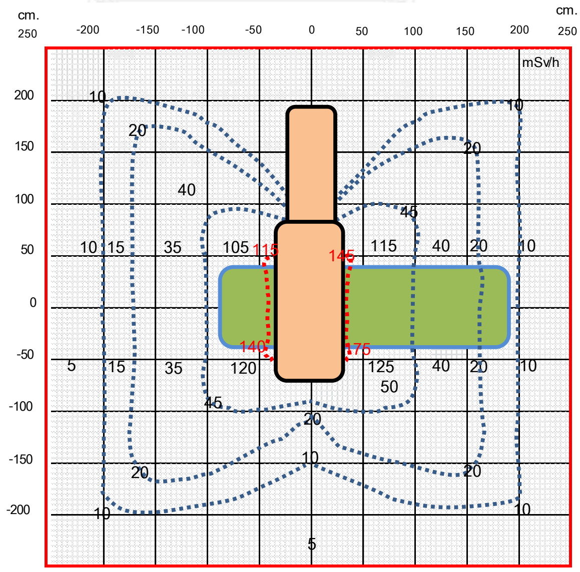

Figure 4.3: Isodose contour from exposure rate (mSv/h) measurement.

(Technique: 120 kVp, 100 mA, 4 Sec).

CHAPTER V
DISCUSSION AND CONCLUSION

5.1. Discussion

The increasing number of intraoperative Percutaneous TLIF surgery has increased awareness of the potential risk to patient and staff. Concerns have been raised about the amount of radiation dose incurred during the procedure.

The radiation dose to patient and staff had been studied from the intraoperative O-Arm system in Percutaneous TLIF surgery in 2D and 3D mode in the same clinical circumstances. The study was based on validated techniques in radiation dosage quantification, and the data before collect was proved by performing QC of the O-Arm system [17].

The factors affecting patient dose are exposure time, exposure technique, number of scans and patient weight as shown in figure 5.1, 5.2, 5.3, 5.4, 5.5 and 5.6.

Figure 5.1 and 5.2, the exposure time in 2D mode (5.6-42.6 s) was longer than in 3D mode (7.8-15.6 s) because at the beginning of the procedure, 2D fluoroscopy was performed for anatomical details of patient. Figure 5.1 shows the dependent of the effective dose on exposure time especially from 5-20 sec. The rest data of the effective dose increased rapidly from 20-42.6 sec. Figure 5.2 shows three vertical lines of constant exposure times at 7.8 sec, 50 mA, acquisition STD3D-Medium, at 11.7 sec, 80 mA, acquisition STD3D-Large and 15.6 sec, 100 mA, HD3D-Large. The increasing effective dose also results from number of scans.

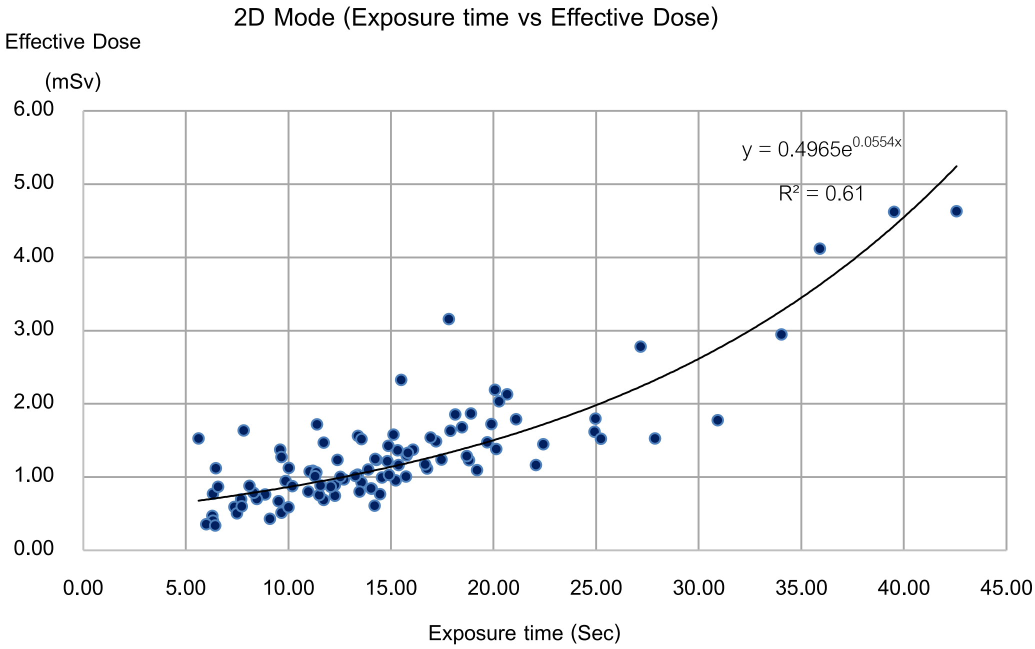

Figure 5.1: 2D Mode; The effect of exposure time (Sec) on Effective Dose (mSv).

