Estimation of the eye lens doses in a catheterization laboratory from available image parameters

Mokete Phutheho

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Supervisor: Dr Sussan Acho

Co-supervisor: Dr William Rae and Dr André Rose

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DECLARATION

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Date: June 2020

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Abstract

Background and objective: New data on eye lens dosimetry supports the theory that the threshold of radiation-induced cataracts could be substantially lower than previously believed with some investigators arguing that cataracts could be classified as a stochastic rather than a deterministic effect. Based on these new data, the International Commission on Radiological Protection (ICRP) has reduced the occupational eye lens dose limit from 150 mSv to 20 mSv averaged over a defined period of 5 years, with no single year exceeding 50 mSv. The new reduction in the annual dose limit will have considerable implications particularly in high exposure environments such as interventional cardiology and radiology. It is therefore imperative that strategies for effective dose reduction, radiation protection, eye dose monitoring, and dosimetry be implemented in countries that have already adopted the new eye dose limit. *The main aim of this study was to develop methods that can be applied to estimate eye dose equivalent from the available imaging parameters and whole-body equivalent measured over the lead apron at the chest level. The study also aimed to establish a method to estimate eye lens dose based on the workload of interventionalists.*

Material and methods: The study included four interventional cardiologists. A total of 127 procedures were performed in a period of three months. The procedures were categorised into diagnostic (CA) and therapeutic (CA+PCI) procedures. During these procedures, two different active dosimeters were used to measure scatter dose (one attached on the canthus of the protective eyewear to measure eye lens dose (ELD) and the other at the chest level to measure whole-body dose) to the cardiologists. The dose area product (DAP), air kerma ($K_{a,r}$), fluoroscopic time, total cine images were recorded after every procedure. The efficacy of the protective eyewear used at Universitas Hospital was evaluated in a separate study.

Results: Average eye dose per CA and CA+PCI procedures were 195.1±112 and 391.8±202.9 μSv, respectively. The average dose per procedure obtained by combining all the monitored procedures was 250.9±168.3 μSv. The minimum workload necessary to exceed the annual eye lens dose limit calculated using an equation established in this study was 80 procedures. The dose reduction factor of the protective eyewear was ~2.

Applying this factor increased the minimum procedures necessary for a doctor to exceed the limit to 160 procedures per year.

Excellent correlation was found between ELD and DAP (R^2 = 0.78). Excellent correlation was also found between ELD and $K_{a,r}$ (R^2 = 0.72). A poor but significant correlation was found between ELD and chest dose (R^2 = 0.45).

Three methods based on the ratios of ELD to DAP, $K_{a,r}$ and chest dose were established. The calculation error using the methods based on DAP and $K_{a,r}$ was ±20%. The respective calculation error was ±37% using the method based on chest dose.

Conclusion: The accumulated eye dose of interventional cardiologists working at the Universitas Hospital can easily surpass the newly set annual eye lens dose limit after performing relatively low numbers of interventional procedures. The high average dose per procedure reported in this study highlights immediate need for implementation of radiation optimization strategies to mitigate the risk of radiation-induced cataracts.

This is the first study in South Africa to establish methods that can be used to estimate eye lens doses at any time. More research is needed in the South African context to further investigate eye lens dose in interventional suits. This will allow for comparison of results obtained at different institutions and improvement in accuracy of estimation methods.

Keywords: Eye lens dose; interventional cardiology; dosimetry; radiation-induced cataracts; dose area product; air kerma; radiation protection; protective eyewear; interventionalists.

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Active personal dosimeters..... **APDs**

Air kerma..... **$K_{a,r}$**

Anterior-posterior..... **AP**

As Low As Reasonably Achievable..... **ALARA**

Atrial septal defect closure..... **ASDC**

Automatic exposure control..... **AEC**

Computed Tomography..... **CT**

Coronary angiography..... **CA**

Defibrillator implantation..... **DI**

Deoxyribonucleic acid..... **DNA**

Body mass index..... **BMI**

Dose area product..... **DAP**

Dose equivalent..... **DE**

Dose equivalent rate..... **DER**

Dose reduction factor..... **DRF**

Electromagnetic radiation..... **EMR**

Eye lens dose..... **ELD**

Field of view..... **FOV**

Flat-panel detector..... **FPD**

Frame per second ..... **f/s**

Gray ..... **Gy**

Health Science Research Ethics Committee ..... **HSREC**

International Commission on Radiological Protection ..... **ICRP**

Interventional cardiologists ..... **ICs**

Kilovolt ..... **kV**

Left anterior oblique ..... **LAO**

Milli-sievert ..... **mSv**

milli-Amperes ..... **mA**

Nuclear Medicine ..... **NM**

Pacemaker insertion ..... **PI**

Percutaneous coronary intervention ..... **PCI**

Personal dose equivalent ..... **Hp**

Personal Protective Equipment ..... **PPE**

Posterior sub-capsular cataract ..... **PSC**

Radiofrequency ablation ..... **RFA**

Reactive oxygen species ..... **ROS**

Right anterior oblique ..... **RAO**

Source image distance ..... **SIDs**

The International Commission on Radiological Units and Measurements ..... **ICRU**

The retrospective evaluation of lens injuries and dose ..... **RELID**

Thermoluminescence dosimeter ..... **TLD**

Time-current-product ..... **mAs**

United States of America ..... **USA**

Chapter 1 : Eye lens dose in interventional cardiology

1.1 Introduction

Over the past few decades, the application of ionizing radiation in medical practice has been extensive and continues to rise (Convens et al., 2007). The application of ionizing radiation in medicine is mostly applied for diagnostic purposes. Computed Tomography (CT) contributes the highest overall to radiation dose to the population from medical exposure. This is followed by Nuclear Medicine (NM) and interventional fluoroscopy procedures (Bolus, 2013). In CT and NM, the high dose refers to the dose received by patients, and operators receive relatively lower exposure as they maintain safe distance from radiation sources during exposures. On the contrary, interventional personnel receive relatively elevated exposure as they are required to remain within the room during exposures. The increase has warranted a concern with regard to occupational radiation safety, particularly in interventional cardiology and radiology. One of the major concerns is the dose that is received by the personnel performing fluoroscopically guided procedures which is associated with radiation induced cataracts (Kim and Miller, 2009).

In interventional cardiology, Interventional Cardiologists (ICs) receive the highest eye lens exposure during interventional procedures because of close involvement with the patient to carry out clinical manipulations (Vano et al., 2010). However, the occupational exposures can be considered low when compared to exposure due to other causes, for example, nuclear accidents and atomic bombing, prolonged exposure to such low levels of ionizing radiation have placed ICs at potential risk of developing the distinct radiation-induced biological effects (Jacob et al., 2013).

The retrospective evaluation of lens injuries and dose (RELID) study indicates a correlation between the level of radiation exposure and the frequency of lens changes among ICs (Papp et al., 2017). Several other studies performed in different countries, although not conclusive also suggest that interventional cardiologists and radiologists, as well as nurses working in the catheterization suites, have an increased risk of developing radiation-induced lens injuries (Jacob et al., 2013; Mrena et al., 2018; Vano et al., 2013).

The lens of the eye is considered to be the most radiosensitive organ in the body (Brown, 1997; Chodick et al., 2018). For radiological protection of the eye, the International Commission on Radiological Protection (ICRP) published its recommendations on the eye lens dose limit in 2007 in Publication 103 (ICRP , 2007). It was recommended that the annual dose limit for the equivalent dose to the eye lens be set to 150 mSv in a planned occupational exposure. This limit was, however, under review by an ICRP task group at the time. Following a comprehensive review of different human epidemiologic studies that suggested a lower threshold model or no threshold at all for radiation-induced lens opacities, it was evident that cataracts caused by ionizing radiation could develop at doses that are much lower than previously believed. In 2011, the threshold of 0.5 Gy for induction of cataract was adapted, a tenfold reduction from the previous 5 Gy for fractionated and prolonged exposure. Furthermore, the eye lens dose limit was reduced to 20 mSv a year, averaged over a defined period of 5 years, with no single year exceeding 50 mSv (ICRP, 2012). This is the same as for the whole-body effective dose limit which has been in place for some time.

Due to the relatively high eye lens dose limit that was set by the ICRP before the new recommendations, eye lens dosimetry was not of great importance and was seldom performed (Carinou et al., 2015). The reduction in the annual dose limit for the eye has further raised concerns regarding radiation safety of the personnel performing fluoroscopically guided procedures. The importance of the proper usage of appropriate protective measures such as lead eyewear and lead glass shields has been emphasized to avoid exceeding the new eye lens dose limit. However, the protective equipment mentioned above is not always used and exposure at some level to the eye is unavoidable. According to Vano, (2003), lack of training and knowledge in radiation protection of interventionalists could be a possible cause of non-use of personal protective equipment. It is therefore important that radiation dose to ICs be monitored effectively.

Occupational dosimetry is imperative for auditing and tracking of exposure levels of radiation workers and raising their awareness regarding radiation levels and safety. Dosimetry in interventional cardiology can, therefore, be crucial in ensuring that ICs and other radiation workers remain within their annual dose limits for their safety as well as to mitigate their risk of developing any radiation-induced injuries (Vano, 2003).

There has been a growing attention towards eye lens dosimetry following the lowering of the occupational dose limit of the eye lens (Farah et al., 2013). Many investigators have conducted research to explore ways of estimating eye lens doses to interventionalists. Some investigators have conducted studies to investigate the relationship between eye lens doses and patient doses (Carinou et al., 2015). On the other hand, other investigators attempted to define the relationship between eye lens dose and dose recorded using dosimeters positioned at various locations on the operators' body and head, unprotected by the shielding apparel, or Personal Protective Equipment (PPE) (Farah et al., 2013; Haga et al., 2017; Martin, 2009).

Clerinx et al., (2008) proposed that the dose to the eyes of interventionalists be estimated by recording effective dose to the personnel using a dosimeter calibrated in terms of H_p (0.07) located at the collar level and applying a correction coefficient of 0.75. It should, however, be noted that accurate estimation of eye lens doses employing such a method is difficult. One of the reasons for the above statement is that the correction factor was determined using Monte Carlo simulations and this means that some of the factors that are usually varied during actual clinical procedures are not taken into consideration.

The best way to estimate the dose to the eye lens is to make use of a dosimeter that is calibrated in terms of H_p (3). The dosimeter has to be worn adjacent to the eye to accurately estimate the eye lens dose (Carinou et al., 2015). The problem presented by this method is that the dosimeter worn adjacent to the eye may provide some level of discomfort and obstruct the view of the wearer. Estimating the eye lens doses from doses recorded at other parts of the body and from the patient related dose quantities such as dose area product (DAP) and air kerma ($K_{a,r}$) seems to be the best substitute for eye lens dosimetry. However, more research is required to estimate the dose with better accuracy, and this can be achieved by conducting studies that take into consideration the effect of exposure parameters that influence the dose to the eyes of interventionalists.

1.2 The motivation for the current study

The lowering of the eye dose limit by the ICRP has raised concerns about the potential risk associated with occupational exposures. With the new and lower eye lens dose (ELD) limit, accurate eye lens dosimetry has become imperative. Studies relating the ELD to dose recorded at other parts of the body and patient related dose quantities, have been conducted elsewhere in the world, but none have been completed in South Africa. These approaches are associated with uncertainties due to many factors, which could differ from one institution to another.

Completion of this particular study has resulted in the development of methods that are useful in retrospective assessment of the eye lens dose in a cardiac catheterization laboratory from available dose quantities. Data were collected at a local hospital that reflects local practice. The methods developed in this study provides a more reliable institutional ELD assessment. The results of this study will further on raise awareness among interventionalists regarding their radiation dose levels and motivate them to improve their radiation safety practices and culture. Furthermore, this study forms a baseline for future studies in South Africa

1.3 The aim of the study

The aim of this study was to develop methods that can be used to estimate eye dose equivalent from the available imaging parameter and whole-body equivalent measured at the chest level. The study also aimed to establish a method to estimate eye lens dose based on the workload of interventionalists.

The following objectives were established to achieve the above-mentioned aims:

- To measure the scatter radiation to the left eye of the operating doctor directly using an eye dosimeter attached on the frame of the protective eyewear
- To measure scatter radiation dose over the lead apron at the chest level of the operating doctor using a whole-body dosimeter
- To record the patient related dose quantities (DAP and $K_{a,r}$) recorded and displayed at the end of a procedure by the fluoroscopic unit
- To evaluate the correlation between the eye dose and the whole-body dose

- To evaluate the correlation between the eye dose and the patient related dose quantities (DAP and $K_{a,r}$)
- To determine the dose reduction factor (DRF) of the protective eyewear through a phantom study

It is worth noting that although the chapter on the investigation of the efficacy of the protective eyewear precedes the chapter on measurements during clinical procedures, the phantom measurements were actually taken towards the end of data collection period. This was because data on the standing positions of doctors, use of PPE, X-ray machine settings were required to simulate typical interventional procedures using phantoms.

Chapter 2 : Literature review

2.1 Introduction

Radiation is the energy that is released from a physical source and can manifest as either particles or electromagnetic radiation (EMR) (UNSCEAR, 2008). Particulate radiation includes particles such as alphas, protons, negatrons, positrons, and neutrons (Bushberg et al., 2012). Electromagnetic radiation at high energies tends to behave as particles. EMR refers to the energy released in the form of photons that have cyclic wave characteristics that consist of both electric and magnetic field components.

EMR comes in various forms and the distinction between these is dependent upon the interactions that the different waves undergo with matter. This is determined by their energy that is manifest in their individual wavelength, which is related to their frequency. Depending on the photon energy, these waves can be categorized as ionizing (short wavelength and high frequency) and non-ionizing (low frequency and long wavelength) radiation (Seibert, 2004). Non-ionizing radiation refers to the types of radiation with insufficient energy to result in ionization of material through which it traverses. Radio waves, microwaves, infrared, ultraviolet, and visible light are examples. On the contrary, ionizing radiation refers to radiation with sufficient energy to ionize atoms of material through which it traverses by ejecting a bound orbital electron from an atom of which all matter is composed (Dance et al., 2014). Cosmic rays, gamma rays, and X-rays are classified as ionizing radiation (Seibert, 2004).

Radiation exists naturally and can also be man-made. The application of radiation in medicine contributes the highest to man-made radiation (X-rays). The use of ionizing radiation for medical purposes began soon after the discovery of X-rays in 1895 by Wilhelm Roentgen. Due to the limited knowledge of its biological effects, cases of radiation damage to humans due to prolonged exposure were reported soon after its discovery, particularly skin damage (Sansare et al., 2011). Cataract caused by radiation was reported a year following the discovery of X-rays (Chalupecky, 1987). Cataract was also reported in an occupationally exposed individual by Treutler (1906), 10 years later. Today, through research on exposed persons and experimental animals, there has been a

vast advancement in the knowledge of the risk associated with exposure to ionizing radiation and the biological damage it can inflict.

2.2 The effects of ionizing radiation on human tissue

Ionizing radiation has been known to produce different types of deleterious effects (Zhao et al., 2017). The biological damage induced by ionizing radiation is dependent on the type and energy of ionizing radiation absorbed by a tissue or organ. The effects of ionizing radiation on tissue are classified as stochastic or deterministic (Kamiya et al., 2015). Stochastic effects are associated with some exposure to ionizing radiation and are characterized by an absence of threshold for the effect to occur. In other words, the effects thus occur by chance, and they either occur or do not occur (such as cancer induction). The severity is not influenced by the radiation dose. The probability of the occurrence of a stochastic effect increases with dose (Kamiya et al., 2015). On the other hand, deterministic effects are characterized by a threshold dose below which no radiation-induced biological effects are clinically observable. The severity of this type of effects proportional to the dose received (ICRP , 2007).

Ionizing radiation traversing through mammalian tissue can directly result in nitrogenous base damage in the deoxyribonucleic acid (DNA), single or double-strand breaks of the cell nuclear DNA. The same effects are produced through the production of reactive oxygen species (ROS) (Nickoloff, 2017). Following DNA damage, a DNA repair process is initiated in an attempt to restore the disturbed DNA chemical integrity, thus maintaining the genomic integrity. Incorrect repair of DNA damage is the main cause of different types of cell mutations (Nickoloff, 2017). Mutated cells divide to further produce other modified cells which may result in cancer at a later stage. In many cases, following exposure to ionizing radiation, DNA repair is not possible and as a result, cells undergo cell death (Stone et al., 2003). In some tissues or organs, a larger number of cells need to be killed before any clinically observable damage can appear (ICRP, 2007).

Radiation effects may also be classified as acute or late effects based on the latency period. Acute effects (erythema, dry or moist desquamation, dermatitis, etc.) manifest during exposure, or a few weeks following the exposure, depending on the dose received (Stone

et al., 2003). On the other hand, late effects (radiation-induced cancer, cardiovascular disorders, cataract, etc.) appear months or years following the exposure (Stone et al., 2003). The eye lens is considered to be one of the most radiosensitive tissues in the body and radiation-induced cataract is of major concern among medical professionals, particularly those performing fluoroscopically guided procedures (Vano et al., 2010). It must be noted though that while changes occur at low doses and there is some concern, cataracts that form can be successfully treated. For this reason and others, cataracts have not attracted as much attention as the more concerning risk of cancer induction following ionizing radiation exposure.

2.3 Cataracts

A cataract is an opacification, or a clouding, found in the lens of the eye. Cataracts develop gradually, affecting one or both eyes. Some of the symptoms include blurred vision, poor vision at night, and increased glare from light and frequent need for change of prescription glasses. Cataracts are considered to be the major cause of visual disability and blindness across the globe (Shichi, 2004; Thylefors, 1999). The only available treatment is surgery (lens extraction and replacement), a medical procedure that consumes 12% of the Medicare budget overall, and 60% of all Medicare costs related to vision in the United States of America (USA) (Stark et al., 1989). Different forms of cataract are characterized by their anatomical position in the eye lens (ICRP, 2012). There are three predominant categories into which cataract is classified: cortical (associated with exposure to ultraviolet light), nuclear (associated with smoking and aging) and posterior subcapsular cataract (PSC) (associated with diabetes, prolonged use of corticosteroids and exposure to ionizing radiation) (Stahl et al., 2016; West, 2007).

Much attention has been given to radiation-induced cataract by medical personnel, particularly interventional radiologists and cardiologists because of the negative impact cataract may have on their career in the long run (Stahl et al., 2016). To date, PSC has been classified as a deterministic effect (Bouffler et al., 2012). However, based on the more recent literature, other investigators argue that radiation-induced cataract may form at doses far below the current threshold and could be classified as a stochastic effect

(Ciraj-Bjelac et al., 2010). This theory is supported by the results of studies that included the Chernobyl liquidators and, the Japanese A-bomb survivors following World War II (Shore et al., 2010).

Radiation-induced lens opacities first appear as small dots and vacuoles and progress to more severe opacities over time (Rehani et al., 2011). These opacities are usually evaluated using a slit-lamp examination and a modified Merriam Focht grading system (Ciraj-Bjelac et al., 2012, 2010; Vano et al., 2013, 2010). These systems look at the frequency of the posterior and anterior lens defects, vacuoles and other lens defects and the percent opacity as a function of lens anterior and posterior surface area observed under slit-lamp examination (Vano et al., 2013). An example of PSC observed via slit lamp bio-microscopy is shown in Figure 2-1.

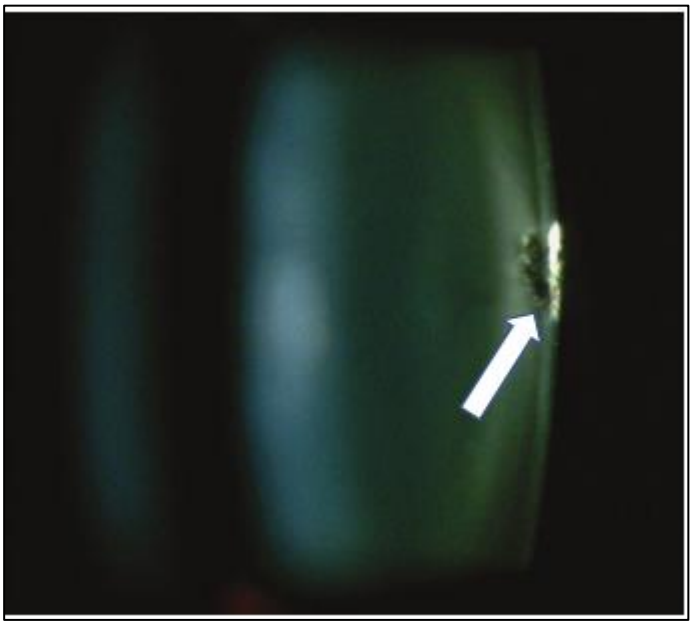

Figure 2-1. PSC observed by slit-lamp bio-microscopy using direct illumination. The cataract was observed after 22 years of performing interventional procedures (Rehani et al., 2011).

Several studies have been carried to evaluate the prevalence of PSC among interventionalists. The results of some of these studies are presented in Table 2-1. These studies demonstrate the existence of a relationship between ionizing radiation and the prevalence of PSC in interventionalists. It should also be remembered that interventionalists are exposed to low levels of radiation and the latency period for

manifestation of detectable opacities is approximately inversely proportional to dose (Shore et al., 2010). Therefore, the radiation-induced cataract may take several years before being clinically detectable.

Table 2-1. Results of different studies that assessed the prevalence of posterior subcapsular cataract (PSC) in interventional cardiologists.

Author (s)	*Cardiologists with detectable opacities (%)*	*Number of participants*	*Years of work in interventional cardiology*
Ciraj-Bjelac et al. (2012)	53	30	8 ± 6 (2-2)
Ciraj-Bjelac, et al. (2010)	52	56	9.2 ± 6.9 (1.0-3)
Vano, et al. (2010)	38	58	14 ± 8 (1-4)
Vano, et al. (2013)	50	54	16.6 ± 9.3

The risk associated with the development of PSC increases with dose that is received by the eyes of interventionalists (Ciraj-Bjelac et al., 2012). Therefore, interventionalists with high workloads are more likely to develop PSC as compared to those with a lower workload. In South Africa, particularly in public hospitals, interventionalists are prone to increased workloads due to a relative shortage of trained medical professionals. The radiation dose that is received by South African interventionalists, especially those working in the public sector may be significant compared to doses received by interventionalists in developed countries, where technology is more advanced, and the culture of radiation protection is more entrenched in the radiation worker community. Therefore, studies that assess the prevalence of PSC in South African interventionalists may provide insight into occupational ocular exposure, or eye doses, and this insight may, therefore, increase the motivation to enforce better safety practices (Rose et al., 2017).

2.4 Interventional Cardiology

Interventional procedures are performed by clinicians of different specialties. These procedures are not limited to the cardiology department but are also performed in radiology, vascular surgery, general surgery, urology, gastroenterology, etc. However, for this dissertation, the focus is on the procedures carried out in the Department of Interventional Cardiology.

Interventional cardiology is a sub-specialization of cardiology dealing specifically with catheter-based management of structural heart diseases. An interventional procedure can be carried out electively or as an urgent surgery (Faxon and Williams, 2012).

Fluoroscopy, an imaging technique that uses X-rays to visualize human internal structures in real-time (Bushberg et al., 2012), is used to guide ICs during interventional cardiac procedures. During an interventional procedure, a catheter is inserted through a small incision into an artery (usually via the femoral artery or radial artery access route), the catheter is then fluoroscopically guided into the heart to a specific site. Different examinations and procedures are made possible using the guidance of fluoroscopy. These include coronary angiography (CA), percutaneous coronary intervention (PCI), pacemaker insertion (PI), defibrillator implantation (DI), radiofrequency ablation (RFA), atrial septal defect closure (ASDC), etc. The common interventional procedures performed at Universitas Hospital in Bloemfontein include CA, PCI, and PI.

Four personnel are usually present during an interventional cardiac procedure; these are, a cardiologist, a radiographer and two nurses (scrub and circulating nurses). Figure 2-2 shows the typical positions of staff in the catheterization laboratory.

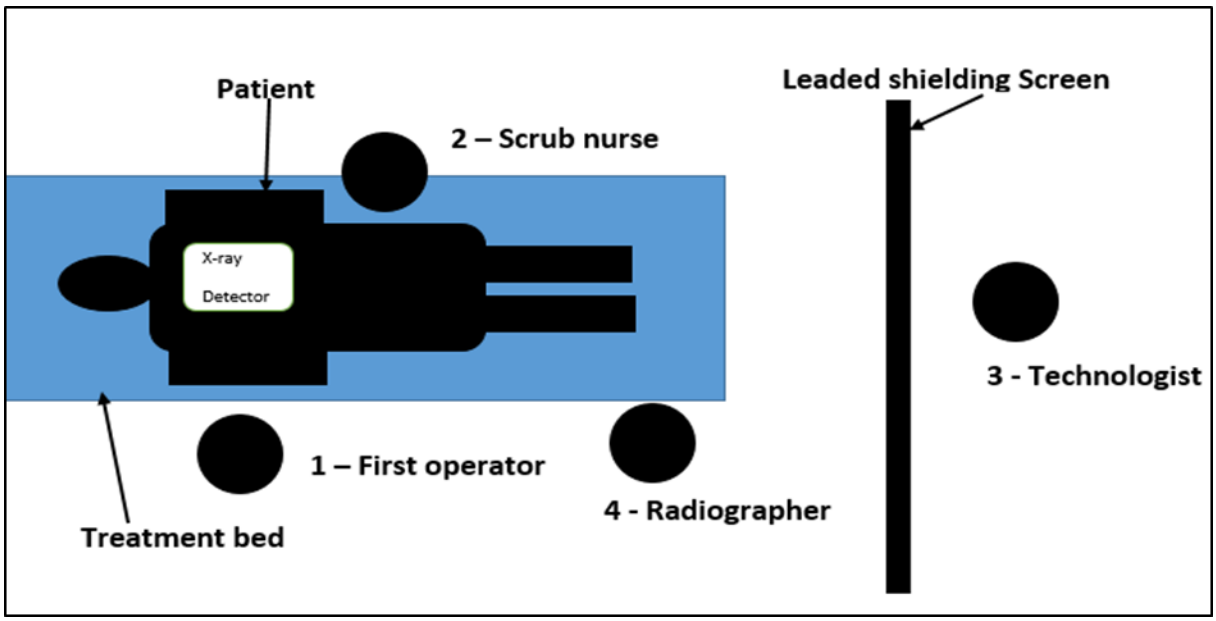

Figure 2-2. Typical locations of interventional cardiology personnel during a clinical procedure; 1, interventional cardiologist (First operator); 2, scrub nurse; 3, technologist, 4 Radiographer.

As demonstrated in Figure 2-2, the first operator, the interventionalist, is the closest to the patient who is the source of scatter producing the largest amount of radiation to the medical staff in this setting. The radiographer and nurses receive lower occupational radiation exposure during procedures as their positions relative to the exposed site of the patient are further away. Moreover, the location of the radiographer and nurses can vary during the procedures, but the first operator remains relatively stationary throughout the procedure.

2.5 Occupational exposure in interventional cardiology

Occupational exposure refers to radiation exposure to workers incurred during their work (UNSCEAR, 2000). As already mentioned, the highest exposure to ICs is due to scatter radiation emanating from patients (Le Heron et al., 2010). Doses to the eyes of ICs can easily reach and exceed the current dose limit if good radiation protection measures are not employed. (Vano et al., 2006). Medical professionals working with ionizing radiation, particularly doctors, tend to underestimate the detrimental effects of radiation

such as cataract and cancer because of the long latency period associated with exposure to low levels of ionizing radiation (ICRP, 2007).

The International Commission on Radiological Units and Measurements (ICRU) has established radiation quantities to quantify the amount of radiation dose that is received by radiation workers, patients and by the general public. It is through these quantities that personal monitoring can be performed and the risks associated with ionizing exposure can be estimated. It is also through these quantities that compliance with the standard regulations is assured. These quantities are briefly described below.

2.6 Quantities used in radiological protection

2.6.1 Physical quantities

Basic physical radiation quantities: exposure, kerma, and absorbed dose can all be related to protection and operational quantities by applying appropriate conversion factors.

"Exposure is defined as the absolute value of the total charge of ions of one sign produced in a small mass of air, when all electrons liberated by photons in air are completely stopped in air, divided by the mass of air. The Unit of exposure is C kg^{-1}" (ICRU, 2011).

Kerma is an acronym for kinetic energy released per unit mass (Podgorsak, 2005). It is defined as the mean energy that is transferred to charged particles (electrons) by indirectly ionizing radiation such as X-rays, gamma rays and neutrons (i.e. Kerma only quantifies the energy that is transferred to charged particles and is not the energy deposited in the volume). Kerma is measured in Gy or J kg^{-1}.

Absorbed dose is a fundamental radiation quantity defined as the quotient of $d\varepsilon$ by dm, where $d\varepsilon$ is the mean energy imparted by ionizing radiation to matter of mass, dm (ICRP, 2010). The unit for absorbed dose is J kg^{-1} and its special unit is the gray (Gy). In other words, absorbed dose describes the amount of radiation that is absorbed by a medium (tissue, water, air). The quantity of the radiation dose absorbed by matter is dependent on the type of radiation and absorbing material. However, the absorbed dose does not give a good indication of the biological effects of different radiation types on tissue.

2.6.2 Protection quantities

The three main protection quantities recommended for use in radiological protection are the mean absorbed dose, the equivalent dose, and the effective dose

Absorbed dose is defined to indicate a specific value at any point in matter. However, in radio-dosimetry, to be able to quantify the amount of radiation dose absorbed by tissue, the absorbed dose is averaged over larger tissue volumes. This leads to a quantity known as organ absorbed dose, D_T, or mean absorbed dose.

The equivalent dose (H_T) is defined by ICRP as:

$$H_T = D_T \times W_R \tag{2-1}$$

Where D_T is the organ or mean absorbed dose imparted by radiation type, R, in an organ or tissue, T, and W_R is the radiation weighting factor for radiation type, R (ICRP, (1999).

In the cases where exposure is due to two different radiation types, the equivalent dose is given by:

$$H_T = \sum_R W_R \times D_T \tag{2-2}$$

The unit of equivalent dose is J kg^{-1} and its special name is Sievert (Sv) (see Page 2.11 below). The radiation weighting factors of different radiation types are given in Table 2-2.

Table 2-2. Recommended radiation weighting factors (ICRP , 2007).

Radiation type	*Radiation weighting factor, W_R*
Photons	1
Electrons and muons	1
Protons and Charged pions	2
Alpha particle, fission fragments, heavy ions	20
Neutron Radiation Weighting Factors	These are a continuous function of neutron energy (see Figure 2-3).

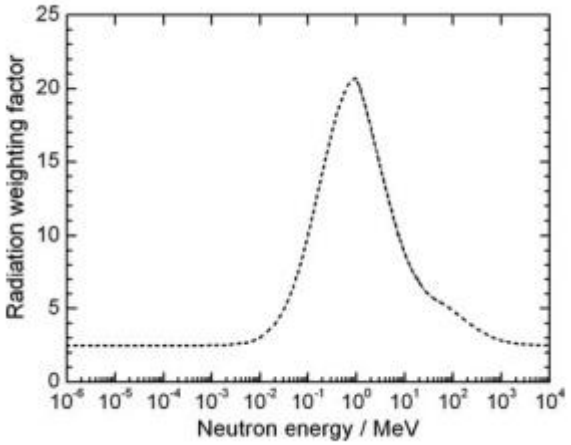

Figure 2-3. Radiation weighting factors, W_R, for external neutron exposure for neutrons of various energies (ICRP International Commission on Radiological Protection, 2007)***.***

The definition of equivalent dose takes into consideration the type of tissue as well as the type of incident radiation. This is because different radiation types have different effects on the same tissue type. It also considers the fact that different tissue reacts differently to ionizing radiation. The effective dose, E, is defined as the weighted sum of tissue-equivalent doses. It is expressed mathematically as:

$$E = \sum_{T} W_T \times H_T \qquad \textbf{(2-3)}$$

Where W_T is the tissue weighting factor for tissue *T.* W_T is included in the definition to account for the difference in radio-sensitivity of different tissues or organs in a uniform radiation field and thus represents the fractional contributions of different organs or tissues to the total stochastic risk in the exposed person. The total weighted some of all the tissue weighting factor is 1. The values of the W_T are listed in Table 2-2.

Table 2-3. The recommended tissue weighting factors (ICRP , 2007).

Tissue	W_T	$\sum W_T$
*Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues**	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

Average for extrathoracic airwaves, gallbladder, heart, kidney, lymph nodes, adrenals, skeletal muscles, oral mucosa, pancreas, SI, spleen, thymus, prostate/uterus-cervix (13 tissues).

The unit of effective dose is also J kg^{-1} with the special name Sievert (Sv). "The main uses of effective dose are the prospective dose assessment for planning and optimization in radiological protection, and demonstration of compliance with dose limits for regulatory purposes" (ICRP, 2007, p13).

2.6.3 Operational quantities

Protection quantities are not readily measurable and thus cannot be used directly in radiation dosimetry (ICRP, 2010). Operational quantities were developed by the International Commission on Radiological Units and Measurements (ICRU) to estimate the effective and equivalent dose in tissue or organ.

The three operational quantities defined by the ICRU are ambient dose equivalent *H*(d),* directional dose equivalent *H'(d, Ω),* and personal dose equivalent *Hp(d).* Ambient and directional dose equivalent are both used for area monitoring, where *d* is the depth in the ICRU sphere (ICRU, 1998). Personal dose equivalent is used for the dose monitoring of a person. *Hp(d)* is the dose equivalent in ICRU soft tissue at an appropriate depth, *d*, below

a specified point on the human body (ICRP, 2010). Within the framework of this dissertation, the main interest is in the operation quantity for individual monitoring of external exposure.

Radiation dosimeters are calibrated to measure doses at different depths on the body of the wearer. These are determined by the quality of the incident beam. The recommended depths for weakly penetrating and strongly penetrating radiation are 0.07 mm and 10 mm respectively (Nikola et al., 2017). A depth of 0.07 mm is considered appropriate for assessing equivalent dose to skin, feet, hands, and wrists. A depth of 10 mm is recommended for the assessment of the whole body dose. For the direct measurements of the eye lens doses, a dosimeter calibrated in terms of *Hp (3 mm)* is recommended. An extremity dosimeter calibrated in terms of *Hp (0.07 mm)* may be used to assess the eye lens dose. However, care should be taken as the accuracy of using an extremity dosimeter to monitor eye lens dose is limited compared to the accuracy of a dosimeter calibrated to specifically measure eye lens dose.

2.7 Exposure factors that influence doses to the eyes of Interventionalists

2.7.1 Time current product, tube potential, and patient thickness

The tube current, measured in milliamperes (mA), refers to the rate at which the electrons flow from the cathode filament to the anode across the X-ray tube. When current is applied to the cathode, electrons are released via thermionic emission. The tube current influences the number of photons that are generated by the X-ray tube. The number of generated photons is also dependent on the exposure time. The product of the tube current and exposure time is often quoted together and referred to as the time-current-product (mAs).

The tube potential, measured in kilovolt (kV), is the high voltage that is applied between the two electrodes inside an X-ray tube housing. Tube potential determines the energy of the electrons that are emitted from the cathode and thus the energy of the photons that are subsequently produced.

Modern Fluoroscopic devices employ an automated exposure control system. The X-ray unit adjusts the kV and mAs to obtain an image of adequate quality of the site that is being imaged. The adjustment of the two parameters mentioned above is among other factors, highly dependent on the anatomical features of the patient being imaged (e.g. the size of the patient). Therefore, a patient with a large size will increase both parameters to ensure that good image quality is achieved. This will result in increased exposure to the patient which in turn will result in elevated exposure to the operator. Furthermore, it was demonstrated in a study by Vano, et al. (2009) that an increase in patient size results in an increase in scattered dose to the eyes of the primary operator. This is because there is increased photon attenuation, with thicker patients resulting in increased radiation backscatter, and this is largely due to more entrance skin dose being needed to achieve enough exposure to the image detector.

2.7.2 Tube configurations

Tube angulation is one of the most important factors influencing the scattered radiation to the eyes of ICs. Measured radiation doses vary substantially as a result of different angulations used in interventional cardiology (Leyton et al., 2014). In a study by Farah, et al. (2013), the lowest eye dose values were recorded for left anterior oblique (LAO45^{o}) and the highest values for anterior-posterior (AP) angulations. Considering the AP angulation, the head (including eyes) is closer to the X-ray tube which is the primary source of radiation and the radiation scattered from the patient is mostly in the direction towards the head of the operator hence the increased doses (Clerinx et al., 2008). For the right anterior oblique (RAO), doses are expected to be low due to a greater distance of the head from the X-ray tube (Martin, 2009).

2.7.3 Location of the operator

The position of the interventionalist is determined by whether radial or femoral access is used for the insertion of the catheter. When using the radial access route, the IC stands closer to the X-ray tube compared to when using the femoral access route and as a result, he/she receives a higher radiation dose. In cases where radiation protection such as ceiling-suspended shielding is utilized, the measured radiation dose to the eyes of the IC is approximately the same for both access routes (Ciraj-Bjelac and Rehani, 2014). Another considerable factor is the distance between the eye lens and the iso-centre. According to the inverse square law, the dose to ICs is expected to be lower with increasing distance from the source (patient). However, during interventional procedures, doctors are required to remain close to the patient to perform clinical manipulations. Nevertheless, the height of ICs remains a factor that can affect the dose reaching the head (eyes), with taller ICs expected to receive a lower dose, due to increased distance from the source (Principi et al., 2016).

2.7.4 Use of personal protective equipment (PPE)

The radiation dose recorded at the eye level of ICs can vary considerably depending on the use of radiation protection equipment and thickness or the amount of lead or attenuating material used. As mentioned already, the use of lead eyewear can be very effective in reducing the dose absorbed by the eye lens. The amount of attenuated radiation depends on the proper use of such equipment. When properly used, the eyewear substantially reduced the dose to the eyes. However, the efficacy of protective eyewear depends on several factors which include, but not limited to factors such as the design on the eyewear and the lead equivalence, and the irradiation geometry. The use of a ceiling-suspended shield is mostly employed in interventional cardiology due to its effectiveness in protecting the upper body including the eyes of interventionalists. Without its use, doses to the eyes can be extremely high. Its effectiveness in dose reduction is therefore very dependent upon the proper use by the user (Koukorava et al., 2011).

2.7.5 Duration of a procedure

The duration taken to complete a cardiac procedure differs according to the type of procedure being carried out. General angiography procedures are usually shorter than other more complex procedures, and complications can be encountered during the procedure. Longer procedures usually mean that patients will be exposed to higher radiation dose, therefore exposure to operators will also be elevated. The experience and technique of the interventionalists also play a role in determining the procedural duration. Watson et al. (1997) showed that the time taken for fellows to complete a procedure was shorter during the second year compared to their first year of training. This observation was on the basis that in their second year of training, fellows had improved their technique in catheter insertion and thus reduced the fluoroscopic time. Moreover, radiation doses received in academic hospitals can be elevated due to lengthy procedures needed to accommodate the teaching needs of registrars (Badawy et al., 2018).

2.8 Occupational radiation safety

The objective of radiation protection is the prevention of the occurrence of deterministic effects and the reduction of stochastic effects in persons exposed to ionizing radiation. The fundamental system of radiation protection consists of three principles, that is justification, optimization and dose limitation. These principles are based on recommendations from the international commission on radiological protection (ICRP, 2007).

The principle of justification implies that every medical procedure that involves the application of ionizing radiation should be justified, that is, the benefits of the application of radiation for either diagnostic or therapeutic reasons should be higher than the harm inflicted (ICRP, 2007). In other words, a radiological examination can only be performed if it is judged that the procedure will result in information useful for the treatment of the patient being screened and thus improving the health of the patient in question.

The principle of optimization was established to mitigate the risks associated with medical radiation exposure. In planned exposure situations, doses to patients and staff should be kept As Low As Reasonably Achievable (ALARA). In interventional cardiology, radiation doses to interventionalists can be minimized by increasing the distance between the source (patient) of radiation and the operator, decreasing the procedural duration and by making use of appropriate PPE. However, increasing the distance between the patient and the interventionalist may not be feasible and emphasis should be made on the proper use of PPE (Kim et al., 2010). It should also be noted that, although the use of PPE is an effective control measure to reduce occupational exposure to the eyes, it is the least important control measure according to the occupational hazard hierarchy of control model. According to the model (see figure 2-4), the most important control is the elimination of the hazard, however, when working with radiation, as in interventional cardiology, one cannot eliminate the hazards posed by ionizing radiation and substitution is not feasible at this point. Engineering controls have improved with the advancement in technology; the development of X-ray systems that deliver lower radiation doses to patients is an example. Administrative control includes measures such as regular dosimetry checks, training and reducing the time that a worker is exposed to the hazard.

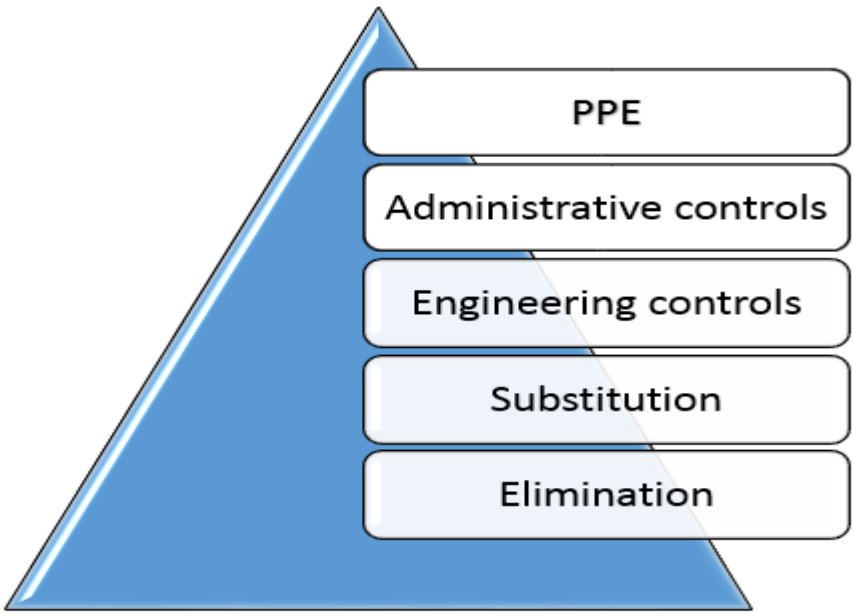

Figure 2-4. Occupational hazard hierarchy of control model.

Dose limitation was introduced to prevent deterministic effects and also to limit the probability of stochastic effects to a level considered acceptable. This principle is only applicable in occupational exposures and public exposures and not in medical exposure of patients (Thome, 1987). Table 2-4 shows the dose limits set for radiation workers and members of the public.

However, as mentioned already, the eye lens dose limit was under review by the ICRP task group at the time of the publication. In the publication, the ICRP stated that new data on the radio-sensitivity of the eye was expected (ICRP, 2007). The dose limit for the eye was substantially reduced in 2011 in *publication* 118 (ICRP, 2012), following a comprehensive review of the literature.

Table 2-4. Recommended dose limits in planned exposure situations (ICRP, 2007).

Type of limit	***Occupational***	***Public***
Effective dose	20 mSv per year, averaged over a defined period of 5 years	1 mSv in a single year
Annual equivalent dose in:		
Lens of the eye	20 mSv	15 mSv
Skin	500 mSv	50 mSv
Hands and feet	500 mSv	-

2.9 Radiation dosimeters

Personal dosimetry can be carried using passive or active dosimeters. However, passive dosimeters have for years been, considered appropriate for legal personal dosimetry. The main arguments given for the use of passive over active dosimeters are that passive dosimeters are accurate and precise in any radiation environment, can be worn for a long period, and are cost-effective and size compatible (Luszik-Bhadra and Perle, 2007). The main disadvantage of passive dosimeters is the inability to provide an instant dose readout. This implies that the wearer should wear the dosimeter for some time before

receiving the dose results. The drawback of this is that the wearer cannot be aware of their dose levels until the dosimeters are read out.