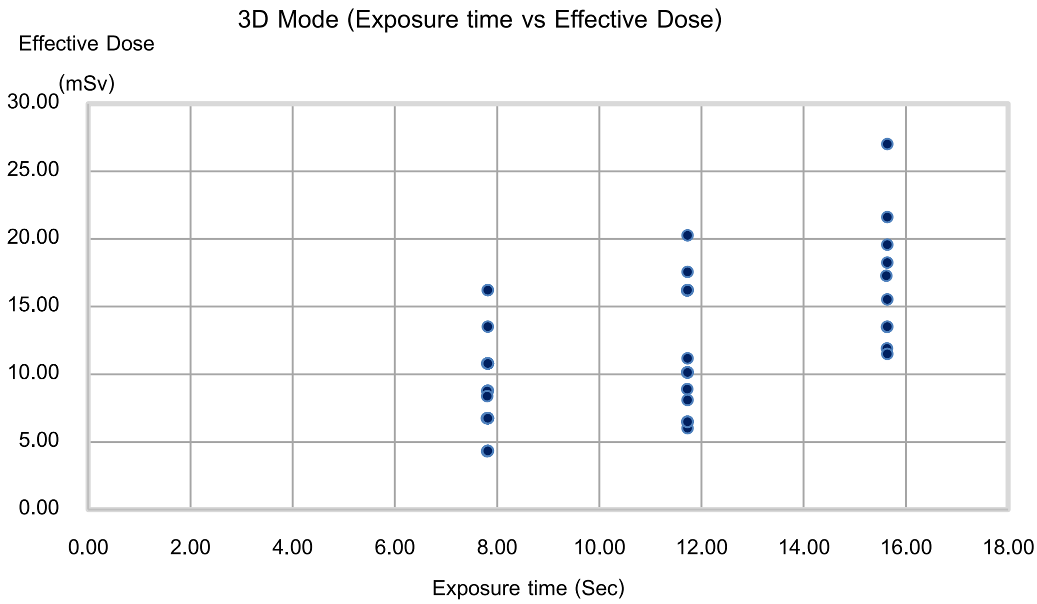

Figure 5.2: 3D Mode; The effect of exposure time (Sec) on Effective dose (mSv).

Figure 5.3 and 5.4 show the linear correlation between DAP (mGycm^2), DLP (mGycm) and the effective dose (mSv) in 100 cases. The effective doses were calculated using conversion coefficients. The effective dose increases with DAP and DLP values. Therefore, the total DAP and DLP per procedure gives a good indication of the radiation dose to the patient with O-Arm. Consequently, the effective dose that characterizes a patient's stochastic risk can be estimated using easily measurable DAP or DLP values. We also believe that the use of an online measurement device such as a DAP meter that provides real-time information regarding the radiation dose is preferable than other complicate method, such as TLD measurement [18].

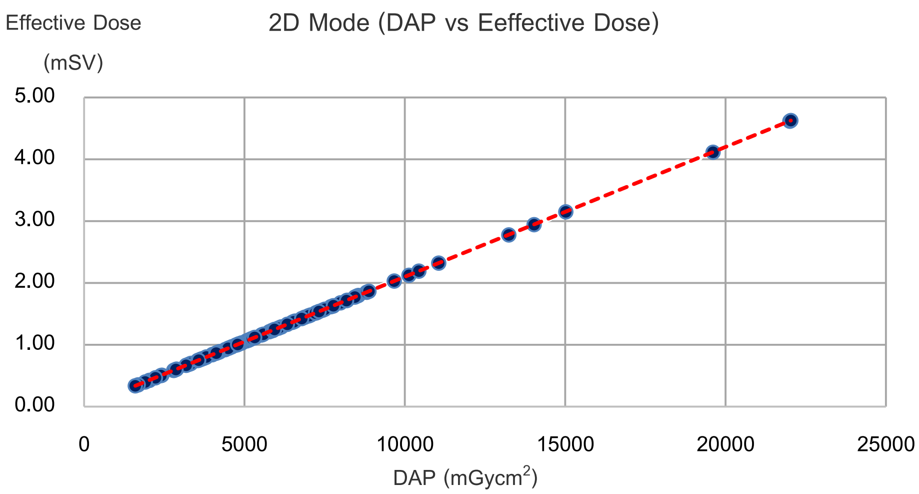

Figure 5.3: 2D Mode; The effect of DAP (mGycm^2) on Effective dose (mSv).

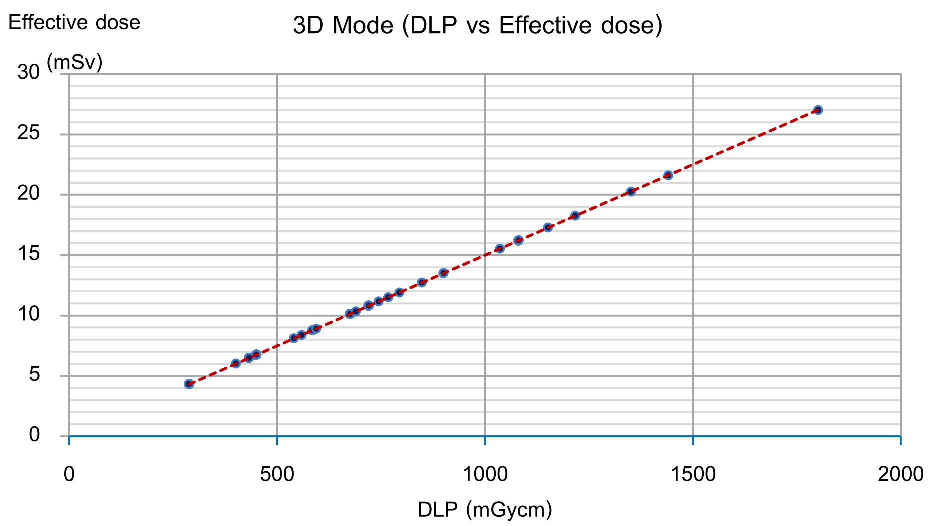

Figure 5.4: 3D Mode; The effect of DLP (mGycm) on Effective dose (mSv).

In this study, the ranges of number of scans are 2 to 4. The most is 2 scan, the rest are 3 and 4 (Table 4.7). The radiation dose imparted associated with TLIF procedures was highest in 4, 3 and 2 scans.