Active Personal dosimeters (APDs), although they are still to be implemented as legal dosimeters in many countries, have shown the potential to bring about improvement in radiation protection. The main advantages of active dosimeters over passive dosimeters include the ability to give instant dose reading, and the inclusion of alarm features. These features are crucial for the optimization of occupational exposure. Active dosimeters are also valuable tools for investigating radiation dose in high dose environments such as interventional cardiology and radiology (Ortega et al., 2001).

APDs are calibrated in terms of H_p *(0.07 mm*) and H_p *(10 mm)* and are used in many states. Dosimeters calibrated to specifically measure eye lens doses are still to be implemented in legal dosimetry (Behrens and Dietze, 2010). The characteristics of APDs should make them suitable to measure doses in the desired environment with adequate accuracy. One of the most important properties to consider when selecting an APD is its energy response, that is, a dosimeter that will be able to measure radiation in the specific energy range typically found in the vicinity where measurements will be taken.

Active dosimeters that can measure radiation energies to as low as 20 keV are available. These dosimeters are suitable for measuring scatter radiation in an interventional catheterization laboratory (Ginjaume et al., 2007). Figure 2-5 presents the typical scatter photon mean energies as a function or tube potential for two X-ray tube projections in an interventional room.

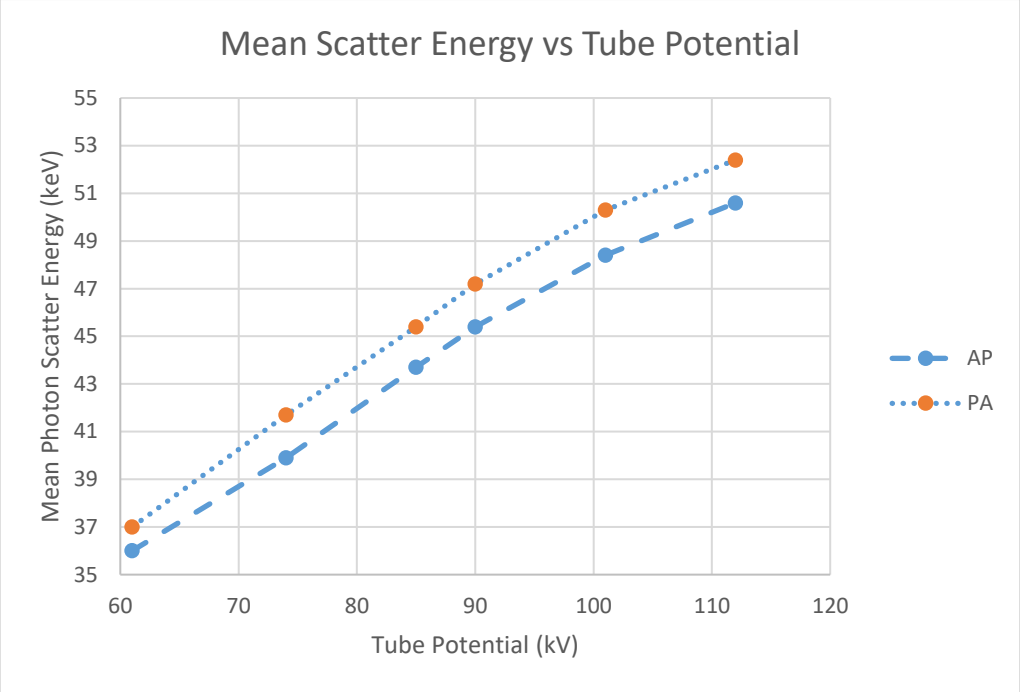

Figure 2-5. Mean scatter photon energy as a function of tube potential for under couch configuration (PA) and over couch configuration (AP) (Marshall et al., 1996).

Moreover, in terms of the calibration, a dosimeter calibrated to measure extremity doses is recommended for measurements of eye doses. However, care should be taken because such dosimeters could overestimate doses in photon energies below 30 keV (Behrens and Dietze, 2010)

2.10 Possible approaches to eye dose assessment

Various methods have been employed to estimate the eye lens dose. Data can be acquired during actual clinical procedures, by performing Monte Carlo simulations, or through phantom studies, or by obtaining data through the completion of a comprehensive questionnaire for retrospective studies (Antic et al., 2013; Carinou et al., 2011; Leyton et al., 2014; Rehani et al., 2011).

2.10.1 Estimation based on questionnaires

One approach to estimating ELD is by assessing the information on workload as well as the typical scatter dose levels of individuals performing fluoroscopically guided procedures through the completion of questionnaires (Ciraj-Bjelac et al., 2010). The value

of 0.5 mSv per procedure is assumed as an initial value in cases of non-use of radiation eye protection. These exposures correspond to a typical interventional cardiac procedure of 10 minutes of fluoroscopy and 800 cine frames (Ciraj-Bjelac and Rehani, 2014; Giorgio, 2014; Vano, et al., 2010a). The initial value is then modified according to the information provided by each individual obtained through a questionnaire. This particular approach is usually employed in studies that aim to correlate the prevalence of lens opacities in interventionalists to low levels of ionizing radiation doses (estimated) scattered to the lens of the eye. This method is associated with large uncertainties that are allowable for the above-mentioned purpose but are not practicable for routine eye lens dosimetry.

2.10.2 Correlation between Eye Lens Dose (ELD) and Dose Area Product (DAP)

Correlation between ELD and dose area product (DAP) has also been used to estimate the scattered doses to the eyes of the primary operators. DAP, measured in $Gycm^2$, is the product of the surface area of the patient that is exposed to the incident radiation at the skin entrance. DAP is valuable because radiation-induced bioeffects are directly related to both the magnitude of the radiation dose and the total amount of tissue that is irradiated. Furthermore, newer fluoroscopic and angiography units have a special ionization chambers integrated into the unit for measurement of DAP.

Table 2-5 shows the results of five studies that employed the same methodology (Vano, et al. (2009) and Leyton, et al. (2014)). The large difference in doses per procedure between the two studies is because one study by Vano, et al (2009) simulated interventional cardiac procedures in paediatric patients (typical DAP values range from 3-30 $Gy{\cdot}cm^2$ per procedure) and the other by Leyton, et al. (2014) in adult patients (typical DAP values range from 59-281 $Gy{\cdot}cm^2$). This wide range of DAP values could be seen as indicating that the methods used are applicable over a wide range of dose values.

Table 2-5.Correlation between the dose area product (DAP) and the scattered dose to the eye of the primary operator without the use of protective equipment.

Study by:	*ELD/DAP ($\mu Sv/Gycm^2$)*	*R^2 value*	*Dose per procedure (μSv)*
Vano, et al. (2009)	7	0.99	21-210
Leyton, et al. (2014)	3.49	0.97	256-981
Leyton, et al. (2016)	8.30	0.83	106-1452
*Antic, et al. (2013)**	0.94	0.68	121
Alejo et al. (2017)	2.21	0.40	40
Principi et al. (2015)	1.81	0.60	171

* ***The study was conducted with the ceiling-suspended shield placed between the patient and the operator***

The studies by Vano, et al. (2009) and Leyton, et al. (2014) demonstrate a strong correlation that exists between the patient dose and the scattered dose to the eyes of the primary operator. It should be noted that the aim for the inclusion of Table 2-5 is to demonstrate the correlation between the variables mentioned and not to directly compare the results of the listed studies. It should also be noted that the two studies have some limitations, for example, the measurements in a study by Leyton, et al. (2014) were carried out using a fixed geometry (post-anterior angulation) and only patients weighing between 70 and 90 kg were simulated. A fixed posterior-anterior (PA) angulation was used in 85% to 90% of the cases in the study by Vano, et al. (2009), so the effects of other angulations were overlooked. In a study by Leyton, et al. (2016), all angulations were taken into account and a strong correlation between ELD and DAP was demonstrated. The limitation of the study was the use of a phantom that only simulated patients weighing in the range of 70 and 90 kg. In studies by Antic, et al. (2013), Alejo et al. (2017) and Principi et al. (2015), measurements were carried during the actual clinical procedures. Worth noting is the difference between the coefficients of determination of simulation studies (Leyton et al., 2016, 2014; Vano et al., 2009) and the studies in which measurements were carried out during actual clinical procedures. For simulation studies, an excellent correlation between ELD and DAP is seen. This is because exposure factors that are usually varied during actual clinical procedures are kept constant. Considering the studies in which measurements were carried during the actual clinical procedures, a poorer correlation between DAP and ELD is observed owing to the variation of

procedural factors and x-ray machine-related factors which are usually kept constant during phantom studies.

The difference seen between phantom measurements and actual clinical measurements (concerning ELD per DAP and correlation between the two quantities) is indicative of the difficulties and uncertainties when it comes to applying the results of phantom studies to estimate occupational eye lens dose in interventional suites. This also highlights the necessity to conduct more research to improve the accuracy of phantom studies. Lastly, the variation of eye lens dose per procedure and dose per DAP between the studies carried during actual procedures is also indicative of lack of consensus as far as eye dosimetry in interventional cardiology is concerned.

2.10.3 Correlation between ELD and dose measured at other parts of the body

Ideally, the radiation dose to the eyes of interventionalists should be measured using a dedicated dosimeter calibrated in terms of personal dose equivalent H_p *(3 mm)* on a cylindrical phantom which is representative of a human head (Bordy, 2015). The dosimeter should be worn as close as possible to the eyes of the operator (Principi et al., 2015). However, this method introduces several challenges. Firstly, the dosimeter should be correctly calibrated to measure H_p *(3 mm)* and dosimeters calibrated in this quantity are expensive and currently scarce. Secondly, a doctor would be required to wear an additional dosimeter (as close as possible to the eye). This approach may be impractical for routine eye lens dosimetry in interventional cardiology and may cause discomfort to operators. Because of these reasons, it is suggested that the eye lens doses be assessed using dosimeters calibrated in terms of alternative quantities and worn at a particular location over the protective garment and then applying an appropriate conversion factor to indicate eye doses (Leyton et al., 2014). In 2000, the ICRP, in its *publication* 85 (ICRP, 2000) recommended wearing two dosimeters, one under the protective apron and another unshielded dosimeter at the collar to give an estimation of the eye dose. The position of the dosimeter is indeed an important parameter in estimating the dose to the eyes of interventionalists. This was demonstrated by Farah, et al. (2013) in a study which investigated the influence of wearing dosimeters at different locations of the body. In the

study, the ratios between ELD and the dose recorded by dosimeters located at various positions on a Rando-Alderson anthropomorphic phantom were calculated. The mean values of the ratios were calculated together with the spread to the mean ratio. Farah, et al. (2013) concluded that measurements at the chest level can be useful in estimating the doses delivered to the eyes, however, the accuracy is limited.

Clerinx et al. (2008), in a simulation study, proposed using an unshielded collar dosimeter calibrated to measure H_p *(0.07 mm),* and applying a correction coefficient of 0.75*.* It is, however, important to note that this is a simplified method and a poorer correlation is likely to be observed under clinical conditions where several parameters vary simultaneously. A critical analysis of recorded doses in studies that recorded both the eye lens doses and thyroid doses showed that the dose scattered to the eyes of the primary operator is between 40% and 90% of that scattered to the collar level (Martin, 2011). This variability in dose highlights the importance and necessity of developing a method for a more accurate estimation of eye lens dose for a specific institution or institutions following a similar protocol.

In a study by Omar et al. (2015), a formalism for estimating occupational eye lens dose from values recorded by a dosimeter at the chest level was provided and its feasibility was evaluated. The following equation was developed:

$$D_{eye}^{operator} = 2.0\ APD_{chest} \tag{2-4}$$

Where active personal dosimeter (APD_{chest}) gives the dose reading at the chest level of the operator. It is important to note that this formalism cannot be directly applied in settings where personal dosimetry is performed using TLDs due to difference in dosimeter characteristics of passive and active dosimeters such as energy and angular dependence (Omar et al., 2015).

This equation differs considerably from the one presented by Clerinx et al. (2008). This highlights the need for further investigation involving critical analysis to accurately quantify eye lens doses without the use of an additional dosimeter.

Although the approaches mentioned can be employed to indicate the head/eye doses, direct eye lens measurements must be carried out using a dedicated dosimeter that is specifically calibrated for measuring eye lens doses in cases where it is suspected that the eye lens dose limit may be exceeded.

2.11 Overall summary

In this chapter, a brief definition of radiation and its benefits and undesirable effects in the medical field was presented. Moreover, a brief explanation of the specific effect (cataract) that the ionization radiation has on the ICs and the radiation protection and safety in interventional cardiology was given. The chapter also gave an overview of the quantities used to quantify ELD and different approaches employed in the estimation of ELD.

Accurate estimation of ELD in interventional cardiology remains challenging and has become the research field of interest to an increasing number of investigators. In this chapter, inconsistent results and methods reported by different investigators were observed and highlighted. The variation in the results reported by different authors is due to many factors, as explained in this chapter vary from one institution to the other. It is thus difficult to obtain or develop a universal method that can be used to accurately estimate ELD (from available dose quantities) of different doctors, with different experiences, working in different Hospitals that employ different working patterns and utilizing different equipment, and applying different protective measures.

The lack of consensus on the estimation methods in many of the published data, however, highlights the necessity for more research in this field of research. Further research on the topic will improve knowledge in the field and possibly result in a method that can be used across different institutions to estimate ELD with better accuracy.

Chapter 3 : Determination of the protective efficacy of lead glasses in interventional cardiology

3.1 Introduction

Following the revision and subsequent reduction in the eye lens dose limit to mitigate the risk of developing radiation-induced cataract (see section 1.1), radiation safety of the eye has been emphasized, particularly in fluoroscopically guided procedures (Donald L et al., 2010). Lead eyewear and the ceiling-suspended lead screen prove to be effective in reducing the amount of scatter radiation reaching the eyes of the operator (Carinou et al., 2015). However, in some scenarios, common in paediatric theatres where interventionalists are often required to be close to the patient, the use of the lead screen may not be practical and lead eyewear is the available means of protecting the eyes (Ubeda et al., 2010). The use of the lead glasses in interventional cardiology and radiology is one of the simplest and most commonly employed strategies to protect the eyes against occupational exposure. The protection efficacy of such glasses, however, varies considerably (Kim and Miller, 2009). The difference in the dose reduction factors (DRFs) of protective glasses may be attributed to several factors, which include the design and fit of the glasses, the lead equivalence and the surface of the lens glasses. The wide range of tube configurations selected during a single fluoroscopically guided procedure is also a considerable factor that influences the efficacy of protective eyewear since the distribution of scatter radiation is partly subject to angulations of the X-ray tube(s). Moreover, the location of the interventionalist concerning the radiation field changes for different procedures (Koukorava et al., 2014) and this can also be a factor influencing the efficacy of the eyewear.

Several investigators have opted for phantom studies that allow for the selection of some specific exposure conditions (McVey, Sandison, & Sutton, 2013; Rooijen, Haan, & Das, 2014; Sturchio et al., 2013) to determine DRFs of various models of commercially available protection eyewear. These studies are performed using fixed angulations and varying the angles of the head (simulated with head phantom) of the operator across the axial plane and selecting imaging parameters for typical interventional procedures. It is appreciated that a realistic approach to determining the efficiency of lead glasses would

be to collect data during an actual interventional procedure by positioning dosimeters outside and behind the protective glasses. This may, however, present challenges because the dosimeter attached behind the glasses may reduce the vision of the operator consequently inconveniencing them. Moreover, due to the simultaneous variation of factors influencing the scatter radiation attenuation by the leaded eyewear, determining with accuracy how various factors influence the efficacy of the eyewear may be cumbersome and difficult.

Eye dosimetry is usually performed with a dosimeter placed on the outside of the protective glasses and therefore the measured dose does not necessarily reflect the dose that is directed to the eye lens. For this reason, it is important to determine the DRFs of lead glasses to account for the attenuation of scattered dose by the glasses. Although phantom measurements come with limitations, they can yield invaluable results necessary in eye lens dosimetry.

The work presented here aimed to experimentally determine the efficacy of the lead eyewear currently used at the interventional cardiology at the Universitas Hospital and to recommend an appropriate DRF from lead glasses to be applied to the results of personal eye dose measurements. The efficacy of a ceiling-suspended lead shield was also explored.

In order to achieve the above mentioned aims, the following objectives were formulated:

- Measure the radiation dose with the dosimeter attached outside (in front of) the lens of the protective eyewear
- Measure the radiation dose with the dosimeter attached inside (behind) the lens of the protective eyewear
- Calculate the ratio of the dose measured on the outside (in front of) the lens of the goggle to dose measured inside (behind) the lens of the eyewear
- Measure scatter radiation at the eye level with and without the lead shield in place between the patient and operator phantom

3.2 Material and Methods

3.2.1 Ethical approval

Approval to perform the study was obtained from the Health Science Research Ethics Committee (UFS-HSD2018/0931/2711), University of the Free State, as well as from the Heads of the Departments of cardiology and Medical Physics, respectively as part of the main study.

3.2.2 Fluoroscopic Unit

Measurements were performed at the Universitas Hospital in the interventional cardiology suit. Measurements were carried out using the Philips Allura X-Per FD 10/10 biplane system. The fluoroscopic system is subjected to quality control testing performed at yearly intervals and is in routine clinical use. The fluoroscopic system employs automatic exposure control which allows for selection of imaging parameters (kV and mAs) based on patient attenuation characteristics. The room is fitted with a ceiling-suspended protective screen with lead equivalence of 0.5 mm.

3.2.3 Eye dosimeter

Measurements of radiation at the eye level were performed using an ED3 Active Extremity Dosimeter (https://johncaunt.com/products/ed3/) shown in Figure 3-1. The dosimeter is based on solid state detectors (Silicon diode). This dosimeter was calibrated in terms of H_p (0.07). The dosimeter was tested prior to being issued for the study. The test measurements were performed against a reference ED-3 dosimeter directly calibrated at the Public Health England (PHE)/UKAS facility and results were deemed satisfactory. The dosimeter consisted of two detectors that can be used simultaneously. However, the two detectors are designed to measure radiation in different energy ranges, therefore, it is important to choose the appropriate dosimeter for dose measurement in a particular exposure environment. One detector measures radiation with photon

energies ranging from 60 keV to 1.25 MeV. The other detector measures radiation photons with energies in the range of 33 to 60 keV. The latter being the most suitable for measurement of scatter radiation encountered in interventional cardiology. The detectors are connected to the electronic unit using a detachable 1.5 m cable. The dosimeter is issued with computer software that can be used to analyse the results of dose measurements and to reset the dosimeter. However, the dosimeter can still be reset without using the software.

Figure 3-1. ED3 active extremity dosimeter used for eye dose dosimetry.

The accuracy of the dosimeter is specified as being within ±12.5%. The angular dependence of the probe between the reference angle (0˚) and +60˚ is within ±12.5%.

3.2.4 Phantoms

A head phantom, depicted in Figure 3-2, composed of tissue-equivalent material of a human skull, was used to simulate an interventional cardiologist. The head was placed on a thorax phantom, thus simulating the upper body of an interventional cardiologist. The figure shows the placement of the detector in front of and behind the leaded glasses.

Figure 3-2. Head phantom used to represent the head of an interventionist. (a) Shows the detector located in front of the glass lens. (b) Shows the detectors located behind the glass lens. (c) Shows a lateral view of a detector in front of the glass lens. (d) Shows a lateral view of the detector located behind the glass lens.

Scatter radiation, similar to that generated by a patient during actual clinical procedures, was generated with Perspex slabs with dimensions of 30 × 30 cm^2. Nine slabs were used to obtain a total thickness of 22 cm as shown in Figure 3-3. The thickness of the phantom was selected to create produce scatter radiation typically encountered in adult cardiology laboratory.

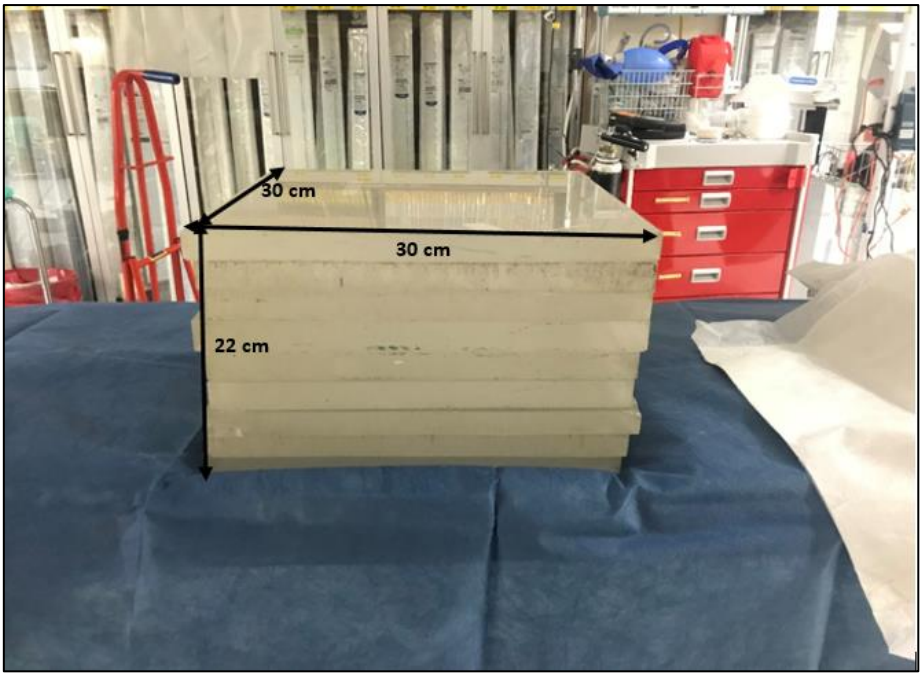

Figure 3-3. Perspex slabs used to generate scatter radiation (simulates the patient chest region).

3.2.5 Protective eyewear

The efficacy of the XR-700™ TORAY glass model with the frontal and lateral nominal lead equivalence of 0.07 mm was tested. The glasses are shown in Figure 3-4. Albeit the eyewear used here provides side shielding, the eyewear does not fit snugly on the head of the operator/phantom and thus leaves a considerable gap between the head and the eyewear. The tested glasses are routinely used by the interventional cardiologists and other cardiology staff (nurses and radiographers) at the Universitas Hospital and are currently the only available type.

Figure 3-4. Tested model of leaded eyewear that is currently being worn by the interventionists and other staff at the Universitas Hospital.

3.3 Experimental setup and methods

Figure 3-5 demonstrates the schematic representation of the experimental setup for both lateral and top view of the anterior-posterior (AP) configuration. The figure also clearly indicates the positions of the patient phantom and the operator phantom. The height of the simulated operator was 170 cm. The operator phantom was located at 40 cm from the centre of the patient phantom, a typical position during a clinical procedure using femoral access. The dosimeter attached adjacent to the position of the left eye of the operator phantom was 80 cm from the centre of the patient phantom. It should be noted that albeit only one plane is shown in the figure, the fluoroscopic unit installed in the laboratory is a biplane X-ray system and both X-ray tubes were used simultaneously in the study as is the case during clinical procedures.

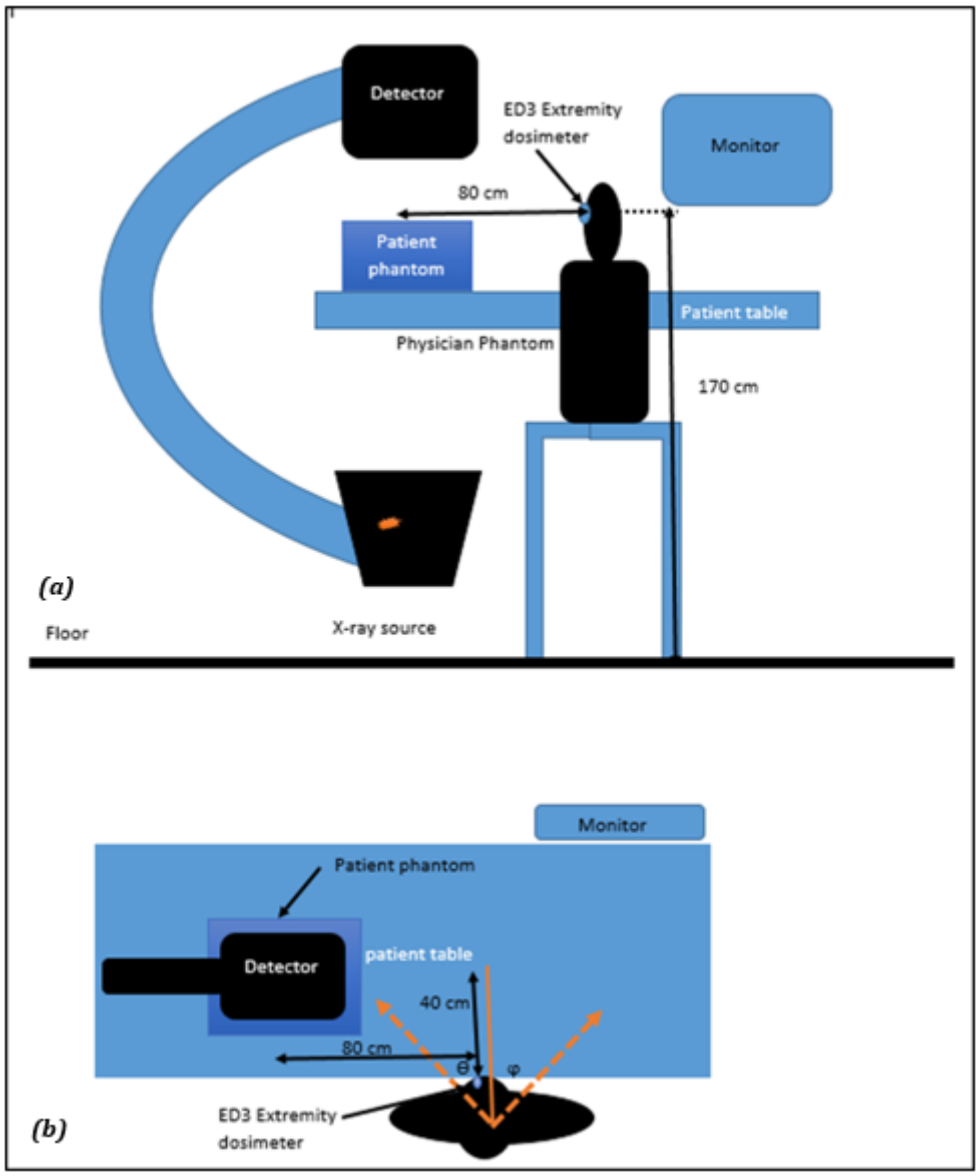

Figure 3-5. Schematic representation of the experimental setup. (a) Lateral view, (b) top view.

Figure 3-6 demonstrates the actual experimental setup. The figure shows the frontal and lateral tubes in AP and LAO 90 configurations, respectively.

Figure 3-6. Experimental setup showing tubes rotated at the angles of anterior-posterior (AP) and lateral-anterior-oblique (LAO) 90 Projections. The setup is that of a typical interventional procedure. This is a simplified setup showing the position of a doc tor during a procedure and the location of the head (including eye level) of a doctor of an average height. An average patient size is simulated with perspex plates.

Table 3-1 shows the projections that are typically selected in the interventional cardiology suite at the Universitas Hospital. From the table, it can be observed that the fluoroscopic system selects different imaging parameters based on the dimensions of the object being imaged. Different source image distance (SIDs) were manually selected to obtain the same image quality of the test object placed in the centre of the patient phantom. All measurements were made with a field of view (FOV) of 25×25 cm^2.

Table 3-1. Typical projections selected during actual clinical procedures and image parameters corresponding to each projection.

Frontal tube				Lateral tube			
Configuration	kV	mAs	SID	**Configuration**	kV	mAs	SID
AP	78	920	110	**LAO 90**	125	572	110
RAO 30	82	874	105	**LAO 45, Caudal 25**	125	572	115
RAO 50, Caudal 15	125	572	110	**LAO 45, Cranial 25**	125	572	116
RAO 30, Cranial 30	96	740	105	**LAO 60**	125	572	110
RAO 30 (30f/s)	90	794	110	**LAO 60**	117	609	110

All exposures in this study were made with cine acquisition mode configured at 15 frames per second (f/s) except for one projection where exposures were made at 30 f/s (typically selected during ventriculogram).

Initially, 10 seconds per exposure was chosen but due to overheating of the system, we opted to 5 seconds per exposure. All measurements in this study were thus made at 5 seconds per exposure. For each exposure, three measurements were taken and averaged to minimize measurement error. The dose area product (DAP) values were noted from the in-room monitor after every procedure.

Measurements were taken with the dosimeter attached on the inside and outside the glasses. The dose reduction factors (DRFs) of the eyewear were determined by calculating the ratio of dose measured outside the glasses to dose measured inside the glasses.

The influence of head rotation of the operator on the efficacy of the glasses was explored through rotation of the head phantom across the axial plane. Three head angulations; -45^0 (towards the patient phantom), 90^0 (perpendicular to the treatment bed) and 45^0 (away from a line perpendicular to the treatment table).

The influence of the ceiling-suspended screen was also investigated by carrying out every measurement with and without the screen.

3.4 Statistical analysis

The analysis of the results of this study was performed using a Windows Microsoft Excel 2016 (Microsoft Corporation, USA) data analysis tool. The results are reported as mean ± standard deviation and range. Comparison of continuous variables was performed with two-tailed t-test. Significance was set at $P<0.05$.

3.5 Results

Figure 3-7 shows the comparison of dose reduction factors (DRFs) obtained at different head rotations averaged over five tube configurations. The figure also provides a comparison of DRFs in the presence and absence of ceiling-suspended screen at the three head orientations.

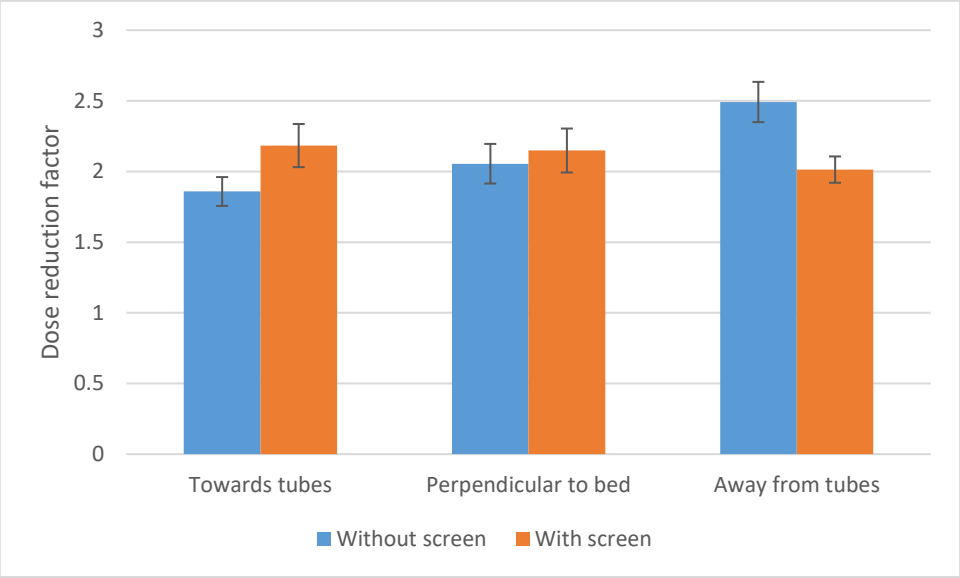

Figure 3-7. DRFs at different operator head rotations in the presence and absence of a ceiling-suspended screen.

Table 3-2 presents the results of dose measured with and without the use of eyewear for different tube projections in the presence of a ceiling-suspended shield located between the patient phantom and operator phantom. These dose values are normalized to DAP values for comparison purposes. The table also shows the results of DRFs at different tube angulations. In this study, a mean DRF (taking into account all the tube configurations and head orientations) of 2.14±0.27 in the range 1.67-2.39 was obtained.

Table 3-2. Dose at the left eye level normalized to DAP measured with and without eyewear in the presence of a ceiling-suspended lead screen. The table also presents the DRF at different tube angulations.

Tube configurations		***Normalized Dose (µGy Gy^{-1}cm^{-2})***		***DRF***
Frontal	***Lateral***	**Without eyewear**	**With eyewear**	
AP	*LAO 90*	0.55±0.09	0.31±0.05	1.67±0.13
RAO 30	*LAO 45, Caudal 25*	0.35±0.07	0.17±0.04	2.36±.0.31
RAO 50, Caudal 15	*LAO 45, Cranial 25*	0.31±0.05	0.13±0.02	2.39±0.39
RAO 30, Cranial 30	*LAO 60*	1.08±0.15	0.45±0.10	2.02±0.48
RAO 30 (30 f/s)	*LAO 60 (30f/s)*	0.89±0.15	0.25±0.10	2.10±0.41

Table 3-3 shows the results of similar dose measurements in Table 3-2 but without the ceiling-suspended screen between the patient and operator phantom. The results of the DRFs for different tube angulations are also presented. Mean DRF of 2.12±0.23 in the range of 1.82-2.29 was obtained when all the tube configurations and head rotations were considered.

Table 3-3. Dose at the left eye level normalized to DAP measured with and without eyewear in the absence of a ceiling-suspended lead screen. The table also presents the DRF at different tube angulations.

Tube configurations		***Normalized Dose (µGy Gy^{-1}cm^{-2})***		***DRF***
Frontal	**Lateral**	**Without eyewear**	**With eyewear**	
AP	*LAO 90*	3.68±0.17	2.15±0.33	1.82±0.25
RAO 30	*LAO 45, Caudal 25*	2.54±0.08	1.09±0.19	2.54±0.08
RAO 50, Caudal 15	*LAO 45, Cranial 25*	2.13±0.01	0.94±0.16	2.23±0.54
RAO 30, Cranial 30	*LAO 60*	3.23±0.62	1.64±0.23	2.29±0.23
RAO 30 (30 f/s)	*LAO 60 (30f/s)*	2.52±0.29	1.25±0.25	2.25±0.14

Table 3-4 shows the results of the Student t-test that was used to determine whether there is any significant difference in DRFs obtained through measurements with and without the use of the ceiling-suspended screen. The results show no significant difference in the two means with $p>0.05$.

Table 3-4. Results of a comparison test performed with t-Test: Paired two sample for means.

t-Test: Paired Two Sample for Means

	Without leaded screen	*With leaded screen*
Mean	2.1	2.1
Variance	0.1	0.1
Observations	6.0	6.0
Pearson Correlation	0.31	
Hypothesized Mean Difference	0.0	
df	5.0	
t Stat	0.2	
P(T<=t) one-tail	0.4	
t Critical one-tail	2.0	
P(T<=t) two-tail	0.9	
t Critical two-tail	2.6	

3.6 Discussion

Concerning the results obtained in the absence of the ceiling-suspended screen, a trend in DRFs at the three head rotations is observed in Figure 3-7. The lowest protection efficacy of the tested eyewear, as seen on the graph, is observed with the head phantom angled at -45^0, that is, when facing the patient phantom. The highest DRF is obtained when the head is orientated away from the tubes for all the tube projections. This observation was however not expected and is not in accordance with the published data (Bolomey et al., 2016; Sturchio et al., 2013; van Rooijen et al., 2014). These phantom studies report the highest DRFs obtained with the head phantom facing the patient phantom. The observation in the referenced studies is because with the head facing

towards the source of radiation, the eyewear tends to attenuate more radiation due to the larger surface area of the lens in front of the eyes.

The trend as seen in this study cannot be confidently attributed to any particular factors. However, noting that the studies referenced herein were conducted using monoplane fluoroscopic systems, it is plausible to surmise that the difference in the results of the current study and the published data could be due to differences in the experimental equipment. Bolomey et al. (2016) tested the protective efficacy of four commercially available leaded eyewear. The results of the study show that for all the glass models, the highest DRFs were obtained with the head phantom oriented towards the patient phantom when a monoplane system was used. However, the same study reports different observations when a biplane system is used, with 50% of the eyewear tested providing better protection with the head facing away from the phantom. These results and the results of the current study suggests that the type of fluoroscopic units used, monoplane or biplane may have some level of influence on the DRFs of protective eyewear. Moreover, the variation in angular dependence of different dosimeters used in different studies could influence the results of different studies.

It is important to remember photons reaching the eye(s) when protective glasses are worn are not only those penetrating through the lens of the glasses and the direction of such photons from the source is an important factor to note because the efficacy of protective eyewear is partially subjected to the direction of radiation. Depending on the direction of the scatter radiation, some photons may slip under the gap between the face and the glasses, some may scatter from the operator's head in different directions towards the eye (in this case, the detector). The difference in the amount of radiation delivered by monoplane and biplane systems is known, with the biplane system reported delivering higher radiation doses (Sadick et al., 2010). However, the difference in dose distribution is not well documented and more research is required to help understand the dose distribution of monoplane and biplane imaging for defined tube configurations, particularly those selected during interventional procedures, which could explain the results presented here.

Another possible explanation of the results obtained in this study could be the design of the eyewear tested. The glass model has a side shield which, although small, still offers protection even when the head is rotated away from the source of radiation. Moreover,

the values obtained with the dosimeters behind the glasses were of the order of a few μSv, thus creating uncertainties in the calculated DRFs.

Considering the results of DRFs at the three head rotations in the presence of a ceiling-suspended screen (see Figure 3-7), the influence of the screen can be immediately seen. The opposite trend when compared to that observed in the absence of a protective screen is seen. Although it is evident that the use of a screen has some level of impact on the DRFs, the reason for the observation is difficult to attribute to a specific factor.

Regardless of the two different trends in DRFs seen in Figure 3-7, the study found no significant difference between mean DRF obtained in the presence and absence of the protective screen. Mean DRF of 2.14±0.27 in the range 1.67-2.39 is obtained by taking into account all the head orientations and tube angulations in the absence of lead screen. A mean DRF of 2.12±0.23 in the range of 1.82-2.29 was obtained in the presence of the lead screen. In other words, the efficiency of the tested eyewear remains the same whether the ceiling-suspended lead shielding is used or not. That is, the glasses will absorb approximately 50% of the incident scatter radiation.

The results of the mean DRF obtained in this study are in accordance with those obtained by Sturchio et al. (2013), who tested the efficacy of eyewear with lead equivalence of 0.07 mm and obtained a DRF of about 2. It should, however, be noted that the experimental equipment and methodology used in the referenced study and the current study are different and selected tube(s) configurations vary. Sturchio et al. (2013) also reported DRFs of other glass models with higher lead equivalence. The results showed that the glasses with higher lead equivalence offer better protection against stray radiation to the eyes during interventional procedures.

Lastly, the use of ceiling-suspended shielding has been shown to decrease dose at eye level by an average factor of ~4 (measured outside the protective glasses) across all tube angulations and head rotations. The results highlight the importance of correct use of all personal protective equipment (PPE) as much as possible to obtain optimal eye protection and to avoid reaching or exceeding the current dose limit to the eye.

3.7 Limitations of the study

The experimental set up of this study only represents the clinical setup at the Universitas Hospital, taking only the tube(s) angulations used at this hospital into consideration. This implies that the results obtained in this study would be most applicable to hospitals employing similar protocol as in the mentioned hospital. Moreover, this study was conducted using a biplane system, this means that the results of the study are not reproducible in facilities equipped with monoplane fluoroscopic systems only.

The study considered the head rotation in the horizontal axis only. During actual clinical procedures the operator head movement is dependent on the positioning of the monitor, this means during such procedures the operator will tilt his/her head up and down and in most cases will look at the monitor during exposures. Sturchio et al. (2013) demonstrated the influence of head rotation in the vertical axis, with the DRFs of different glass models decreasing with the head tilted upward. This implies that the results obtained in this study may overestimate the protection offered to the eyes by the tested protective eyewear.

Another limitation of the study is that, contrary to other studies, only the protection afforded to the left eye was explored.

3.8 Conclusion

The study found a small variation in DRFs of the leaded glasses for different head rotations. The study also found no significant difference in mean DRF of the tested eyewear obtained with and without the use of the ceiling-suspended screen. The study reports mean DRF of 2.14±0.27 (1.67-2.39) and 2.12±0.23 (1.82-2.29) in the presence and absence of the protective screen, respectively. The study shows the protective eyewear currently used at the Universitas Hospital offers less protection as compared to other glass models with higher lead equivalence as reported in the literature. It is therefore recommended that a new protective glass model with higher lead equivalence (0.5 mm or 0.7 mm) be purchased. The glasses should also have lateral protection and fit snugly on the wearer's face (this will, however, depend on the shape of the wearer's face)

for the optimal protection of the eyes. It is important to remember that there is a trade-off between the protection efficacy and comfort offered by glasses with higher lead equivalence. Glasses with higher lead equivalence tend to be heavier and less conformable for the wearer and this may discourage the use of such PPE. It is, therefore, important that the preferences of the operators are determined through communicating with them before purchasing the eyewear. This will help the users of such PPE to select goggles that will offer comfort and sufficient protection to their eyes at the same time. This study has also demonstrated the importance of the use of ceiling-suspended lead shield, with a dose reduction factor of ~4

In conclusion, this study has demonstrated the importance of the use of the available protective tools in interventional cardiology laboratories. These tools (leaded screen and goggles) have proven effective in reducing exposure to the eyes of intervetionalists. Good radiation protection practice, where these protective tools are appropriately and consistently used, is therefore strongly recommended. This is imperative in reducing the occupational exposure and mitigating the risk of developing radiation-induced cataracts.

Chapter 4 : Measurements of personal related dose metrics in real clinical conditions and evaluation of their correlation with patient-related dose metrics

4.1 Introduction

Eye dosimetry of medical staff, as discussed in chapter 2, has become imperative, particularly in high exposure environments such as in interventional cardiology laboratories. Interventional cardiologists are the most highly exposed professionals amongst other professionals in these departments due to their position relative to the patient during fluoroscopy-guided procedures. For this reason, interventional cardiologists are at higher risk of developing radiation-induced effects to the eye (cataract) than any other staff working in interventional cardiology. Therefore, developing new strategies to optimize the radiation protection of the eye is of great importance.

In light of the new dose limit and due to the previously expressed uncertainty surrounding the risk of cataracts as the result of prolonged exposure to ionizing radiation reduction, as discussed in Chapter 2, particular dose optimization strategies need to be adhered to avoid exceeding the annual limit and thus reduce the risks associated with occupational exposure (ICRP International Commission on Radiological Protection, 2007). This means that a good radiation protection culture, where available protection equipment in conjunction with radiation protection principles is used to obtain maximum protection, should be emphasized and occupational exposure should be appropriately monitored.

All medical staff working with radiation are required to wear a radiation dosimeter for a determined period (usually on a monthly rotation basis) to monitor their radiation exposure. This is a form of monitoring of the working environment or conditions to which an individual worker is exposed. In most hospitals around the world, passive dosimeters are issued to staff as official dosimeters to monitor their whole-body effective dose. In some countries, France for example, active personal dosimeters (APDs) are also required

by law to monitor occupational whole-body dose even though only passive dosimeter readings are used for official dose records (Ginjaume et al., 2006). However, there is still no clear method in place for estimating dose to the eyes of staff exposed to ionizing radiation.