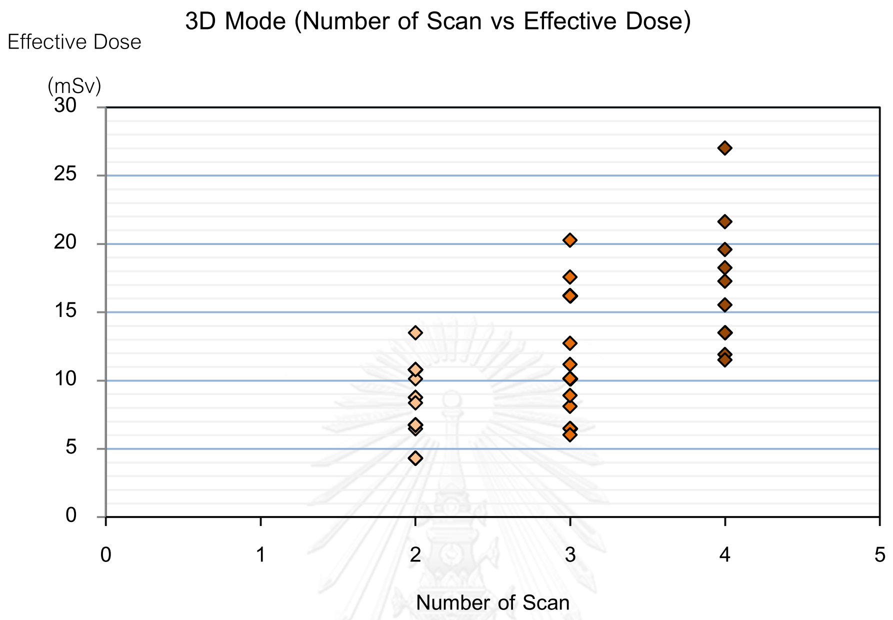

Figure 5.5: 3D Mode; Number of scans and the effective dose (mSv).

Figure 5.6 shows the graph plot between patient weight and effective dose. The average and range of patient weight were 75.57(45.70-139.10) kg and the average and range of effective dose were 11.69(4.66-28.74) mSv. The highest and lowest of patient weight were Australian and Thai. The highest patient weight received 20 mSv not highest effective dose, therefore the patient weight and effective dose were not directly dependent. The highest effective dose at 28.7 mSv was received by 96.9 kg.

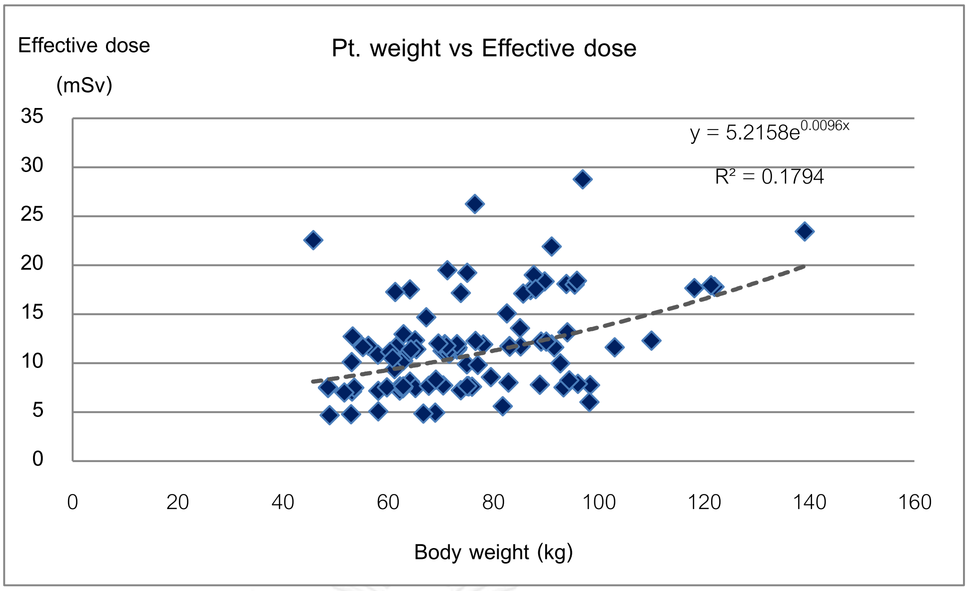

Figure 5.6: The patient body weight (kg) and the effective dose (mSv).

Table 4.4 and Table 4.5 show parameters from case number 99, lowest body weight of 48.80 kg, the exposure time in 2D was 0.34 sec., the absorbed dose was 7.1 mGy, DAP was 1,595.8 mGy.cm^2. In 3D, the exposure time was 7.80 sec., $CTDI_{vol}$ was 18.00 mGy, DLP was 287.79 mGy.cm and total effective dose was lowest at 4.66 mSv.

Case number 9, the body weight was 96.9 kg. In 2D mode, the exposure time was 19.90 sec., the absorbed dose was 36.25 mGy, DAP was 8,205.41 mGy.cm^2. In 3D mode, the exposure time was 15.64 sec., $CTDI_{vol}$ was 112.6 mGy and DLP was 1801 mGy.cm. The total effective dose was highest at 28.74 mSv.

The factors affecting staff dose are staff position, patient size, number of scans, the exposure time and the available protective barriers. Table 4.11 and Figure 3.9: Right show staff position 1 at 50 cm. received highest dose rate of 174.95 mSv/h and staff position 5 at 200 cm. radiologic technologist with protective barrier stayed behind the equipment control received lowest dose rate of 0.28 mSv/h at the largest distance 200 cm. from radiation source. The radiologic technologist is the only staff available during exposure.

International Commission on Radiological Protection Publication number 60 recommended 20 mSv per year of effective dose equivalent for occupational exposure, averaged during a 5-year period. The recommended annual effective dose for public is 1 mSv averaged for a 5-year period.

There is only patient dose constraint for each procedure. However, the ALARA concept and the optimization of patient dose and image quality should be in consideration for the safety of the patient[19].

From this study, the maximum effective dose imparted to a large patient using the O-Arm in HD3D mode was 28.74 mSv from 4 total intraoperative scans.