As mentioned in Chapter 2, various methods for eye lens dose (ELD) estimation of interventional cardiologists have been suggested. The best and most practical way of estimating dose to the eye is by using a dosimeter calibrated in terms of H_p (3). The dosimeter should be placed as close as possible to the eye (Principi et al., 2015). However, dosimeters calibrated in this quantity are not readily available and the wearing of such dosimeters on a routine basis can prove to be time-consuming and uncomfortable for the doctors due to their size (Carinou et al., 2015). The use of a whole-body dosimeter located at other parts of the body, unshielded by the protective garment has been suggested as a substitute for assessing ELD.(Carinou et al., 2015). A study by Farah et al. (2013) reports the best correlation between the eye dose and left chest dose when CA and CA+PCI procedures are considered. Thus, the descriptive parameters in estimating occupational radiation dose in fluoroscopic examinations are mainly dose to the eyes of the personal and radiation dose to the chest. These doses can either be measured directly during a clinical examination or they can be estimated from patient-related dose metrics such as DAP or air kerma at a reference point.

This study aimed to develop methods that can be used to estimate eye equivalent from the available imaging parameter and whole-body equivalent dose measured at the chest level. The study also aimed to establish a method to estimate eye lens dose based on the workload of interventionalists.

To achieve the above-stated aims, the following objectives needed to be achieved:

- To measure the scatter radiation to the left eye of the operating doctor directly using an eye dosimeter
- To measure scatter radiation dose at the chest level of the operating doctor using a whole-body dosimeter
- To record the patient dose metrics (DAP and $K_{a,r}$) recorded and displayed at the end of a procedure by the fluoroscopic unit
- To evaluate the correlation between the eye dose and the whole-body dose

- To evaluate the correlation between the eye dose and the patient dose quantities (DAP and $K_{a,r}$)

4.2 Methods and Material

4.2.1 Ethical approval

Ethical approval to conduct the study was obtained from the Health Science Research Ethics Committee (UFS-HSD2018/0931/2711), University of the Free State. Permission to perform the study at the Universitas Hospital was obtained from the Free State Department of Health and the department of cardiology. All participants gave informed consent to be involved in the study.

4.2.2 Study population

The study included four doctors. The doctors included two qualified interventional cardiologists and two interventional cardiology registrars. All the doctors followed a similar radiation safety protocols and stood at similar positions during interventional procedures. Table 4-1 show the characteristics of the doctors involved in the study.

Table 4-1. The characteristics of the doctors.

Dr	*Years working with radiation*	*Height (m)*	*Use of protective eyewear*	*Use of protective screen*
Dr.A	±3	1.78	Yes	Yes
Dr.B	±4	1.68	Yes	Yes
Dr.C	±1	1.66	Yes	Yes
Dr.D	±29	1.65	Yes	Yes

4.2.3 Fluoroscopy unit

All measurements were carried out in the catheterization laboratory at the Universitas Hospital, Bloemfontein. The catheterization laboratory is equipped with a Phillips (Allura X-Per FD 10/10) biplane system with a flat panel detector (FPD) system. The system employs an automatic exposure control (AEC) which selected imaging parameters (kV, mAs, etc.) automatically based on the patient's anatomical features. The pulse sequence

of the unit offers a range of 3.75 to 30 frames per second (fps) for fluoroscopic modes. For cine acquisition, two available options are 15 and 30 f/s. Appropriate modes were selected to best suit the procedures in hand and doctor preference.

Tubular angulations were selected during each procedure. These projections are recorded by the unit and stored on the computer. Typical projections in succession from start-to-end of most typical procedures in this setting, as observed during preliminary data collection, are presented in Table 4-2.

Table 4-2. Typical projections selected for normal coronary angiography and intervention.

	Rotations	*Angles (degrees)*
Frontal tube	RAO 30	0
	RAO 30	0
	RAO 50	Caudal 15
	LAO 10	0
Lateral tube	LAO 60	0
	LAO 45	Caudal 25
	LAO 45	Cranial 25
	LAO 80	Cranial 25

However, the angulation can be varied extensively in some procedures to obtain optimal views of the patient's heart structure and arteries.

There is a range of selectable fields of view, however, 25×25 cm^2 is the commonly selected field of view in the adult catheterization laboratory. Other imaging parameters known to influence scatter radiation are recorded by the fluoroscopic unit and displayed on the in-room monitor and the computer in the control room during and after each procedure. The parameters include total acquired images, fluoroscopic time, air kerma ($K_{a,r}$) at a reference point and dose area product (DAP) readings.

$K_{a,r}$ is the measure of radiation dose in air at 15 cm from the isocentre and is used to monitor the patient dose. $K_{a,r}$ can, therefore, be used to predict the patient tissue reactions due to ionization radiation. DAP is a product of air kerma per unit area and field size, both measured at a particular distance. It is a surrogate measurement for the total radiation imparted onto a patient by both X-ray tubes throughout a fluoroscopically

guided procedure. It is usually measured by an ionization chamber integrated into the fluoroscopic system. Readings measured for each tube are recorded separately at the end of each procedure.

4.2.4 Description of dosimeters used in the study

4.2.4.1 Whole-body dosimeter

Polimaster PM1610 active dosimeters (http://www.rugift.com/polimaster-pm1610-gamma-radiation-personal-dosimeter-geiger-counter.php) were used to measure scatter radiation at the chest level of the operating doctor. The dosimeter is the energy-compensated GM counter. It measures the dose equivalent (DE) and dose equivalent rate (DER) by converting photon radiation quanta into electric pulses. The dosimeter is designed for monitoring and measuring the personal dose equivalent H_p (10) and personal dose equivalent rate from both gamma and X-ray radiation.

The dosimeter is capable of measuring radiation with energies ranging from 0.02 to 10 MeV with an accuracy of ±20%. This adequately covers the range of energies encountered as a result of scatter in the catheterization laboratory (see section 2.9).

4.2.4.2 Eye dosimeter

Eye dosimetry was performed using an ED3 Active Extremity Dosimeter as described in section 3.2.3. Additionally, to its advantage of providing real-time dose measurement, the detector is small and is light in weight, this advantage made it to be easily attachable onto the frame of the protective eyewear.

4.2.5 Clinical setup for dose measurements

4.2.5.1 Location of clinical staff relative to the Patient

A schematic representation of the set-up in the catheterization room is demonstrated in Figure 4-1. The sketch of typical working positions of staff during most common procedures. Staff, particularly first operators, may be required to occupy different positions based on the nature of the procedure being carried out.

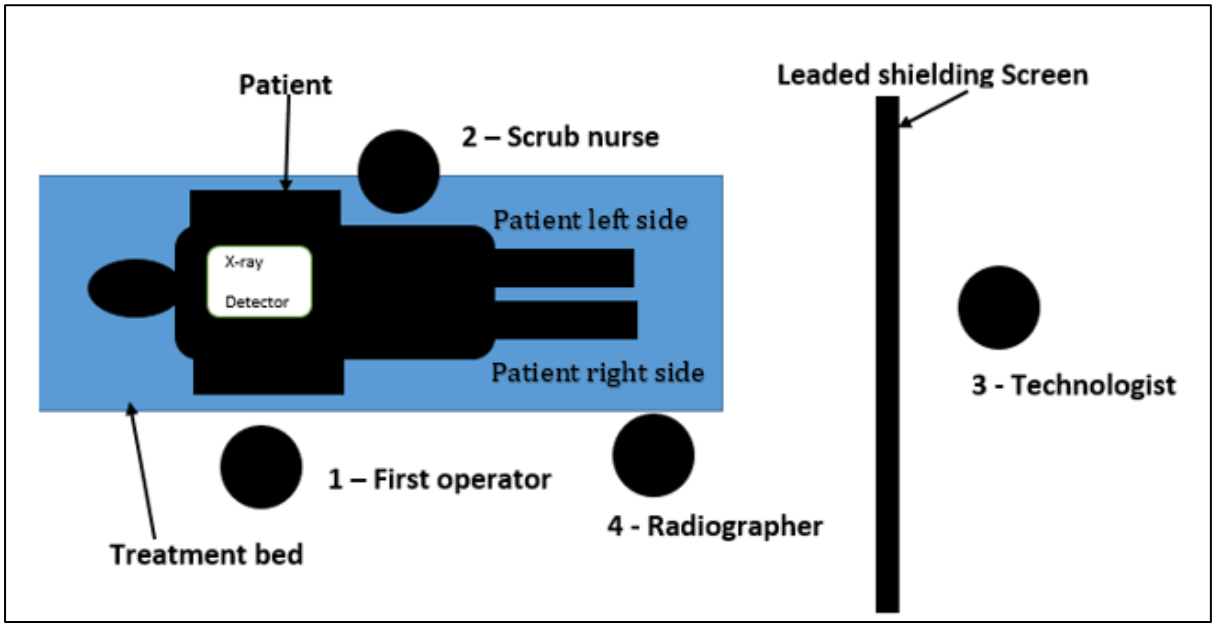

Figure 4-1 Schematic representation of the set-up and positions of medical staff during a fluoroscopy-guided procedure.

4.2.5.2 Placement of the dosimeters

Figure 4-2 demonstrates the placement of the two types of dosimeters on operating doctors during procedures. The figure demonstrates the attachment of the eye dosimeter adjacent to the left eye and the attachment of the whole-body dosimeter at the chest level outside the lead apron.

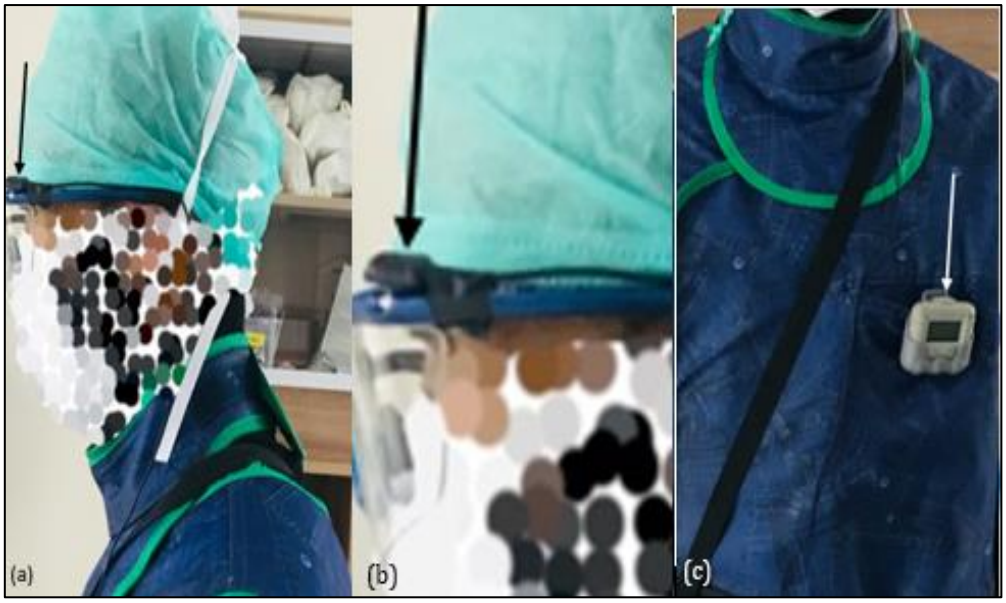

Figure 4-2 Placement of the dosimeters on the doctor during a procedure. (a) Shows the attachment of the dosimeter adjacent to the left eye. (b) Close up image of the attached dosimeter. (c) Demonstrate the position and the attachment of the chest dosimeter.

4.2.6 Data collection

Data were collected for three months, during which 127 procedures were monitored. The procedures for which data was collected included: Diagnostic, coronary angiography (CA) and therapeutic, percutaneous coronary intervention (PCI). Therapeutic procedures included both CA and PCI, that is, a decision to intervene was only made after a diagnosis was made. It is acknowledged that PCI procedures can vary substantially due to their relative complexity, however, no categories were created to account for degrees of complexity of different intervention procedures.

Pacemaker implantation (PI) procedures were also monitored. However, data collected for these procedures was insufficient to produce meaningful statistics required and make a valid inference. The results of the PI procedures will thus not be presented in this work.

4.2.7 Personal dosimetric data collection

A common protocol was established for data collection for all the interventional procedures performed during the project. Each doctor was issued an alarm dosimeter

and an eye dosimeter throughout the course of the study. Since the two dosimeters used in this study were both active dosimeters, they offered the opportunity to measure and analyse the radiation received during each procedure separately.

The eye dosimeter was attached on the outside of the left side of the goggle's fame during each monitored procedure as demonstrated in Figure 4-2 (a). The decision to place the dosimeter on the outside of the protective eyewear was because it would provide considerable discomfort to the doctor and obstruct his/her view when placed inside the glasses. The dosimeter was placed adjacent to the left eye because it is the most exposed eye due to its proximity to the X-ray tubes. The eye dose measured during each procedure was recorded and the dosimeter was reset before being issued for another procedure.

The whole-body dose was measured with a dosimeter placed at the chest level as demonstrated in Figure 4-2 (c). All the doctors who participated in the study wore wrap-around protective aprons. All aprons had pocket on the left chest level, the dosimeter was therefore easily attached on to the pocket. The dosimeter measured cumulative dose and could not be reset after every procedure. To obtain the dose measured for a single procedure, the dose measured for a previously performed procedure was subtracted from the latter procedure to obtain the radiation dose of the latter procedure.

The researcher was present during all the monitored procedures to ensure that the dosimeters used in the study were switched on and properly functioning before the start of every procedure. Furthermore, it was important for the researcher to be present to ensure that the dosimeters were properly positioned during every procedure.

4.2.8 Fluoroscopic output data collection

The patient dose metrics, that is, the total DAP and $K_{a,r}$ were recorded and stored on the computer in the control room after every procedure. This information was collected and related to corresponding staff doses. Data on the fluoroscopic time, number of cine runs and images, tube angulations, kV and mAs were also gathered and entered into a spreadsheet.

4.3 Statistical analysis

Summary and descriptive statistics were performed with Windows Microsoft Excel 2016 (Microsoft Corporation, USA) data analysis tool. The results are presented as Mean±SD, range, and median. The difference in average dose among doctors was evaluated using a bar chart. Statistical significance between two variables was performed with a t-test: two-sample assuming unequal variances. The distribution of eye dose normalized to patient dose and the dose measured at the chest was demonstrated with box and whiskers diagrams. Moreover, normalized eye dose for the different doctors was compared using box and whiskers diagrams. Correlation between the eye dose and the dose measured at the chest of the interventionalists was evaluated with linear regression. Linear regression was also used to evaluate the correlation between eye dose and patient dose. Correlation between the available parameters (DAP and $K_{a,r}$), and the chest dose and eye dose were considered poor if the R^2 values were between 0.3 and 0.5. A correlation was considered good with R^2 values between 0.5 and 0.7 and excellent between 0.7 and 1. Statistical significance was defined as $p < 0.01$.

4.4 Results

4.4.1 Summary statistics of dose per procedure

Table 4-3 presents the summary of left eye dose (eye dose mentioned herein refers to dose readings made on the frame of the protective eyewear; the dosimeter was thus not shielded by the lead glass of the eyewear) per CA procedure. Table 4-3 also presents the summary statistics of procedural information such as fluoroscopy time and the number of cine images per procedure. The results are presented separately for each doctor. Similarly, the summary results of measured left eye dose per CA+PCI procedure together with the procedural information are presented in Table 4-4.

Table 4-3. Summary statistics of left eye dosimetry measurements per diagnostic (CA) procedure for the four doctors.

DR	*Sample (N)*	*Eye dose (μSv) Mean±SD (range) median*	*Fluoroscopic time (min) Mean±SD (range) median*	*Number of cine images (N) Mean±SD (range) median*
Dr.A	22	163.1±85.3 (26.9-371) 164.5	2.5±1.5 (1.4-7.1) 2.1	1061.1±358.4 (298-1730) 1107
Dr.B	13	188.6±118.1 (38.6-413) 161	3.7±2.3 (1.3-16.4) 2.5	1227.7±447.9 (732-2156) 978
Dr.C	38	191.4±129.6.9 (9.1-539) 175.9	5.9±6.9 (0.9-32.7) 3.7	1098.5±480.4 (256-2141) 1100
Dr.D	18	246.7±82.8 (121.4-412.0) 225.5	4.2±3.2 (1.7-16.1) 3.6	1157.3±261.3 (622-1556) 1136
All Drs	91	195.1±112 (9.1-539) 179.3	4.4±5.1 (0.9-32.7) 2.83	1118.2±407.4 (256-2156) 1110

Table 4-4. Summary statistics of left eye dosimetry measurements per therapeutic (CA+PCI) procedure for the four doctors

DR	*Sample (N)*	*Eye dose (μSv) Mean±SD (range) median*	*Fluoroscopic time (min)) Mean±SD (range) median*	*Number of cine images (N) Mean±SD (range) median*
Dr.A	5	420.8±172.9 (202-590) 507	10.6±7.1 (3.2-20.9) 8.5	2425.2±850.8 (1520-3346) 2662
Dr.B	5	636.2±259.2 (379-1002.0) 596	19.8±8.2 (7.6-26.2) 25.1	3741.6±1809.3 (1990-5827) 2857
Dr.C	17	293.7±152.1 (19.2-580) 257.0	13.7±6.9 (2.2-25.7) 14.4	2189.6±703.5 (860-3296) 2090
Dr.D	9	425.4±160.7 (168.3-701.0) 459.0	11.9±5.8 (6.4-23.4) 9.02	1998.9±448.8 (1168-2638) 1984
All Drs	36	391±202.9 (19.2-1002) 395	13.7±7.1 (2.2-26.2) 13.7	2335.4±977.4 (1168-5827) 2202

It is important to note that taking the average left eye dose measured for all procedures, (CA and CA+PCI) to report a mean left eye dose per interventional cardiac procedure may contribute to uncertainties because the mean left eye dose of measurements taken during CA procedures varies significantly to that of CA+PCI procedures. This difference is indicated in Table 4-5*.*

Table 4-5. Comparison of dose measured per CA and CA+PCI procedure using t-test: two-sample assuming unequal variance

t-Test: Two-Sample Assuming Unequal Variances

	CA	*CA+PCI*
Mean	195.1	391.8
Variance	12552.8	41187.8
Observations	91	36
Hypothesized Mean Difference	0	
df	44	
t Stat	-5.5	
P(T<=t) one-tail	9.3×10^{-7}	
t Critical one-tail	1.7	
P(T<=t) two-tail	1.8×10^{-6}	
t Critical two-tail	2.0	

4.4.2 Comparison of dose quantities per procedure among doctors

Figure 4-3 shows the comparison of the mean left eye dose measured for each doctor during diagnostic and therapeutic procedures.

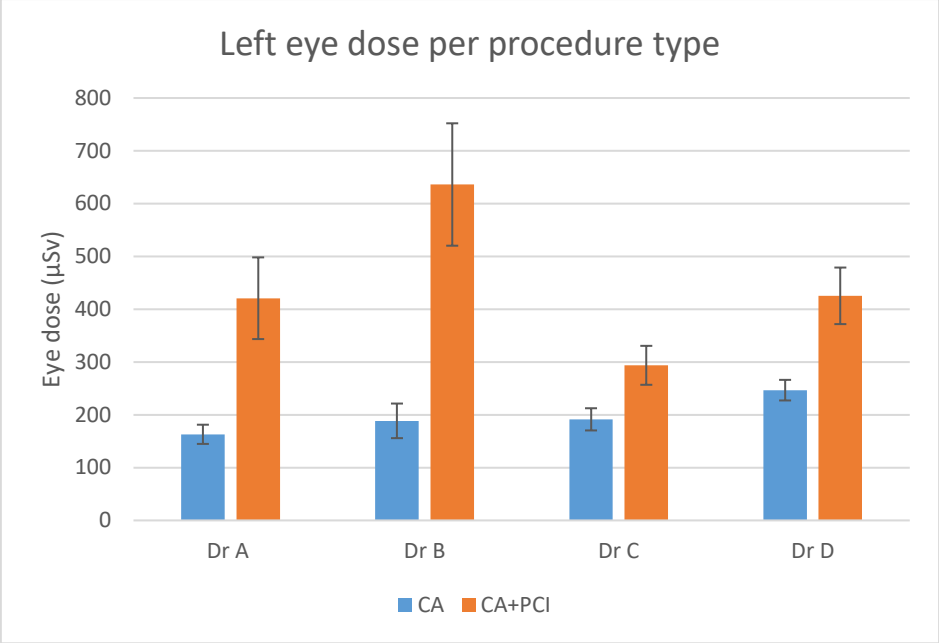

Figure 4-3. Comparison of left eye dose quantities per procedure type among the four doctors.

Figure 4-4 shows the comparison of mean left chest dose measured outside the leaded protective apron among the four doctors. The comparison is made for both diagnostic and therapeutic procedures.

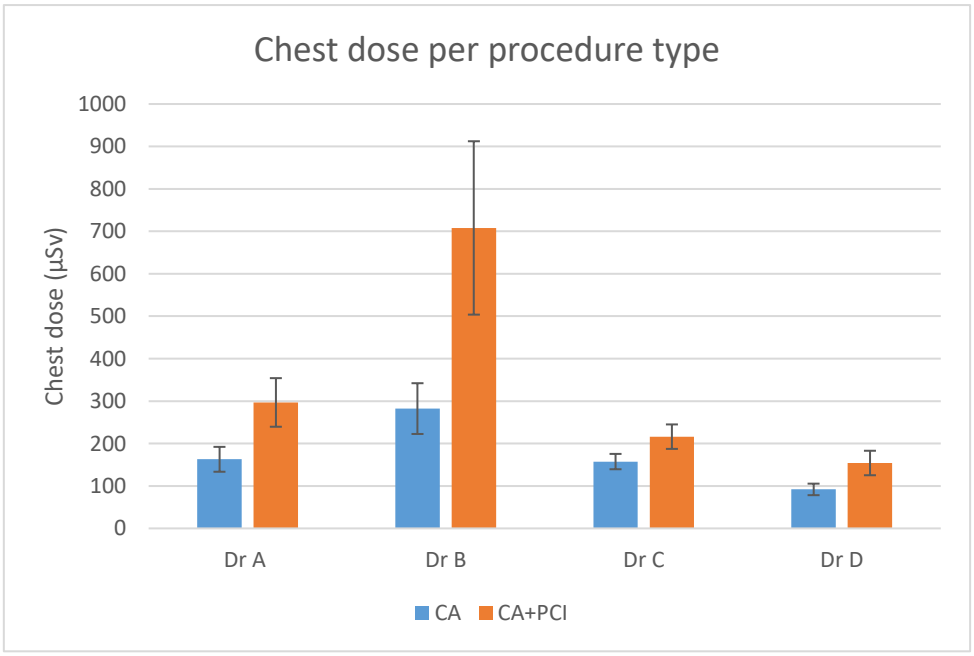

Figure 4-4. Comparison of chest dose procedure type among the four doctors.

Figure 4-5 shows the comparison of mean DAP among the doctors. The comparison is made separately for diagnostic and therapeutic procedures.

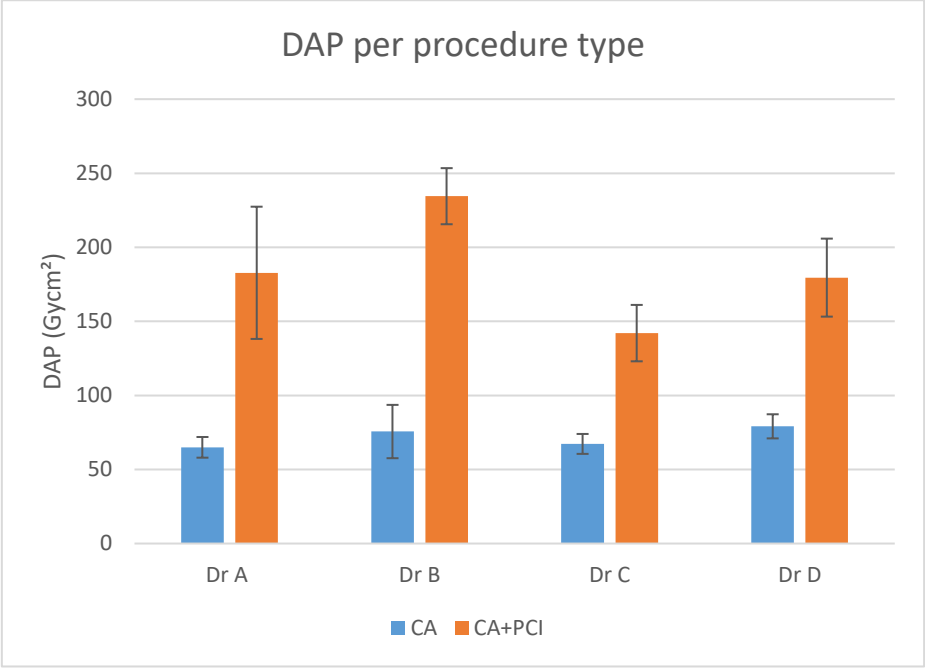

Figure 4-5. Comparison of DAP per procedure type among the four doctors.

Figure 4-6 shows the comparison of mean Ka,r among the doctors. The comparison is made separately for diagnostic and therapeutic procedures.

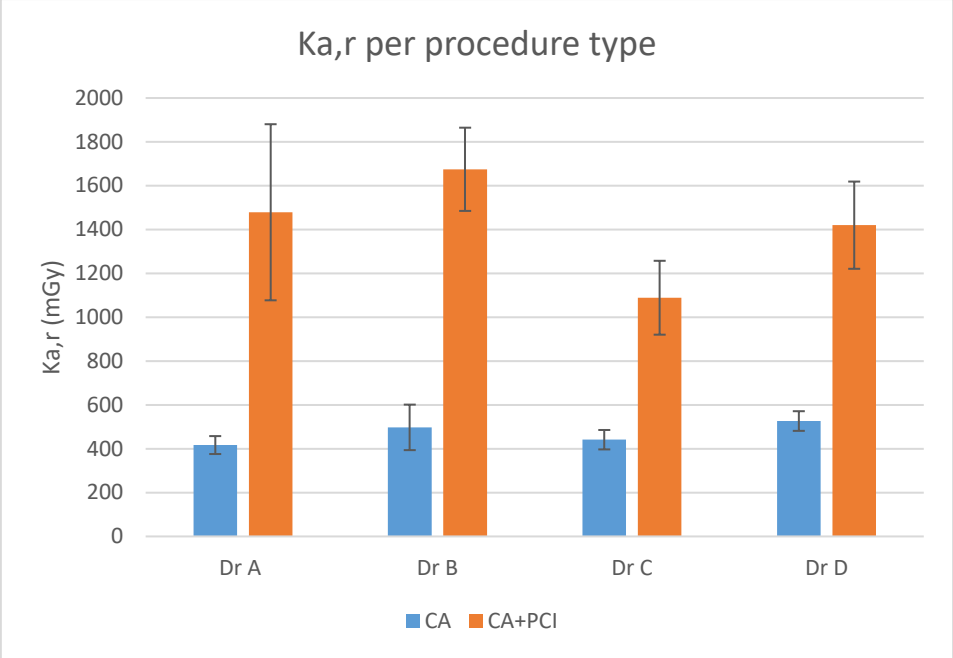

Figure 4-6. Comparison of Ka,r per procedure type among the four doctors.

4.4.3 Summary statistics of eye dose values normalized to patient dose and chest dose

Table 4-6 shows the results of the dose measured for four doctors. The results are presented as left eye dose normalized to DAP, $K_{a,r,}$ and over-apron left chest measurements. Similarly, Table 4-7 shows the results of all the CA and CA+PCI procedures performed by all the doctors combined.

Table 4-6. Eye doses of all the cardiologists measured on the left eye during both diagnostic (CA) and therapeutic (CA+PCI) procedures normalized to patient doses (DAP and Ka,r) and the dose measured above lead apron.

DR	*Procedure*	*Sample (N)*	*Eye dose/DAP ($\mu SvGy^{-1}cm^{-2}$) Mean±SD (range) median*	*Eye/K_{IRP} ($\mu SvmGy^{-1}$) Mean±SD (range) median*	*Eye dose/Hp(10) Mean±SD (range) median*
Dr.A	CA	22	2.6±0.8(0.8-4.0)2.6	0.4±0.1(0.1-0.6)0.4	1.1±0.4(0.4-1.7)1.2
	CA+PCI	5	2.6±0.8(1.8-3.8)2.4	0.3±0.2(0.2-0.6)0.3	1.7±0.8(0.8-2.9)1.6
	All procedures	27	2.6±0.8(0.8-4.1)2.6	0.4±0.1(0.1-0.6)0.4	1.2±0.5(0.5-2.9)1.1
Dr.B	CA	13	2.8±1.0(0.7-4.3)2.9	0.4±0.2(0.1-0.6)0.5	0.9±0.6(0.4-2.4)0.7
	CA+PCI	5	2.8±1.1(1.5-4.6)2.7	0.4±0.1(0.3-0.6)0.3	1.2±0.8(0.4-2.4)1.1
	All procedures	18	2.7±1.0(0.7-4.6)2.7	0.4±0.2(0.1-0.6)0.4	1.0±0.6(0.4-2.4)0.8
Dr.C	CA	38	3.1±1.7(1.5-9.7)2.5	0.5±0.3(0.2-2.0)0.4	1.6±1.1(0.4-5.9)1.3
	CA+PCI	17	2.3±1.2(0.3-4.6)2.3	0.3±0.2(0.1-0.8)0.3	1.7±1.0(0.6-4.0)1.7
	All procedures	55	2.8±1.6(0.3-10.0)2.5	0.4±0.3(0.1-2.0)0.4	1.6±1.1(0.4-5.9)1.3
Dr.D	CA	18	3.4±1.1(1.9-6.4)3.4	0.5±0.6(0.3-0.9)0.5	4.2±3.3(0.911.5)3.2
	CA+PCI	9	2.5±0.7(1.5-3.7)2.5	0.3±0.1(0.5-2.8)0.3	3.8±2.3(1.6-8.4)2.8
	All procedures	27	3.1±1.1(1.5-6.4)2.8	0.4±0.2(0.-20.9)0.4	4.1±3.0(0.9-11.5)3.0

Table 4-7. Eye doses of all the cardiologists measured on the left eye during all the monitored procedures normalized to patient doses (DAP and Ka,r) and the dose measured above lead apron

Procedure	*Sample (N)*	*Eye dose/DAP ($\mu SvGy^{-1}cm^{-2}$) Mean±SD (range) median*	*Eye/ K_{IRP} ($\mu SvmGy^{-1}$) Mean±SD (range) median*	*Eye dose/Hp(10) Mean±SD (range) median*
CA	91	3.0±1.3(0.7-9.7)2.8	0.5±0.2(0.1-2.0)0.4	1.9±2.0(0.4-11.5)1.3
CA+PCI	36	2.4±0.9(0.3-4.6)2.3	0.3±0.2(0.1-0.8)0.3	2.6±1.9(0.4-8.4)2.2
All procedures	127	2.8±1.3(0.3-9.7)2.6	0.4±0.2(0.1-2.0)0.4	1.9±1.9(0.4-11.5)1.4

The following Box and Whisker plots diagrams (Figure 4-7, 4-8 and 4-9) provide visualization of the data of doses measured near the left eye normalized to patient dose

(DAP and $K_{a,r}$) and dose measured on the left chest level. From Figure 4-7, 4-8 and 4-9, the minimum, first quartile, median, third quartile, and the maximum values are depicted. The mean data are also included. The spread of data is indicated by the space between the different parts of the box as well as the length of the box.

The diagrams also indicate the normality and skewness of the presented data as well as an indication of data to be considered as outliers.

The diagrams further provide a non-pragmatic comparison approach of the data obtained for the doctors. Figure 4-7 displays the results of the eye dose normalized to DAP. Figure 4-8 shows the results eye dose normalized to $K_{a,r}$. Results of eye dose measurements normalized to chest dose measurements are presented in Figure 4-9.

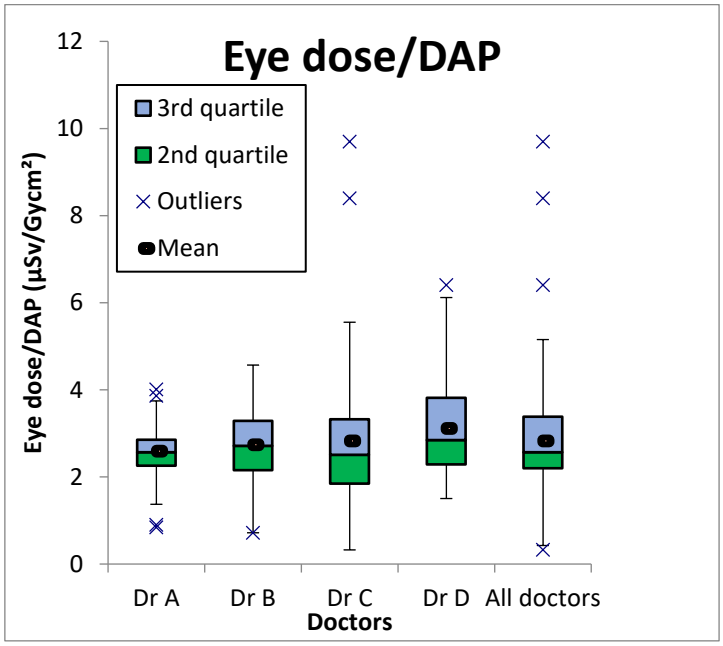

Figure 4-7. Boxplot of eye dose to DAP ratio. The boxplot shows the distribution of the ratio values for four doctors separately for all the procedures performed (diagnostic and therapeutic). Data for all the doctors combined is reported.

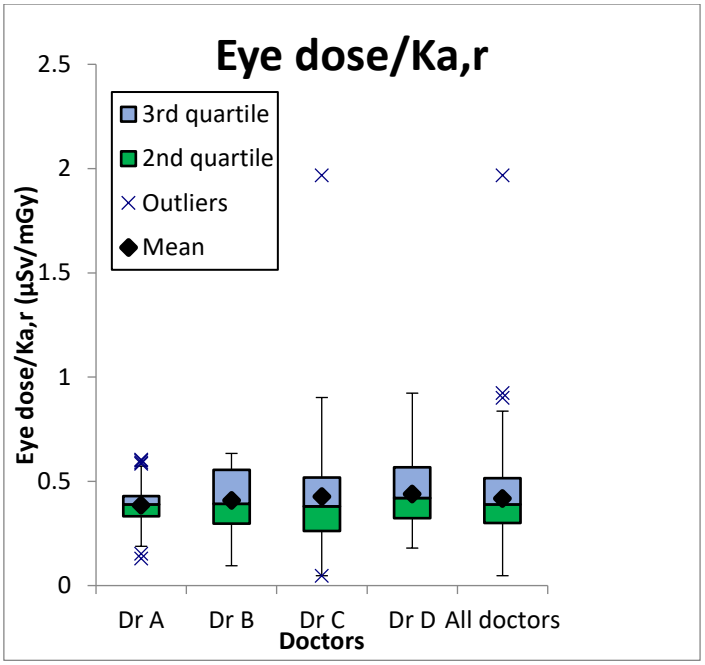

Figure 4-8. Boxplot of eye dose to Ka,r ratio. The boxplot shows the distribution of the ratio values for four doctors separately for all the procedures performed (diagnostic and therapeutic). Data for all the doctors combined is reported.

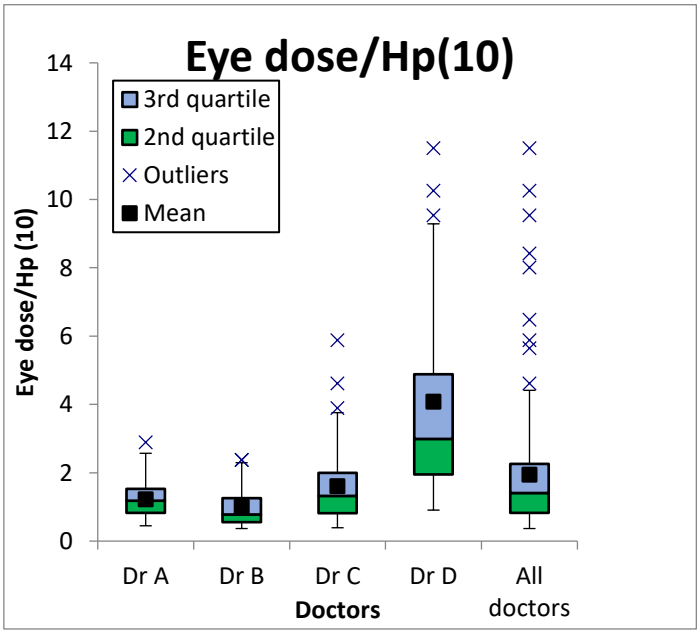

Figure 4-9 Boxplot of eye dose to chest dose ratio. The boxplot shows the distribution of the ratio values for four doctors separately for all the procedures performed (diagnostic and therapeutic). Data for all the doctors combined is reported.

4.4.4 Correlation between eye dose and patient dose and chest dose

The correlation between DAP and dose measured at the left eye for four doctors is shown in Figure 4-10. (a), (b), (c) and (d) shows the correlation results of Dr. A, Dr. B, Dr. C, and Dr. D, respectively. The dotted lines represent the 95 % confidence interval for the fitted regression line and the solid lines represent the 95 % confidence interval for the predicted points. Excellent correlation was found between eye dose and DAP for all the operating doctors with the R^2 values of 0.88, 0.80, 0.70 and 0.78 for Dr. A, Dr. B, Dr. C, and Dr. D, respectively. This correlation between eye dose and DAP is significant with the value of $p<0.01$ for all doctors. The graphs further demonstrate the consistency in the correlation factors by comparing the results of each doctor separately.

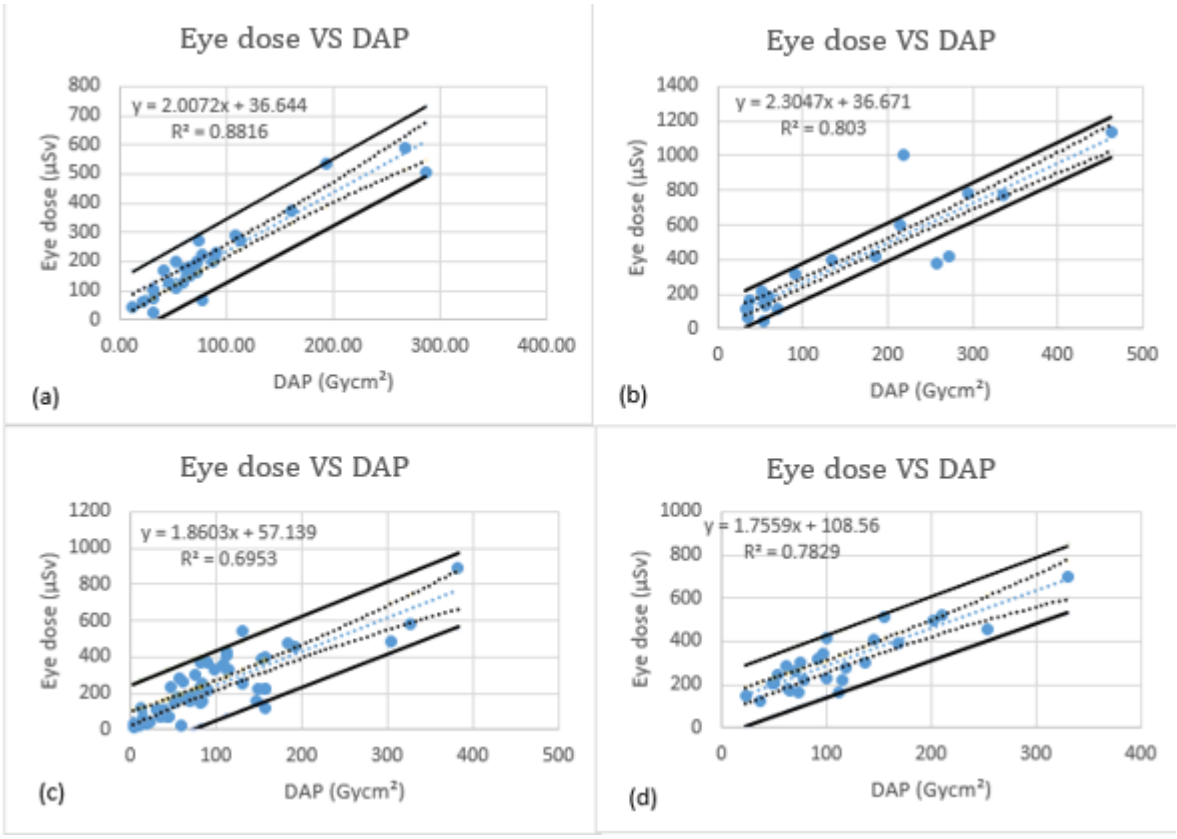

Figure 4-10. Correlation between DAP(x) and left eye (y) dose for four doctors. (a) Dr A (R^2=0.88, p < 0.01), (b) Dr B (R2=0.80, p<0.01). (c) Dr C (R2=0.69, p<0.01). (d) Dr D (R2=0.78), p<0.01). Dashed line: 95% confidence interval, Solid line: 95% prediction interval.

Figure 4-11 demonstrates the results of the correlation between $K_{a,r}$ and left eye doses for four operating doctors. Excellent correlation was found between $K_{a,r}$ and left eye dose for all the doctors with R^2 values of 0.84, 0.85, 0.53 and 0.72 for Dr. A, Dr. B, Dr. C, and Dr. D, respectively. The correlation between the aforementioned quantities is significant with the values of $p<0.01$ for all the doctors.

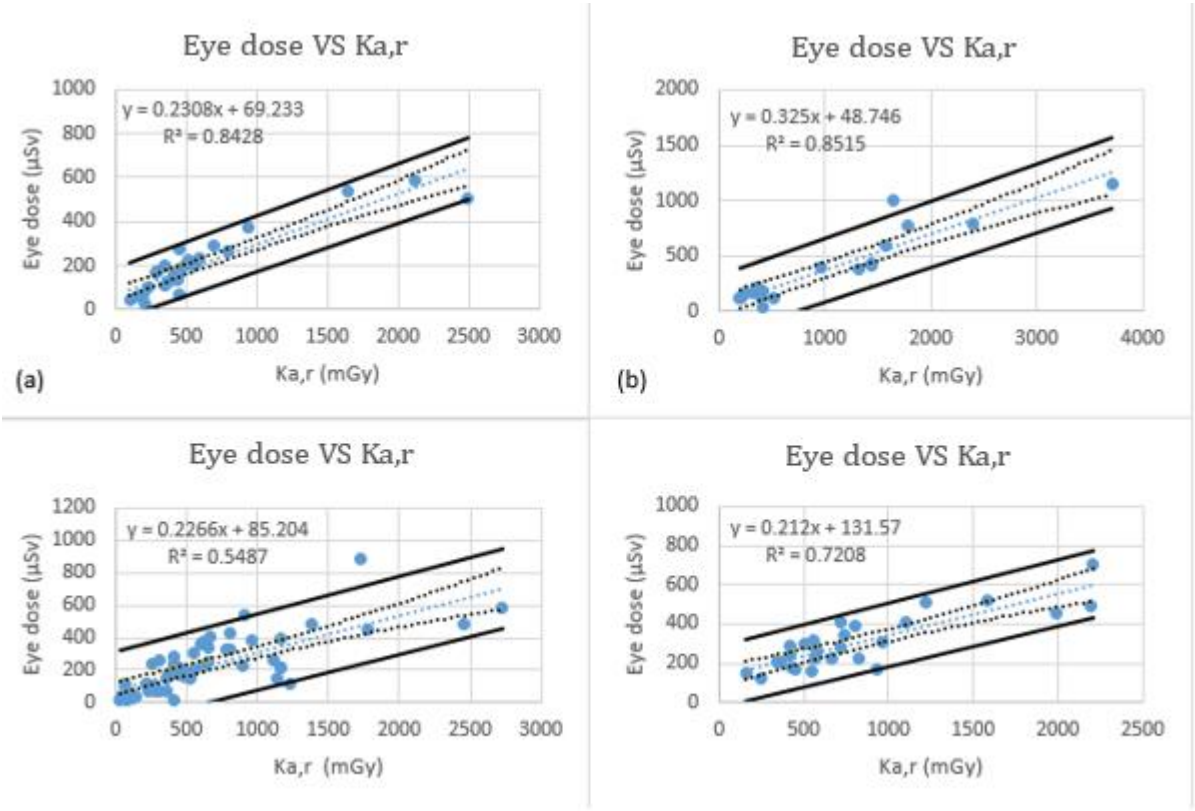

Figure 4-11. Correlation between Ka,r (x) and left eye dose (y) for four doctors. (a) Dr A (R^2=0.84, p < 0.01), (b) Dr B (R2=0.85, p<0.01). (c) Dr C (R2=0.55, p<0.01). (d) Dr D (R2=0.72), p<0.01). Dashed line: 95% confidence interval, Solid line: 95% prediction interval

Correlation between doses measured over the protective garment at the chest level and doses measured at the left eye is illustrated in Figure 4-12. A weaker but statistically significant ($p<0.01$) correlation between the aforementioned dose quantities is obtained for doctors. The R^2 for Dr. A, Dr. B, Dr. C, and Dr. D, are 0.48, 0.55, 0.53 and 0.34, respectively.