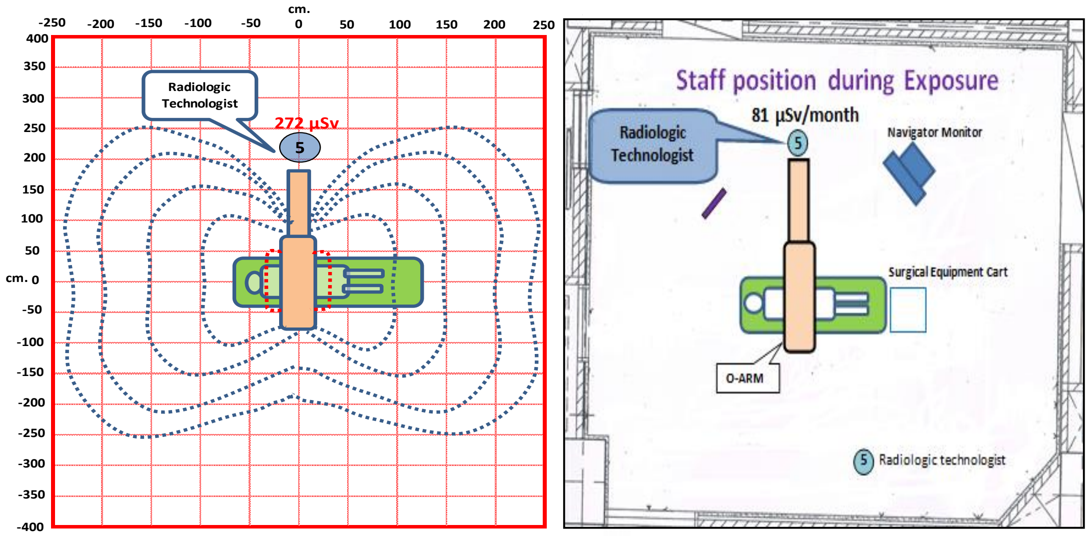

Figure 5.7: Left; Isodose contour around the patient. Right; Calculated scatter dose per month at radiologic technologist position.

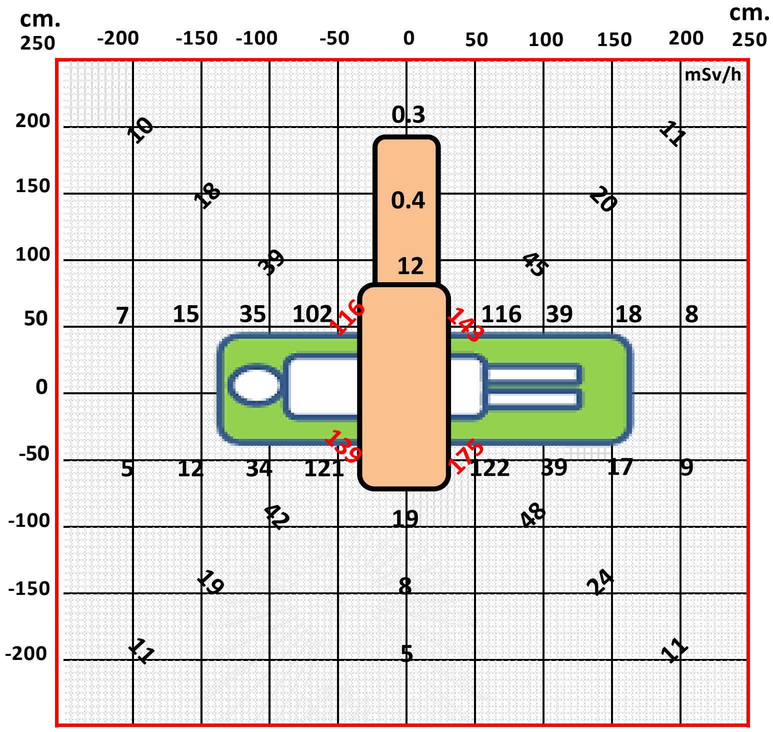

Figure 5.8: Scatter exposure rate (mSv/h) around patient.

For 2D mode (normal fluoroscopy), the number of medium and large patient sizes was 94 and 6. In STD3D, the number of medium and large patient sizes was 67 and 30. In HD3D mode, the number of large patient size was 3. In 2D and 3D mode, the medium size patient received less radiation dose than large size patient.

Lange J. et al [9] calculated dosages for many full-length procedures using the small and large patients. The effective doses of abdominal CT scans ranged 3.24–30.81 mSv when the maximum number of scans was 3.

In this study, the range of effective dose is 4.66-28.74 mSv when the number of scan is 2 in 52 patients, 3 in 38 patients and 4 in 10 patients. In order to reduce the patient dose, the number of scans should be reduced to 2-3 resulting in patient dose reduction of more than 45 percent.

5.2. Conclusion

The result from this study shows the patient and staff received doses from the TLIF procedures. The average patient effective dose from 2D and 3D modes during Percutaneous TLIF surgery were 11.69 (4.66-28.74) mSv. The maximum scattered dose rate received by radiologic technologist was 81 μSv/month at 200 cm from patient. The dose is much less when compare to the monthly dose limit of 4000 μSv. The staff is quite safe in working for this procedure. Radiation dose to staff and patient can be reduced by decreasing exposure time in 2D and reduce number of scans, not exceed 3, in 3D. The appropriate exposure parameters should be used to avoid the radiation risk the patient would receive.

When the intraoperative Percutaneous TLIF surgery under O-Arm system requires multiple intraoperative scans, the effective radiation doses imparted to patients is important for assessing the risks and benefits in using this technology. Proper exposure parameters for individual patient should be arranged to optimize the patient effective dose.

5.3. Recommendations

For the patient weight more than 100 kg, the preset parameters and default patient size should be carefully chosen to optimize patient dose in Percutaneous Transforaminal Lumbar Interbody Fusion surgery using O-Arm system. The procedure should be started with 2D high level in large mode and the number of scan should not exceed 3 for any size of patients in 3D mode.

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APPENDICES

Appendix A: Case Record Form

1. Data Collection Form of Patient Radiation Dose

Table A.1: Case Record Form: Patient Radiation Dose

Case Record Form

Patient Radiation Dose

Study date:	Operator number:	Study number:

Patient Information

Gender: ______ (M/F) Age: ______ yrs.