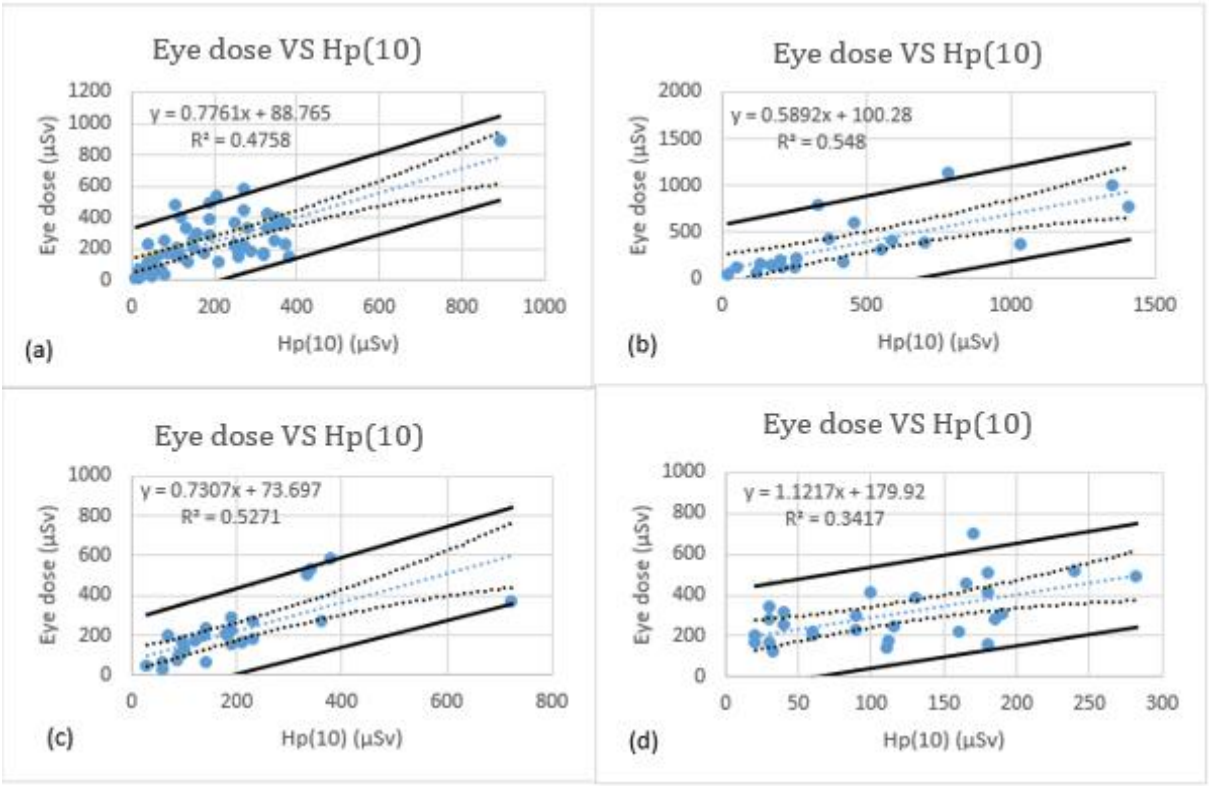

Figure 4-12. Correlation between chest dose (x) and left eye dose (y) for four doctors. (a) Dr A (R^2=0.46, $p < 0.01$), (b) Dr B (R^2=0.55, $p<0.01$). (c) Dr C (R^2=0.53, $p<0.01$). (d) Dr D (R^2=0.34), $p<0.01$). Dashed line: 95% confidence interval, Solid line: 95% prediction interval.

Correlation statistics were further carried out to explore the correlation between the left eye dose and patient dose when all the procedures are combined. Correlation between the eye dose and DAP was explored. Figure 4-13 illustrates the correlation between the DAP and eye dose. As expected, an excellent correlation is obtained with the R^2=0.78 and p<0.01.

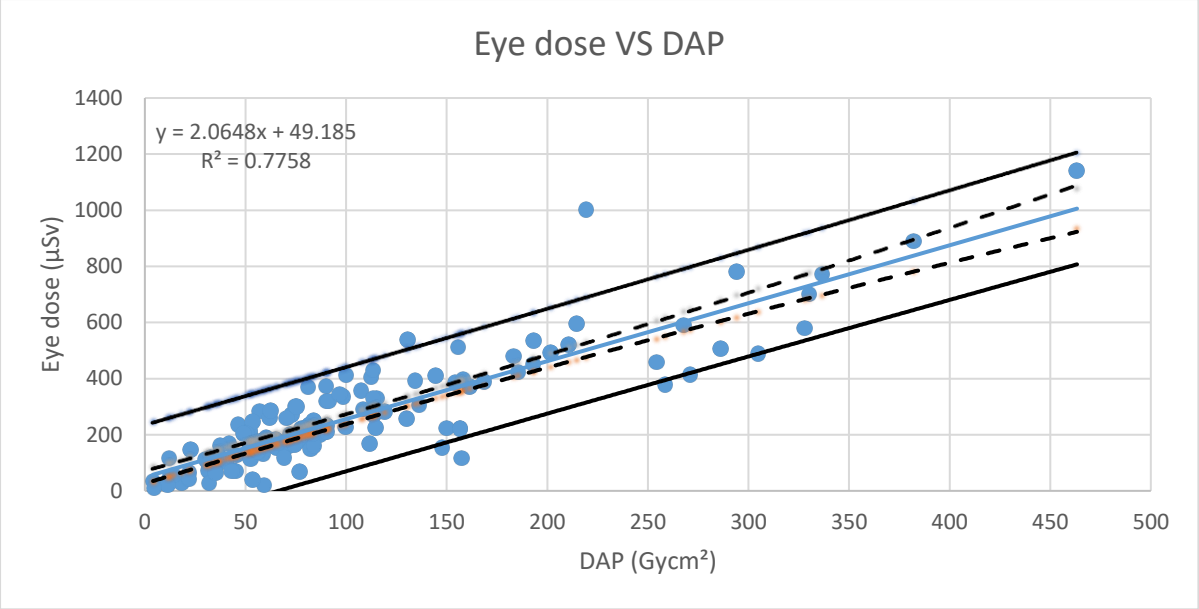

Figure 4-13. The correlation between dose area product (DAP) (x) eye dose (y) when all the procedures are considered (R^2=0.78, p < 0.01). Dashed line: 95% confidence interval, Solid line: 95% prediction interval.

The relationship between $Ka_{,r,}$ and dose measured at the left eye is illustrated in Figure 4-14. An excellent correlation is seen between the above-mentioned variables with R^2=0.72 and p<0.01.

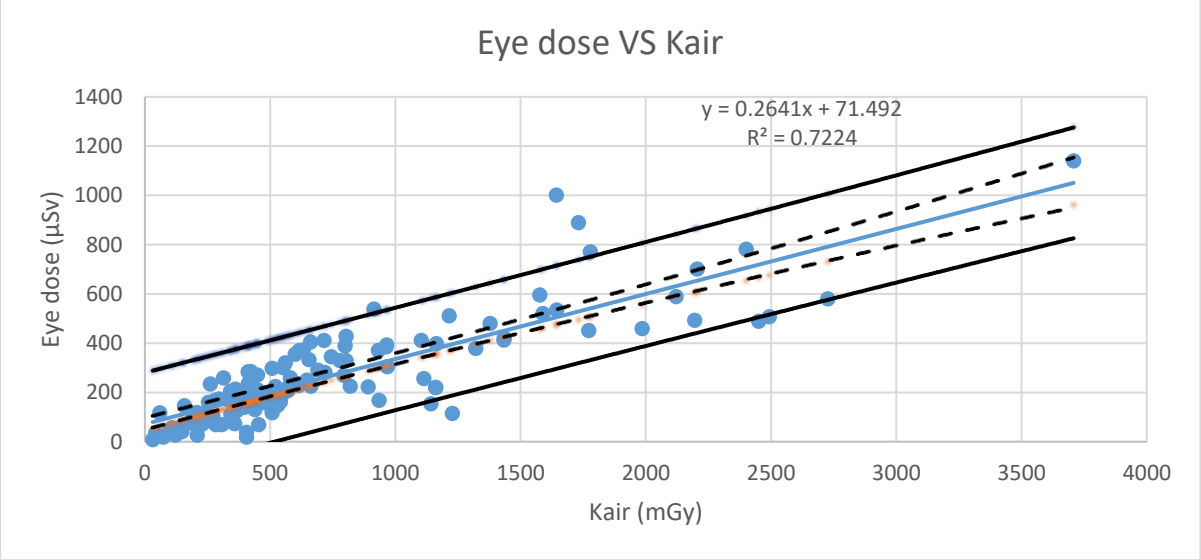

Figure 4-14. Correlation between air kerma(x) and eye dose(y) at the reference point (Ka,r) when all the procedures are considered (R^2=0.72, p < 0.01). Dashed line: 95% confidence interval, Solid line: 95% prediction interval.

Figure 4-15 illustrates the relationship between dose measured at the chest level and left eye dose. A weak but significant correlation exists between the two parameters with R^2=0.45 and p<0.01).

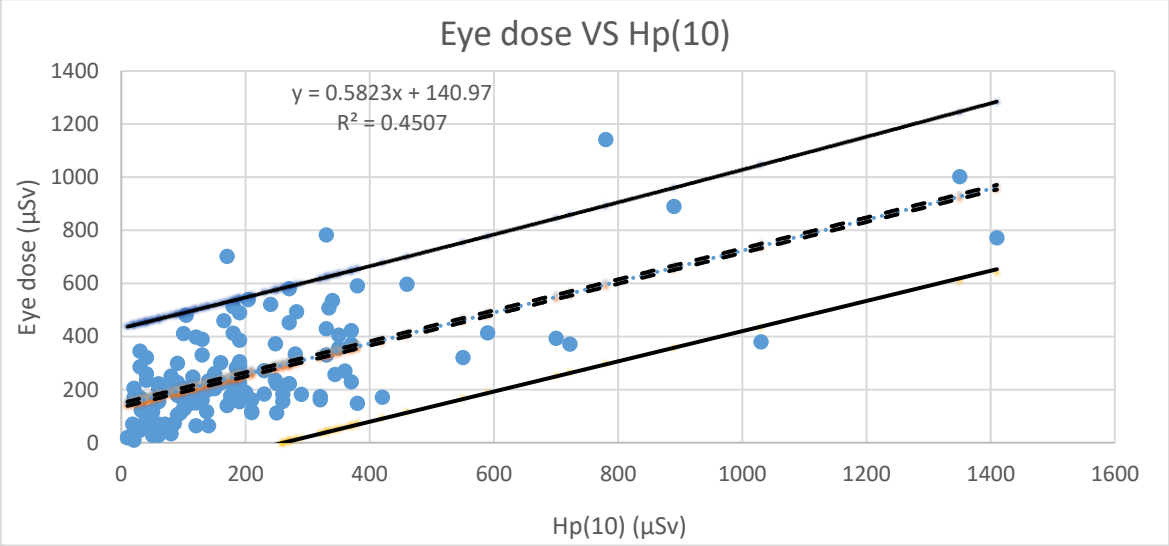

Figure 4-15. Correlation between chest dose (x) and eye dose (y) for all the procedures (R^2=0.45, p < 0.01). Dashed line: 95% confidence interval, Solid line: 95% prediction interval.

4.5 Dose estimation model

The following equations are formulated based on the ratio of ELD to DAP, $K_{a,r}$ and chest dose. The ratios are presented in Table 4-7. Equation 4-1 provides a means of estimating eye dose based on DAP values. The total DAP included in the equation is determined by summing the DAP values of all the CA and CA + PCI procedures performed in a year.

$$D_{Eye} = \frac{1}{k_i} \times 2.8 \sum DAP \qquad (4\text{-}1)$$

Were the factor k_i is a coefficient factor that takes into account the attenuation of protective eyewear. k_i , will, as expected depend on the type of protective eyewear being used as different models provide different radiation attenuation.

Equation 4-2 provide means estimating left eye dose based on values of $K_{a,r.}$ similarly to DAP in equation 4-1, the total $K_{a,r}$ is also determined by summing the $K_{a,r}$ values of all the CA and CA + PCI procedures performed in a year

$$D_{Eye} = \frac{1}{k_i} \times 0.4 \sum K_{a,r} \tag{4-2}$$

Equation 4-3 provides means of estimating left eye dose based on the dose measurement at the left chest level of ICs.

$$D_{Eye} = \frac{1}{k_i} \times 1.9 \sum D_{chest} \tag{4-3}$$

Where the coefficient factor k_i is similar to those in Equation 4-1 and 4-2.

4.6 Error calculation

Considering eye dose estimation from DAP and $K_{a,r}$ values using equation 4-1 and 4-2, uncertainty in the calculated values can arise from three sources of error, that is, uncertainty in measurement accuracy of the eye dosimeter of ±12.5%, error from angular dependency of ±12.5%, and ±10% estimated error of the ionization chamber integrated into the fluoroscopic system to record DAP and $K_{a,r}$ The total error, $Error_{Tot}$, is therefore calculated as:

$$\text{Error}_{\text{Tot}} = \sqrt{(0.125)^2 + (0.125)^2 + (0.1)^2} = \pm 20\%. \quad (4\text{-}4)$$

When using Equation 4-3, additional sources of error arise, that is, error due to the measurement accuracy of ±20% of the whole-body dosimeter as well as error arising from the angular dependence (not exceeding ±25% at -60˚) of the dosimeter. The error calculations also include errors due to the eye dosimeter as well (similar errors included in equation 4-4). The total error propagation calculated is:

$$\text{Error}_{\text{Tot}} = \sqrt{(0.125)^2 + (0.125)^2 + (0.20)^2 + (0.25)^2} = \pm 37\% \quad (4\text{-}5)$$

4.7 Discussion

4.7.1 Dose per procedure

With the increasing concerns regarding occupational exposure to interventionalists as a result of scatter radiation emerging from patients, active dosimeters have proven to be invaluable tools. These dosimeters can be employed to audit dose to the eyes of interventionalists per procedure and can thus be used as educational tools for improvement of radiation safety. In this study, an active dosimeter was used to estimate scatter radiation to the left eye of doctors in the cardiac catheterization laboratory. Results of dose per diagnostic and therapeutic procedure for the four doctors are reported in Table 4-3 and Table 4-4, respectively. The mean dose per CA procedure determined by combining all the CA procedures was 195.1±112 μSv. Dose per CA+PCI procedure was 391.8±202.9 μSv. Moreover, the current study reports an overall eye dose per cardiac procedure of 250.9±168.3 μSv obtained by combining all the monitored procedures and calculating the sample mean.

The reported dose per diagnostic and therapeutic in this study are larger than the dose reported by Antic et al. (2013) who reported average doses per CA and CA+PCI procedure of 71±75 and 141±84 μSv, respectively. Antic et al. (2013) also reports the overall mean eye dose of 121 μSv, determined by combining all the monitored procedures (CA and

CA+PCI). This value is approximately one-half of the value reported by the current study. Alejo et al. (2017) who conducted a similar study report a mean eye lens dose values of 40±9, which is substantially lower than the value reported in our study. The lower dose can be attributed to the fact that the referenced study was conducted in a paediatric interventional suit, where lower doses can be expected due to the low patient thickness, thus low scatter production.

Albeit the overall mean scatter dose measured at the left eye level does not accord well with the results of left eye doses reported in literature, the current study is however in accordance with the reported eye dose data in terms of variability in eye dose per procedure even for individual doctors, particularly when complex procedures are concerned.

Dose per cardiac procedure values can be used for a rough estimation of the risk of exceeding the new eye lens annual dose limit of 20 mSv/year. Table 4-8 presents the estimated number of procedures necessary to exceed such limit.

Table 4-8. Comparison between the current study and published data on the estimated workload necessary to exceed the annual eye lens dose limit.

	Workload per year
This study	80
Antic et al. (2013)	160
Alejo et al. (2017)	500

The results presented in the table indicate the differences between the studies, with the current study reporting the least number of procedures required to exceed the annual eye lens dose limit. This is because of the high mean eye dose per procedure reported in this study. The difference in eye dose per procedure can be explained by considering the following: working patterns of doctors and protocols employed by different hospitals, the experience of doctors in interventional cardiology, the type of fluoroscopic equipment used and the use of protective equipment. It is also important to remember that the scatter radiation varies between adult and paediatric interventions, with paediatric interventions resulting in less scatter radiation to the operators due to the small size of

patients. This is demonstrated by the low mean eye dose value reported by Alejo et al. (2017) in which measurements were made in paediatric cardiology suit compared to measurement collected in adult cardiology, as in the current study. The difference in eye dose per procedure and the minimum workloads necessary to exceed the annual eye lens dose limit demonstrates the lack of consensus on the dose per procedure. This, therefore, highlights the need for more research in eye lens dosimetry, as it is evident that there is currently no general approach to estimating eye lens dose to ICs working in different institutions.

To improve the accuracy of estimating annual dose limits based on workload, based on the results of this study, it is important to take into consideration the significant difference that exist between the mean doses of different procedures, as indicated in Table 4-5. For example, considering the results of this study, reaching a conclusion that two-thirds of the procedures monitored were CA and one-thirds were CA+PCI procedures, a simple equation:

$$D_{eye} = \left(\frac{2D_{CA}}{3} + \frac{D_{CA+PCI}}{3}\right) \times Total\ workload \tag{4-6}$$

Where D_{CA} is the dose per CA procedure and $D_{CA_{+PCI}}$ is the dose per CA+PCI procedure can be applied to give a rough estimation of annual left eye dose.

The eye dose measurements of the studies included in Table 4-8 were made with the dosimeter unshielded by the protective eyewear, therefore the influence of the eyewear was not taken into consideration. In Chapter 3, an average dose reduction factor of the eyewear worn by staff at the Universitas Hospital where eye dose measurements were carried for this study was determined to be ~2. Applying this factor to the results of the eye dose measurements increases the minimum workload necessary to exceed the annual dose limit to 160 procedures. Furthermore, when considering the two types of procedures separately, a minimum of 140 CA plus 30 CA+PCI per year would be necessary to reach or exceed the annual eye dose limit.

4.7.2 Comparison of dose quantities per procedure among doctors

The comparison of eye dose per procedure type amongst the four doctors is demonstrated in Figure 4-3. Considering CA procedures, comparable eye dose per procedure amongst the four doctors is observed. On the contrary, a large variation in the dose per CA+PCI procedure is seen amongst the doctors. This is expected since such procedures are lengthy, and several factors can influence the dose received by individual doctors. The experience of the doctors, their height and the correct use of PPE are some of the factors that can explain the variation observed. However, considering the results of this study it is difficult to attribute the variation to any of the above-mentioned factors for several reasons. Firstly, all the doctors made use of similar PPE. Secondly, the results of this study do not clearly indicate the influence of the experience on the eye dose. Lastly, a study by Principi et al. (2016) showed the influence of height on the dose to the eyes. The study indicated, as can be expected, the reduction in dose to the eye with increasing height of a primary operator. However, considering the results of this study, the influence of height on the dose to the left eye is not evident even though the doctors had different heights. This is because of the many factors that are varied simultaneously during each procedure making it difficult to determine the influence of each factor separately. Nevertheless, the results tabulated in Table 4-4, suggest that the working patterns of doctors and how they operate the fluoroscopic system may have a great impact on the eye dose. For example, in the table, the highest average cine images are reported for Dr. B and consequently, the highest eye dose is reported for the doctor. The above-mentioned reason can also explain the results of dose measurements made at the chest level demonstrated in Figure 4-4. From the figure, it can again be seen that the highest dose was received by Dr. B.

Figure 4-5 and Figure 4-6 show the comparison of average patient dose-related quantities, that is, DAP and $K_{a,r}$, respectively amongst the four doctors. Considering DAP per CA procedure, it can once again be concluded that the results are fairly comparable amongst the operators. This is because of the short duration of such procedures. The median duration of such procedures is approximately the same for all operators working in interventional cardiology at the Universitas Hospital as can be seen in Table 4-3. Due to the short time taken to complete such procedures, the tube(s) angulations selected are

in most cases the same. Furthermore, the access route and the positioning of the doctors are the same. Similar results are observed for $K_{a,r}$ as far as CA procedures are performed

One of the factors that may result in a slight variation in the dose delivered to the patient during CA procedures is the size of the patients as it is known that thicker patients are exposed to higher radiation to obtain images of sufficient quality. Another reason is, as mentioned before the working pattern and the manner that the doctor operates the fluoroscopic system.

Considering CA+PCI procedures, it can once again as it has been demonstrated for other dose quantities be seen that there is a variation in DAP per procedure amongst the four doctors. A similar observation is made for $K_{a,r}$.

A more robust comparison of dose amongst the doctors is achieved through comparison of normalized left eye dose rather than simple eye dose as it permits for comparison of procedures of varying complexities (Antic et al., 2013). The box and whisker box plots (Figure 4-7, 4-8 and 4-9) have been used to provide a good visualization of the compared normalized eye dose, indicating the minimum, mean, median and the maximum dose values measured for each doctor. The figures also indicate the spread of dose data as well as values considered as outliers.

Figure 4-7, Figure 4-8 and Figure 4-9 show the comparison of eye lens dose normalized to DAP, $K_{a,r}$ and chest dose, respectively. Considering the comparison of normalized eye dose to DAP amongst the doctors, a small difference is observed. Moreover, the spread of the normalized dose is minimal, even when the data is combined and presented for all the procedures. It is important to note the few outliers indicated in the figure. A similar observation is made when comparing the data of eye dose normalized to $K_{a,r}$ and fewer outliers are seen.

When comparing the values of left eye dose normalized to chest values, differences can be seen amongst the doctors. A marked difference is seen when comparing the results of Dr. D with the results of the other three doctors. This is demonstrated in Figure 4-9. From the figure, it can be seen that the median normalized dose of Dr. D considerably higher that of other doctors with the mean being even higher. Furthermore, the analysis of all the procedures combined shows a number of values outliers.

The importance of comparing the dose amongst the doctors is that it indicates the consistency of the results obtained in this study. The small difference observed in the comparison of eye dose normalized to DAP and $K_{a,r}$ strengthens the results of this study. This implies that a general value that applies to the monitored doctors can be used. On the contrary, the results of the eye dose normalized to chest dose indicate that a general value would consist of large uncertainties and care should be taken when applying such value to the individual doctor.

4.7.3 Correlation between eye dose, and chest dose, and patients dose

As discussed in section Chapter 1, the difference between dose measured in different studies, states, and hospitals is noticeable. This implies that results obtained in a particular hospital would not necessarily apply to the next hospital, particularly if different hospitals employ different protocols, and radiation safety strategies, use different fluoroscopic equipment, etc. This is particularly true when the correlation between eye dose and other parameters are considered.

In this study, the correlation between the left eye dose and the patient-related dose quantities has been determined. The correlation between the left eye dose and the chest dose has also been determined. Figure 4-10 indicates the correlation between the eye dose and DAP measured for four doctors. A strong correlation is observed with the correlation coefficient between 0.69 and 0.88 among the four doctors. Furthermore, a strong correlation with the Pearson correlation coefficient of 0.76 is also indicated when all the procedures are pooled. This is shown in Figure 4-13. The correlation coefficient determined in this study is in agreement with the coefficient obtained by Krim et al. (2011), who obtained a correlation coefficient of 0.78. Antic et al. (2013) also obtained a weaker but significant correlation between the eye dose and DAP, with a correlation coefficient of 0.68. The findings of the aforementioned studies indicate that DAP is directly linked to ELD and can thus be used to estimate ELD in cases where a dedicated eye dosimeter is not available.

Considering the correlation between the left eye dose and $K_{a,r}$ as measured by the fluoroscopic system, an excellent correlation is also demonstrated in Figure 4-11.

However as can be seen from the figure, the correlation is weaker for Dr. C with the correlation coefficient of 0.54 whereas an excellent correlation is observed for Dr. A, Dr. B and Dr. D with correlation coefficients of 0.88, 0.8 and 0.78, respectively. The weaker correlation between the eye dose and $K_{a,r}$ shown for Dr. C is difficult to attribute to any specific factor since the measurements are collected during the actual clinical procedures in which several parameters vary simultaneously. Nonetheless, it can be inferred with confidence that there exists a strong correlation between dose measured on the outside of the protective eyewear (near the left eye) and $K_{a,r}$ recorded by the fluoroscopic system. This is demonstrated in Figure 4-11. The figure indicates the correlation between left eye dose and $K_{a,r}$ when all the procedures are pooled. A correlation coefficient of 0.72 is reported. Moreover, the consistency of the correlation strength indicated for individual doctors strengthens the results of the current study. There is currently a scarcity in studies that aims to find a correlation between $K_{a,r}$ and ELD and thus more studies are required to further explore the link between the two quantities.

A weak correlation was found between ELD and chest dose for all the monitored doctors. Correlation coefficients of 0.48, 0.55, 0.52 and 0.34 are reported for Dr. A, Dr. B, Dr. C, and Dr. D, respectively. Moreover, a weak but significant correlation (R^2 = 0.45) was found when all the procedures were combined and analysed. These results agree well with the results obtained by Principi et al. (2015) who found a correlation factor of R^2 = 0.4. However, it important to note that there are authors who have found a strong link between the dose to the eye and dose measured over an apron. For example, Alejo et al. (2017), found a strong link between the two dose measurements, with R^2 =0.89. This highlights the difficulty and inconsistencies in eye dosimetry, especially where correlation studies are concerned. Furthermore, it worth remembering that the influence of tube angulations, energy and angular response of the dosimeters used in different studies can be substantial, resulting in studies with varying results due to the different materials used. Lastly, the results of this study show that using the values of chest dose for estimating eye dose includes large uncertainties that can lead to extreme overestimation or underestimation of ELD.

4.7.4 Dose estimation model

Three methods have been formulated to estimate ELD of ICs in cases where a dedicated eye dosimeter is not available. The ELD can be estimated from patient-related dose quantities such as DAP and $K_{a,r}$, and the dose measured at the left chest level. Equations (4-1, 4-2 and 4-3 can be used to estimated ELD from recorded values of DAP, $K_{a,r}$ and chest dose, respectively. These equations are strongly dependent on the ratio of eye dose and the mentioned dose quantities. The normalized eye doses are shown in Table 4-7, where 1 Gycm^2 DAP is equivalent to 2.8 µSv, 1 mGy $K_{a,r}$ is equivalent to 0.4 µSv and 1 µSv chest dose is equivalent to 1.9 µSv eye dose.

Considering the ratio of ELD to DAP reported in this study, variation can be seen when compared to the results reported in the literature. Antic, et al. (2013), Principi et al. (2015) and Alejo et al. (2017) report ratios of 0.94, 1.81 and 2.21 µSv/Gycm^2, respectively. These studies, including the current study, demonstrate the variation in the optimization of radiation protection strategies in different institutions, which makes it difficult to develop universal methods that can be used across different institutions to estimate ELD using patient-related dose quantities. Considering the ratio of ELD to $K_{a,r}$, there is currently a dearth of studies that investigated the correlation between the two quantities and the results of this study cannot be compared to any study in the literature. With this study having shown a good correlation between the two quantities, further investigation should be carried out in different institutions and the results be compared to the results of this study. The ratio of ELD to chest dose reported in this study does not accord well with that reported in literature. A critical analysis of recorded doses in studies that recorded both the eye lens doses and thyroid doses showed that the dose scattered to the eyes of the primary operator is between 40% and 90% of that scattered to the collar level (Martin, 2011). Considering the placement of the whole-body dosimeter and the eye dosimeters, and also applying the inverse square law, it is expected that the dose to the eye be lower than the dose to the chest or collar. The ratio of 1.9 reported in this study is indicative of the underestimation of dose by the chest dosimeters used in this study.

The formulated equations are simple and do not contain many factors such as the influence of height, the position of operators during procedures, the tube configurations,

etc. The influence of such factors has been investigated through phantom and Monte Carlo simulations studies already. However, applying the results of these studies to the results of measurements obtained during actual clinical measurements can be challenging and with large errors. This is because phantom studies are usually performed with simplified set-ups, with fixed angulations and imaging parameters, and Monte Carlo simulations usually allow for the investigation of one factor at a time. This cannot be the case during the actual clinical procedures in which many factors vary simultaneously, which makes it difficult to confidently identify the influence of one factor separately.

One factor that was investigated as part of the main study and included in the equations is the protective efficacy of the protective eyewear. This factor considers the attenuation of lead glasses in protecting the eye of the doctors. This factor will vary depending on the glasses model used and its design.

The accuracy of the equations is limited due to the measurement errors associated with the equipment used including the ionization chamber integrated into the fluoroscopic unit to measure patient-related dose quantities. The error calculations are shown in section 4.6. Using equations 4-1 and 4-2, the calculated total error in the eye dose estimation is 20%. A larger error is reported when using equation 4-3, with a total error of 37%. The latter highlights that using the chest dosimeter reading to estimate ELD can result in extensive overestimation or underestimation of ELD. Therefore, estimating eye dose from chest dose (using the dosimeter used in this study) is not a good estimator of ELD. This was also demonstrated in section 4.7.3.

4.8 Conclusion

This study has shown that the mean dose per procedure obtained at the Universitas Hospital is considerably higher than that reported in the literature. Furthermore, applying the mean dose per procedure, the study has established a method to estimate the eye dose based on doctors' workload. The study showed that the annual dose limit of 20 mSv can easily be surpassed in the case where PPE such as protective leaded glasses are not utilized, with only 80 procedures required to exceed the limit. The number of

required procedures to exceed the annual eye dose limit reported in this study are substantially lower than those reported in the literature.

The main aim of this study was to establish methods for estimating ELD from the available imaging parameters such as DAP and $K_{a,r}$, and from the chest dose. A strong link was found between ELD and the imaging parameters, which is indicative that the two parameters are good estimators of ELD. On the contrary, a poor correlation was observed between ELD and chest dose. Nevertheless, the three equations obtained by factoring in the above-mentioned dose quantities can be useful in the retrospective ELD assessment in the cases were dedicated eye dosimeters are not available. It is important to take note of the uncertainties involved in the application of these equations as it was shown that they can overestimate or underestimate ELD due to the measurement uncertainties of the dosimeters used in the study, particularly when estimating the ELD from chest dose measurements.

The comparison of normalized eye dose of the four doctors showed that the results of the four doctors were fairly comparable (comparing the results of ELD normalized to DAP and $K_{a,r}$), leading to the conclusion that a general equation can be applied to all the doctors working In the interventional cardiology at the Universitas Hospital. On the other hand, comparing the results of ELD normalized to chest dose showed variation among the doctors.

In conclusion, the results of this study will raise awareness with regard to occupational eye lens exposure and enforce a better radiation protection culture in interventional cardiology. Using the methods presented here, the cumulative eye dose of interventionalists can be calculated on selected intervals. In cases where doctors' eye doses are deemed abnormally high, appropriate steps can thus be followed to investigate the cause.

Lastly, this study has shown that there is a high probability of interventional cardiologists exceeding the new annual eye lens dose limit, particularly if the use of PPE is not optimized. It is therefore, important that efforts be made to reduce radiation exposure to the eyes in order to mitigate the risk of developing radiation-induced cataract if future. Some of the strategies reported by Miller et al. (2010) to mitigate occupational exposure include reduction of fluoroscopic duration and images, utilization of available patient

dose reduction technologies, reduction of scatter by using collimation, appropriate and consistent use of PPE, and protective shielding and good radiation protection training.

4.9 Limitations of the study

The study did not make the inclusion of other professional staff working in the interventional suite (due to resource constraints) even though these personnel are also occupationally exposed and are also at risk of developing radiation-induced cataracts.

This study included only four doctors. This number is low to study how the difference in the doctors' characteristics (height, experience working with radiation and technique) influences the dose to the eye. Nevertheless, the study has helped give insight to eye lens exposure in interventionalists and have laid good foundations for future research.

The study only monitored the dose to the left eye. Although it is known that the left eye is the most exposed, thus it is more prone to developing cataract, the right eye is also exposed and can be at risk of developing similar effects.

The study was performed in one Hospital and this means that the results of this study are mostly applicable to the doctors working at the Hospital where measurements were carried. The results of this study may however be transferable in settings using similar machines, employing similar working patterns, having similarly trained personnel and using similar radiation protection tools. The results cannot, however, be generalised to all interventionalists.

Lastly, the choice of the chest dosimeter did not produce the satisfactory results. This is because of the high angular dependence of the dosimeter, which has resulted in large uncertainties in the methods that can be used to estimate ELD from chest dose.

Chapter 5 : Conclusion

5.1 Summary and findings

With the reduction of the annual eye lens dose limit by the ICRP from 150 mSv to 20 mSv in 2011 concerns with regard to the risk of induction of radiation-induced effects among medical professionals working with radiation have been raised, particularly those carrying out fluoroscopically guided procedures. The reduction has consequently stimulated the interest in radiation dosimetry in many countries. To the best of the researcher's knowledge, this is the first study to investigate eye lens dose to interventionalists in the South African context.

The main aim of this study was to establish methods for estimating eye lens dose from available imaging parameters. The study also aimed to establish a method to estimate eye lens dose based on doctors' workload. To achieve these aims, several objectives were established which included measuring the dose to the left eye using a dosimeter attached on the frame of the protective eyewear, measuring whole-body dose with a dosimeter attached over the leaded apron at the chest level, and recording the procedural information such as DAP and $K_{a,r}$.

With the eye dosimeter attached on the outer canthus of the protective eyewear, it was deemed necessary to conduct a study to investigate the protective efficacy of the eyewear used at the Universitas Hospital.

This study has demonstrated that the new annual eye dose limit can be easily exceeded when protective eyewear is not utilized consistently. The study showed that a minimum of 80 procedures are necessary to exceed the annual eye dose limit when protective eyewear is not used at all. In the study that investigated the protective efficacy of the protective eyewear, a dose reduction factor of ~2 was determined. Applying this factor to the results of eye dose measurements showed that if protective eyewear is consistently used, the minimum workload can be increased to 160 procedures a year. However, care should be taken when applying the DRF as its application may provide a false sense of protection to the eye if the protective eyewear is inconsistently utilized.

The correlation study showed that the ELD can be directly linked to patient dose-related quantities such as DAP and $K_{a,r}$ with Pearson correlation coefficients of 0.78 and 0.72, respectively. On the other hand, the correlation between ELD and chest dose was found to be poor with a correlation coefficient of 0.45.

This study has developed three methods that can be used to retrospectively estimate ELD based on DAP, $K_{a,r}$ and chest dose. However, the study has also shown that the use of whole-body dose as an estimate of ELD can produce erroneous calculations due to the large errors associated with the characteristics of the whole-body dosimeter used in this study.

With the study being first of its kind in South Africa (SA), there is currently no available data to compare the results of this study within SA. Therefore, the results of this study can only be compared to published data in other countries. The comparison of the results of this study and the published data showed variation, particularly in the dose per procedure, the approximate number of procedures necessary to exceed the annual dose limit and the normalized eye dose to DAP and chest dose. Furthermore, the accuracy of the methods for estimating the left eye dose may be limited, even in Hospitals in South Africa due to different factors (Doctors' work experience, protective measures, fluoroscopic systems etc.)

Lastly, with the study having shown that the annual eye dose limit can be easily surpassed, steps should be taken to reduce the dose to the eyes of the interventionalists. Some of the steps that can ensure compliance with the ALARA principle and thus reduce the chances of exceeding the annual eye lens dose limit include the reduction of fluoroscopic duration and images, utilization of available patient dose reduction technologies, reduction of scatter by using greater collimation, appropriate and consistent use of PPE, and protective shielding and good radiation protection training. On the other hand, increasing the distance between the operator and the patient (main source of scatter radiation) to reduce exposure may be deemed not feasible as the operators are required to remain in close proximity with the patient during procedures.

5.2 Recommendations

The study only focused on primary operators (doctors) because they are the mostly exposed staff during interventional procedures. Moreover, the funds allocated for the study allowed for a purchase of one eye dosimeter, therefore eye doses to other staff (nurses, radiographers) could not be measured simultaneously. It is recommended that future studies include all the occupationally exposed personnel working in the interventional cardiology. Furthermore, the eye doses should also be investigated in other interventional suits in such as interventional radiology.

We recommended that future studies investigate the dose to both the eyes as the present study focused only on the dose to the left eye which is thought to be at a higher risk of developing cataract (because of being on the side of the X-ray tube). Albeit the right eye is further away from the X-ray tubes and considered to receive lower dose, risk of developing cataracts exist.

The measurements were done at a single hospital. These findings can only be generalised to hospitals with similar characteristics. Future studies should include a variety of settings and participants to allow for generalisability.

Lastly, some of the results of this study are not optimal because of sub-optimal selection of measuring instrument (whole-body dosimeter). It is therefore important that future researchers in eye dosimetry select equipment (dosimeters) that will measure the chest dose more precisely.

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Appendix A: Pacemaker implantation data

Appendix A-1. Data of all the monitored pacemaker implantation procedures.

Procedure	Sample (N)	Eye dose (µSv) Mean±SD (range) median	*Chest dose* µ(Sv) Mean±SD (range) median	DAP (Gy/cm^2) Mean±SD (range) median	K_{air} (mGy) Mean±SD (range) median	Time (min) Mean±SD (range) median
VVI	6	27.3±7.9 (17.9-37.3) 26.9	60.5±25.4 (40-110) 54	7.9±4.3 (3.8-13.6) 6.9	88.5±51.3 (37-156) 71.5	3.67±2.0 (2.27-7.49) 2.8
DDD	4	20.9±9.4 (11.4-29.5) 21.4	155±122.4 (80-320) 110	13.1±7.3 (5.6-22.9) 11.9	158.3±86 (89-282) 131	8.6±6.6 (5.1-18.4) 5.3
Bivent	2	463±353.6 (213-713) 463	1166±910.8 (522-1810) 1166	222.2±97.5 (153.2291.1) 222.2	2705±429.9 (2401-3009) 2705	76.9±6.3 (72.5-81.4) 76.9

VVI-Single chamber pacemaker, DDD-Dual chamber pacemaker, Bivent- Biventricular pacemaker.

Appendix B: Approval letters

Appendix B-1. Ethical clearance

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

Health Sciences Research Ethics Committee

27-Nov-2018

Dear **Mr Mokete Phutheho**

Ethics Clearance: **Estimation of the eye lens doses in a catheterization laboratory from available imaging parameters**
Principal Investigator: **Mr Mokete Phutheho**
Department: **Medical Physics Department (Bloemfontein Campus)**
APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is:**UFS-HSD2018/0931/2711**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email EthicsFHS@ufs.ac.za.

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

Dr. SM Le Grange
Chair: Health Sciences Research Ethics Committee

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za
IRB 00006240; REC 230408-011; IORG0005187; FWA00012784
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa www.ufs.ac.za

Appendix B-2. Head of the Department of Medical Physics

UNIVERSITY OF THE FREE STATE
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YUNIVESITHI YA FREISTATA
UFS UV

DEPARTMENT MEDICAL PHYSICS
P O Box 339 ☎ (051) 4052104
BLOEMFONTEIN 🖷 (051) 4488610
9300

To whom it may concern.

Reference: **Permission to do MMedSc: Mr Mokete Phutheho: Student No. 2012178048**
Date: **Monday 22 January 2018**

Mr M Phutheho
Department of Medical Physics
Faculty of Health Sciences
University of the Free State
Bloemfontein
9301

Dear Mokete

This letter serves as conformation that you may carry out your studies as a MMedSc student in the Department of Medical Physics at the University of the Free State commencing in July, 2017. The registered title for your project is: "Estimation of eye lens dose in a catheterization laboratory from available imaging parameters and the impact of protective measures on the eye lens dose".

Yours faithfully

Dr FCP du Plessis [Ph.D.]
Acting Head of Department
Medical Physics Department
University of the Free State

Appendix B-3. Head of Department of Cardiology

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HEALTH SCIENCES
YUNIVESITHI YA FREISTATA
YAGESONDHEIDSWETENSKAPPE

25/06/2018

TO WHOM IT MAY CONCERN

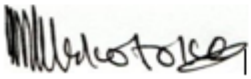
Re: Mokete Phutheho
MMedSc in Medical Physics

Research Title: Estimation of the eye lens doses in a Catheterization Laboratory from available image parameters

I hereby give permission for Mr Mokete Phutheho to conduct his abovementioned study in the Catheterization Laboratory at Universitas Academic Hospital.

The stated aim of the study is "to develop a method that can be applied to more accurately estimate eye lens doses in cardiac catheterization laboratory from available imaging parameters."

Yours sincerely.



Appendix B-4. Free State Department of Health Ethics.

health
Department of Health
FREE STATE PROVINCE

22 October 2018

Mr. M Phutheho
Dept. of Medical Physics
UFS

Dear Mr. M Phutheho

Subject: Estimation of the eye lens doses in a catheterization laboratory from available imaging parameters.

- Please ensure that you read the whole document. Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to** scheclats@fshealth.gov.za or lithekom@fshealth.gov.za **before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are required to present your study findings/results at the Free State Provincial health research day

Trust you find the above in order.
Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 1/11/2018

Head : Health
PO Box 227, Bloemfontein, 9300
4th Floor, Executive Suite, Bophelo House, cnr Maitland and Harvey Road, Bloemfontein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail khusemi@fshealth.gov.za@fshealth.gov.za/chikobvup@fshealth.gov.za
www.fs.gov.za

Appendix C: Consent form

Appendix C-1. An example of a consent form signed by interventional cardiologists participating in the study

Consent form

Consent form to participate in the study: Estimation of the eye lens doses to interventionalists in a catheterization laboratory from the available imaging parameteers.

I, the undersigned, comfirm that (please tick box as appropriate):

1.	I have read and understood the information about the study, as provided to me	☐
2.	I understand that there will be no remuneration for participation in the study.	☐
3.	I voluntarily agree to participate the study.	☐
4.	I understand that I am required to provide my name and that a unique identifier will be used.	☐
5.	The procedures regarding the confidentiality have been clearly explained to me.	☐
6.	I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data.	☐
7.	I understand that an active dosimeter will be clipped on my lead goggles or attached/taped to your head at the same position (if you do not wear leaded goggles) during procedures. I also understand that the wearing of the dosimeter may provide a slight discomfort	☐
8.	I understand that I will have to wear additional dosimeters (one under and one above the lead apron) during procedures.	☐
9.	I understand that I can withdraw from the study at any point and will not be penalized for doing so nor will be questioned on why I have withdrawn.	☐
10	I understand that the findings of the study will be published and presented at relevant conferences	☐
11.	I, along with a witness, agree to sign and date this informed consent form.	☐

Participant:

_____ _____

Signature Date

Witness

_____ _____

Signature Date