Height: ______ m. Weight: ______ kg.

Technical Parameter

2D Mode (Fluoro)

Mode of operation: __________ (Normal/Boost) Size of patient _____ (S/A/L)

kVp: __________ mA: __________ Time: __________ sec

Exposure: __________ mGy DAP: __________ $mGycm^2$

3D Mode (STD3D / HD3D Protocol)

Mode of operation: __________ (STD3D/HD3D) Size of patient: _____ (S/A/L)

kVp: __________ mA: __________ mAs: __________

$CTDI_{vol}$: __________ mGy DLP: __________ mGy.cm

Number of scan: __________

Table A.2: Data Entry Form: Patient Radiation Dose

No	SEX	age	Exam	No. of level	No. scan	Height	Height	BMI		2D Mode - Fluoroscopy dose (Normal Flu)				E(mSv)	3D Mode		kVp				mAs				Total	mA				Exposure time (Sec)				Total	CTDIvol (mGy)							DLP(mGycm)					
																	No. Scan				No. Scan					No. Scan				No. Scan						No. Scan				Total	AVG.	No. Scan				Total	AVG.
						(m)	(m^2)	($kg./m^2$)	Pt. weight (kg)	Mode of operation	Exposure time (Sec)	Exposure (mGy)	DAP ($mGycm^2$)		STD3D/ HD3D	Pt. weight (kg)	3D#1	3D#2	3D#3	3D#4	3D#1	3D#2	3D#3	3D#4	mAs	3D#1 (mA)	3D#2 (mA)	3D#3 (mA)	3D#4 (mA)	3D#1 (sec)	3D#2 (sec)	3D#3 (sec)	3D#4 (sec)	(sec)	Total no. of scan	3D#1	3D#2	3D#3	3D#4	CTDIvol (mGy)	CTDIvol (mGy)	3D#1	3D#2	3D#3	3D#4	DLP (mGycm)	DLP (mGycm)

2. Data Collection Form of Staff Radiation Dose

Table A.3: Case Record Form: The scattered dose in 2D Mode (Antero-posterior view, AP and Lateral) and 3D Mode.

2D / 3D Distance(cm) from radiation source	Scattered dose rate in μSv/h									
	0°	45°	90°-**	90°	135°	180°	225°	270°-**	270°	315°
50										
100										
150										
200										

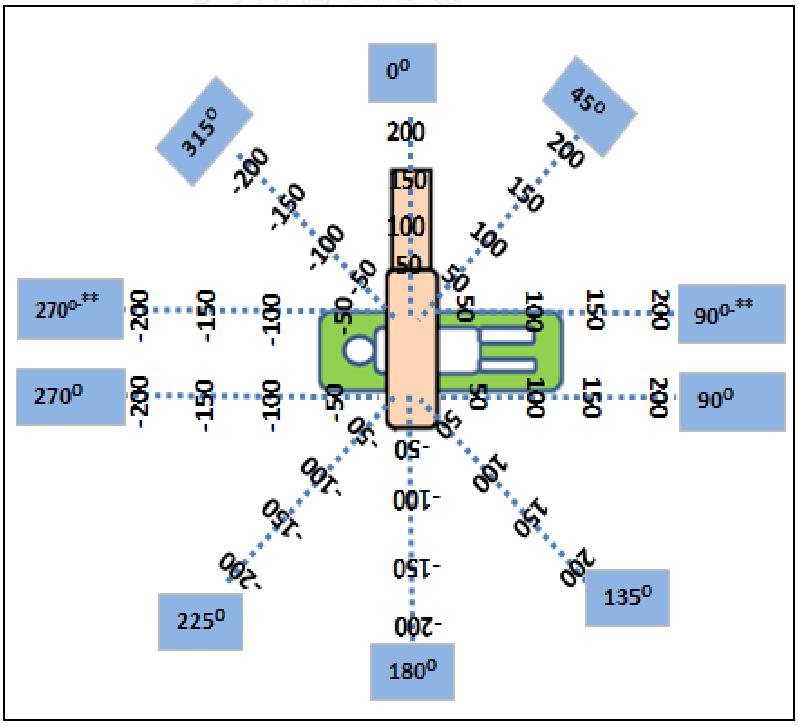

Figure A.1: The position of scatter dose measurement around O-Arm gantry.

Appendix B: Quality control of the Medtronic O-Arm System

The quality control of Medtronic O-Arm system was performed following manufacturer and IAEA procedures.

1. Maximum Air Kerma Rate and Exposure Rates in 2D Mode (Normal and Boost fluoro modes).

Purpose: To perform the maximum Air Kerma Rate and Exposure Rate .

Method:
- Set the X-Ray tube positioned on top of the gantry.
- Set Cu filter that covers the range from 50-125 kVp.
- Set focal spot to the solid state detector distance at 83 cm (estimate the patient entrance dose).
- Set operation mode at Normal, Boost fluoro, 30 frames/sec and Automatic Exposure Rate Control (AERC).

Tolerance: The maximum Air Kerma Rate and Exposure Rate should not exceed 88 mGy/min or 10 R/min (normal fluoro) and 180 mGy/min or 20 R/min (boost fluoro) at the specified measurement point.

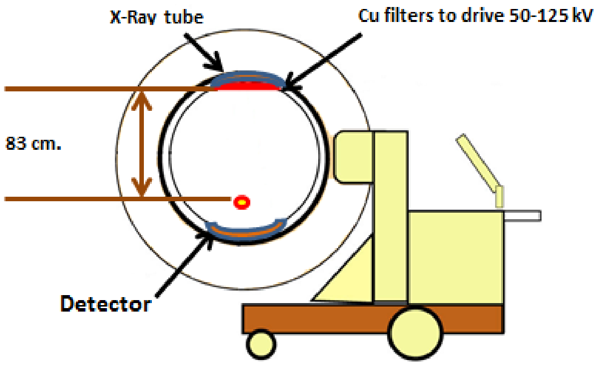

Figure B.1: Set up QC material to measure the maximum Air Kerma rate and exposure rate.

Results:

Table B.1: Maximum Air Kerma Rate and Exposure rate in Normal Fluoro and Boost Fluoro with the criteria from IAEA.

Protocol	kVp	mA	Maximum Air Kerma Rate (mGy/min) and Exposure Rate (R/min)			
			Measurement	Criteria	Measurement	Criteria
Normal Fluoro	118	12.0	86.3	<88	9.8	<10
Boost Fluoro	122	22.0	168.0	<180	19.1	<20

Comment: The maximum Air Kerma Rate and Exposure rate of measurement in normal fluoro and boost fluoro are 86.3 mGy/min, 9.8 R/min, 168 mGy/min and 19.1 R/min, respectively.

PASS

2. Patient entry Air Kerma Rate (AKR) and Exposure Rate (Fluoro)

Skin entry dose for patient positioned at iso-center, reference point is typically 15 cm. from iso-center towards the tube. 2D Mode (Normal and Boost fluoro modes).

Purpose: To verify the Air Kerma Rate at iso-center.

Method: - Set the X-Ray tube position on top of the gantry.

- Set Cu filters to drive the kVp range from 50-125,
- Set the Solid state detector at reference point.
- Set 30 frames/second
- Operate mode: Automatic Exposure Rate Control (AERC).

Tolerance: Allowable error: ± 35%.

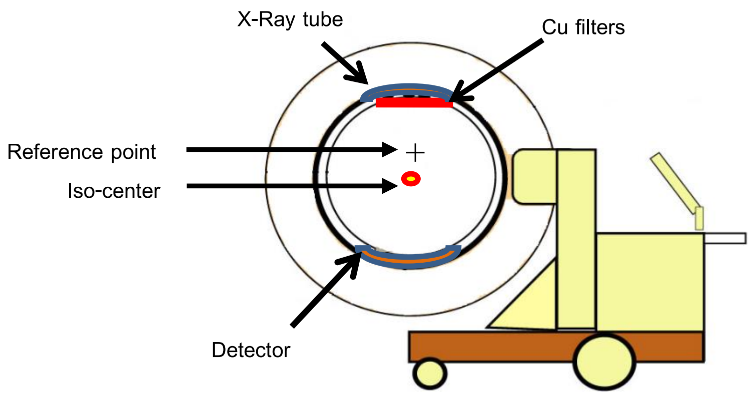

Figure B.2: Set up QC material to perform the maximum Air Kerma rate and exposure rate at iso-center.

Results:

Table B.2: The displayed and measured AKR values in normal fluoro at iso-center. Conversion factor: 1 R/min = 8.8 mGy/min = 0.147 mGy/sec.

Field size	Phantom	Patient size	kVp	mA	Displayed AK	Measured values			% Difference displayed AK vs Measurement
					AK rate (mGy/min)	AK rate µGy/sec	Converted to mGy/min	Exposure (R/min)	
Protocol: Normal Fluoro									
30 x 40 cm	1.0 mmCu	small	56	9.0	28.4	2.25	37.50	4.3	32.1
	1.5 mmCu	Average	64	9.6	35.2	2.75	45.83	5.2	30.2
	3.0 mmCu		78	10.2	63.1	3.75	62.50	7.1	-1.0
	4.5 mmCu		90	10.8	93.1	5.45	90.83	10.3	-2.4
	5.5 mmCu		99	11.2	117	7.20	120.00	13.6	2.6
	7.0 mmCu		109	11.6	149	9.50	158.33	18.0	6.3
	9.0 mmCu	Max	118	12.0	193	11.50	191.67	21.8	-0.7

Table B.3: The displayed and measured AKR values in boost fluoro at iso-center. Conversion factor: 1 R/min = 8.8 mGy/min = 0.147 mGy/sec.

Field size	Phantom	Patient size	kVp	mA	Displayed AK	Measured values			% Difference Displayed AK vs Measurement
					AK rate (mGy/min)	AK rate (µGy/se)c	Converted to mGy/min	Exposure (R/min)	
Protocol: Boost Fluoro									
30 x 40 cm	1.0 mmCu	small	60	18.2	59.8	3.6	60.2	6.8	0.6
	2.0 mmCu	Average	72	19.4	105.0	6.9	114.2	13.0	-8.7
	3.0 mmCu		81	20.0	151.0	9.1	152.3	17.3	-0.9
	4.5 mmCu		92	21.0	209.0	12.7	210.8	24.0	-0.9
	5.5 mmCu		101	21.0	262.0	15.2	253.8	28.8	3.1
	7.0 mmCu		110	22.0	325.0	19.1	318.7	36.2	1.9
	9.0 mmCu	Max	122	23.0	418.0	24.5	408.3	46.4	2.3

Comment: The maximum percent difference between displayed and measured AKR of normal fluoro were 32.1 and boost fluoro is -8.7 so the values within the regulatory limit of ± 35%.

PASS

3. The radiation output measurement in 3D modes.

Purpose: To verify the $CTDI_{vol}$ and DLP with manufacturer's values.

Method:
- Set the X-Ray tube position on top of the gantry.
- Put the PMMA Body phantom diameter 32 cm. at iso-center.
- Put the Pencil Ionization chamber with an active length of 100 mm at center and 3'Clock holes in body phantom.
- Use Standard 3D protocols and HD3D protocols scans for all abdomen, chest and head protocols.
- Entrance = CTDI at 3 O'clock, $CTDI_w$ = (1/3*Center) + (2/3*Entrance) and 1 R = 8.7 mGy

Tolerance: Compare measured $CTDI_{vol}$ and DLP values with manufacturer's values.

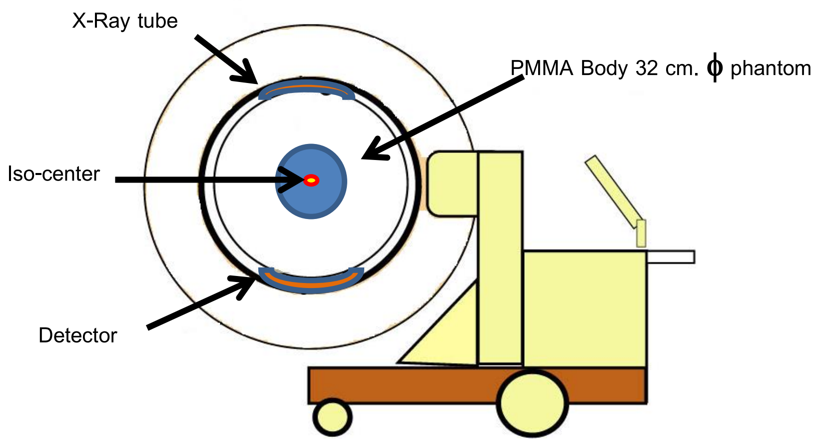

Figure B.3: Set up QC material to measure the $CTDI_{vol}$ and DLP

Results:

Table B.4: Standard 3D protocols determine $CTDI_{100}$ and $CTDI_w$ ($CTDI_{vol}$) in abdomen, chest and head protocol.

Anatomy	Pt size	Technique		Measurement Exposure (R)		$CTDI_{100}$ (mGy)		$CTDI_w(CTDI_{vol})$(mGy)			% Difference of $CTDI_{vol}$		
		kVp	mAs	Center	Entrance	Center	Entrance	Measured	Displayed	Manuf.	Measured vs Displayed	Measured vs Manuf.	Displayed vs Manuf.
Abdomen	Small	120	128	0.56	1.43	4.83	12.44	9.90	10.12	10.01	-2.14	-1.06	1.10
	Medium	120	200	1.06	2.15	9.22	18.71	15.54	15.45	15.66	0.61	-0.74	-1.34
	Large	120	320	1.72	3.43	14.96	29.84	24.88	24.76	24.89	0.49	-0.03	-0.52
	Extralarge	120	400	2.10	4.18	18.27	36.37	30.33	29.98	30.37	1.18	-0.12	-1.28
Chest	Small	120	128	0.67	1.41	5.83	12.27	10.12	10.20	9.99	-0.77	1.31	2.10
	Medium	120	160	0.80	1.90	6.96	16.53	13.34	13.55	12.48	-1.55	6.89	8.57
	Large	120	200	1.12	2.25	9.74	19.58	16.30	15.98	15.38	1.99	5.97	3.90
	Extralarge	120	320	1.95	3.85	16.97	33.50	27.99	26.98	24.68	3.72	13.39	9.32
Head	Small	120	100	1.53	1.86	13.31	16.18	15.23	15.98	14.54	-4.72	4.71	9.90
	Medium	120	100	1.65	1.90	14.36	16.53	15.81	15.98	14.54	-1.10	8.70	9.90
	Large	120	128	1.94	2.12	16.88	18.44	17.92	17.86	18.8	0.35	-4.67	-5.00
	Extralarge	120	160	2.34	2.45	20.36	21.32	21.00	22.15	23.29	-5.21	-9.85	-4.89

Table B.5: HD3D protocols determine $CTDI_{100}$ and $CTDI_w$ ($CTDI_{vol}$) in abdomen, chest and head protocol.

Anatomy	Pt size	Technique		Measurement Exposure (R)		$CTDI_{100}$ (mGy)		$CTDI_w(CTDI_{vol})$(mGy)			% Difference of $CTDI_{vol}$		
		kVp	mAs	Center	Entrance	Center	Entrance	Measured	Displayed	Manuf.	Measured vs Displayed	Measured vs Manuf.	Displayed vs Manuf.
Abdomen	Small	120	187	0.94	1.78	8.13	15.44	13.01	13.12	13.26	-0.87	-1.91	-1.06
	Medium	120	300	1.46	3.06	12.70	26.62	21.98	21.70	21.96	1.30	0.10	-1.18
	Large	120	480	2.34	4.53	20.36	39.41	33.06	33.56	34.23	-1.49	-3.42	-1.96
Chest	Small	120	187	0.90	1.98	7.83	17.23	14.09	13.95	13.43	-1.02	4.94	3.87
	Medium	120	240	1.65	2.45	14.36	21.32	19.00	18.54	17.32	-2.40	9.67	7.04
	Large	120	300	1.88	3.00	16.31	26.06	22.81	22.21	22.11	-2.62	3.16	0.45
Head	Small	120	150	2.01	2.76	17.49	24.01	21.84	21.78	22.15	-0.26	-1.41	-1.67
	Medium	120	150	2.20	2.86	19.14	24.88	22.97	22.56	22.15	-1.78	3.69	1.85
	Large	120	187	2.78	3.23	24.14	28.10	26.78	26.78	27.87	-0.01	-3.91	-3.91

Table B.6: The measured, displayed $CTDI_{vol}$ and manufacturer values for Standard 3D protocols.

Anatomy	Pt size	$CTDI_w(CTDI_{vol})$(mGy)			% Difference of $CTDI_{vol}$		
		Measured	Displayed	Manuf.	Measured vs Displayed	Measured vs Manuf.	Displayed vs Manuf.
Abdomen	Small	9.90	10.12	10.01	-2.14	-1.06	1.10
	Medium	15.54	15.45	15.66	0.61	-0.74	-1.34
	Large	24.88	24.76	24.89	0.49	-0.03	-0.52
	Extralarge	30.33	29.98	30.37	1.18	-0.12	-1.28
Chest	Small	10.12	10.20	9.99	-0.77	1.31	2.10
	Medium	13.34	13.55	12.48	-1.55	6.89	8.57
	Large	16.30	15.98	15.38	1.99	5.97	3.90
	Extralarge	27.99	26.98	24.68	3.72	13.39	9.32
Head	Small	15.23	15.98	14.54	-4.72	4.71	9.90
	Medium	15.81	15.98	14.54	-1.10	8.70	9.90
	Large	17.92	17.86	18.8	0.35	-4.67	-5.00
	Extralarge	21.00	22.15	23.29	-5.21	-9.85	-4.89

Table B.7: The measured and displayed $CTDI_{vol}$ and manufacturer values of HD3D protocols.

Anatomy	Pt size	$CTDI_w(CTDI_{vol})$(mGy)			% Difference of $CTDI_{vol}$		
		Measured	Displayed	Manuf.	Measured vs Displayed	Measured vs Manuf.	Displayed vs Manuf.
Abdomen	Small	13.01	13.12	13.26	-0.87	-1.91	-1.06
	Medium	21.98	21.70	21.96	1.30	0.10	-1.18
	Large	33.06	33.56	34.23	-1.49	-3.42	-1.96
Chest	Small	14.09	13.95	13.43	-1.02	4.94	3.87
	Medium	19.00	18.54	17.32	-2.40	9.67	7.04
	Large	22.81	22.21	22.11	-2.62	3.16	0.45
Head	Small	21.84	21.78	22.15	-0.26	-1.41	-1.67
	Medium	22.97	22.56	22.15	-1.78	3.69	1.85
	Large	26.78	26.78	27.87	-0.01	-3.91	-3.91

Table B.8: DLP (mGy.cm) and the percent difference of DLP for Standard 3D protocols.

Anatomy	Pt size	DLP (mGy.cm)			%Diff of DLP		
		Calculated	Displayed	Manuf.	Calculated vs Displayed	Calculated vs Manuf.	Displayed vs Manuf.
Abdomen	Small	148.55	151.80	150.11	-2.14	-1.04	1.13
	Medium	233.16	231.75	234.95	0.61	-0.76	-1.36
	Large	373.23	371.40	373.35	0.49	-0.03	-0.52
	Extralarge	455.01	449.70	455.49	1.18	-0.11	-1.27
Chest	Small	151.82	153.00	149.89	-0.77	1.28	2.07
	Medium	200.10	203.25	187.13	-1.55	6.93	8.61
	Large	244.47	239.70	230.77	1.99	5.94	3.87
	Extralarge	419.78	404.70	370.22	3.72	13.39	9.31
Head	Small	228.38	239.70	218.12	-4.72	4.70	9.89
	Medium	237.08	239.70	218.12	-1.10	8.69	9.89
	Large	268.83	267.90	282.07	0.35	-4.69	-5.02
	Extralarge	314.94	332.25	349.37	-5.21	-9.85	-4.90

Table B.9: The DLP (mGy.cm) and percent difference for HD3D protocols.

Anatomy	Pt size	DLP (mGy.cm)			%Diff of DLP		
		Calculated	Displayed	Manuf.	Calculated vs Displayed	Calculated vs Manuf.	Displayed vs Manuf.
Abdomen	Small	195.10	196.80	198.84	-0.87	-1.88	-1.03
	Medium	329.73	325.50	329.45	1.30	0.08	-1.20
	Large	495.90	503.40	513.41	-1.49	-3.41	-1.95
Chest	Small	211.41	209.25	201.45	1.03	4.94	3.87
	Medium	284.93	278.10	259.75	2.45	9.69	7.06
	Large	342.13	333.15	331.63	2.69	3.17	0.46
Head	Small	327.56	326.70	332.18	0.26	-1.39	-1.65
	Medium	344.52	338.40	332.18	1.81	3.71	1.87
	Large	401.72	401.70	418.10	0.01	-3.92	-3.92

Table B.10: The Effective dose, mSv for abdomen chest and head protocols.

Anatomy	Pt size	Technique		DLP (mGy.cm)		Effective dose (mSv)		%Diff of Effective dose (mSv)	k factor
		kVp	mAs	Calculated	Manuf.	Calculated	Manuf.		
Abdomen	Small	120	128	148.55	150.11	2.23	2.25	-0.97	0.015
	Medium	120	200	233.16	234.95	3.50	3.52	-0.64	
	Large	120	320	373.23	373.35	5.60	5.60	-0.03	
	Extralarge	120	400	455.01	455.49	6.83	6.83	-0.07	
Chest	Small	120	128	151.82	149.89	2.58	2.55	1.21	0.017
	Medium	120	160	200.10	187.13	3.40	3.18	6.97	
	Large	120	200	244.47	230.77	4.16	3.92	6.02	
	Extralarge	120	320	419.78	370.22	7.14	6.29	13.45	
Head	Small	120	100	228.38	218.12	0.53	0.50	5.05	0.0023
	Medium	120	100	237.08	218.12	0.55	0.50	9.05	
	Large	120	128	268.83	282.07	0.62	0.65	-4.88	
	Extralarge	120	160	314.94	349.37	0.72	0.80	-9.45	

Table B.11: The Effective dose, mSv for: HD3D protocols.

Anatomy	Pt size	Technique		DLP (mGy.cm)		Effective dose (mSv)		%Diff of Effective dose (mSv)	k factor
		kVp	mAs	Calculated	Manuf.	Calculated	Manuf.		
Abdomen	Small	120	187	195.10	198.84	2.93	2.98	-1.80	0.015
	Medium	120	300	329.73	329.45	4.95	4.94	0.12	
	Large	120	480	495.90	513.41	7.44	7.70	-3.40	
Chest	Small	120	187	211.41	201.45	3.59	3.42	5.09	0.017
	Medium	120	240	284.93	259.75	4.84	4.42	9.59	
	Large	120	300	342.13	331.63	5.82	5.64	3.12	
Head	Small	120	150	327.56	332.18	0.75	0.76	-0.87	0.0023
	Medium	120	150	344.52	332.18	0.79	0.76	4.26	
	Large	120	187	401.72	418.10	0.92	0.96	-3.75	

Comment: The percent differences were 0.01 – 13.45 from the Standard 3D and HD3D Protocols.

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