THE AVERAGE GLANDULAR DOSE IN DIGITAL MAMMOGRAPHY AND BREAST TOMOSYNTHESIS

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DECLARATION

I declare that this is my original work and that it has not been presented in any other place to the best of my knowledge.

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DEDICATION

I dedicate this to my parents, Dr. James Ochieng Ger and Margret Atieno Banda.

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I am eternally grateful to God for his grace and blessings that enabled me to successfully complete this work.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AGD-	Average Glandular Dose
Al-	Aluminum
ALARA-	As Low As Reasonably Achievable
BI-RADS-	Breast Imaging Reporting and Data System
BRCA1-	Breast Cancer Gene 1
BRCA2-	Breast Cancer Gene 2
CBT-	Compression Breast Thickness
CC-	Cranio-Caudal
CT-	Computed Tomography
DDIRM-	Department of Diagnostic Imaging and Radiation Medicine
D_{gN}-	Normalized Glandular Dose
EAR-	Excess Absolute Risk
ERR-	Excess Relative Risk.
ESAK-	Entrance Surface Air Kerma
ESD-	Entrance Skin Dose
ESE-	Entrance Surface Exposure
GE-	General Electric
HIV-	Human Immunodeficiency Virus
HVL-	Half Value Layer
ICRP-	International Committee on Radiological Protection
KNH-	Kenyatta National Hospital
KNH/UON-ERC	Kenyatta National Hospital/University of Nairobi Ethics & Research Committee

kVp-	Peak Kilovoltage
MGD-	Mean Glandular Dose
MLO-	Medio-Lateral-Oblique View
Mo-	Molybdenum
MRI-	Magnetic Resonance Imaging
Rh-	Rhodium
Se/TFT-	Selenium Thin Film Transistors
SNR-	Signal to Noise Ratio
TB-	Tuberculosis
UON-	University of Nairobi
USA-	United States of America
X_{ESE}-	Entrance Surface Exposure

DEFINITIONS OF TERMS

Mammography: This is an imaging technique that uses ionizing radiation for the detection of breast cancer. The machines used are either the conventional film screen mammography or digital full field mammography units.

Mammogram: This is the term used to describe the image or film acquired during a mammography exam.

Ionizing Radiation: This is radiation with enough energy to cause an ejection of a tightly bound electron from the orbit of the atom its' interacting with. The ejection of an electron from the orbital shell of the atom leads to ionization of the atom and release of energy.

Breast Dosimetry: This is the measurement of absorbed dose to the breast tissue delivered by ionizing radiation during examinations like mammography. It is usually represented as the average glandular dose.

Breast Tomosynthesis: This is a 3D imaging software provided for in the Digital Mammography machine. The X-ray tube moves in an arc angle of 15-45 degrees while taking a series of 10-20 images. These images are then re-constructed to create a CT like study to enable the radiologist to view the breast in thinner slices about 1mm.

Mean Glandular Dose: Also known as average glandular dose. This is the mean dose of radiation received by the glandular tissue during different examinations, inclusive of mammography.

ABSTRACT

Background and Purpose: Imaging is essential for accurate breast diagnosis and early detection of breast cancer. Population screening with mammography is the only intervention proven to reduce mortality from breast cancer through early detection. The Government of Kenya therefore embarked on a program to equip all county hospitals with digital mammography machines. Because mammography uses ionizing radiation, any exposure must be justified and doses kept as low as reasonably possible. Currently there are no studies that have been done in Kenya or Africa to determine whether the radiation doses are within acceptable dose reference ranges. The aim of this study was to determine the average glandular dose (AGD) in digital full-field mammography (2 D) and in breast tomosynthesis (3 D).

Study Design and Site: This was a cross sectional study carried out at Kenyatta National Hospital (KNH) using the GE Essential Senographe Digital Mammography unit recently installed at the radiology department of the Hospital.

Study Population: The study included patients referred for mammography at Kenyatta National hospital.

Sampling Method and Size: A total of **200** patients were included and the sequential sampling method was used to select the patients.

Study time: The study was conducted over a period of 4 months, November 2016- May 2017.

Materials and Methods: All patients included in the study had CC and MLO exposures of both breasts. Each patient's data was recorded as provided by the machine. A dosimeter to measure radiation dose, was placed on a breast phantom which was placed on the mammogram machine and exposed to ionizing radiation.

A data collection sheet was used to record radiation doses obtained from cranial-caudal view during mammography and also included the AGD, ESE, kVp, and type of anode and filter material, CBT and MODE. The patient's age was also recorded.

Main Outcome and Measures: Both the mean glandular doses automatically displayed by the digital mammography unit and those measured indirectly using TLD dosimeters on breast phantom were collected. The data was eventually analyzed using the statistical package for social scientists (SPSS) computer software package and the results presented in the form of tables, charts and graphs.

Results: The AGD values were 1.2±0.5mGy and 1.3±0.6 mGy for CC and MLO views respectively. The statistical difference of (-0.1) was significant. The number of patients who underwent breast tomosynthesis (3D) were too few and therefore not analyzed.

Conclusion: In this study the AGD values were within the recommended dose reference levels and also AGD values were higher in the CC compared to the MLO view having a statistical significant difference of (-0.1) that is in agreement with other previously reported studies.

The data has been made available to UON and KNH.

1.0 CHAPTER ONE

1.1 Introduction

1.1.1 Global Epidemiology of Breast Cancer

According to statistics by WHO, over 508 000 women died in 2011 due to breast cancer worldwide(1). Although breast cancer is thought to be a disease of the developed world, almost 50% of breast cancer cases and 58% of deaths occur in less developed countries (2). Incidence rates vary greatly worldwide from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe(1). In most of the developing regions the incidence rates are below 40 per 100,000 (2). The lowest incidence rates are found in most African countries but the rates are currently reported to be increasing. Low and middle income countries such as Kenya accounts for 70% of the world's cancer burden.

Breast cancer survival rates vary greatly worldwide, ranging from 80% or over in North America, Sweden and Japan to around 60% in middle-income countries and below 40% in low-income countries (1). The low survival rates in less developed countries can be explained mainly by lack of breast cancer screening programs, resulting in a high proportion of women presenting with late-stage disease, as well as lack of adequate diagnosis and treatment facilities. Statistics also show that 30% of cancers can be cured if detected early while the same percentage can be treated and survival rate improved. Furthermore another 30% of cancer Patients can be better provided with palliative care early enough(3).

1.1.2 Kenya Statistics on Breast Cancer

Estimated cancer statistics show that cancer causes more deaths globally, more than malaria, TB and HIV combined(3).The 3rd most common cause of death in Kenya after infectious and cardiovascular disease is cancer(3). It is important to point out that in Kenya, there is no proper national cancer registry. Most patients who are captured and documented are those in Nairobi and who seek medical attention in private facilities. On the basis of estimates from the Nairobi cancer registry, there are 39,000 new cancer cases each year with 27,000 deaths annually from cancer(3).

Breast and cervical cancers are the leading in women with an incidence rate of 34 per 100,000 and 25 per 100,000 respectively(3). Elsewhere it has been reported that breast cancer is the most common cause of cancer related mortality in women younger women (< 50 years) in Kenya(4).

Breast cancer incidence rates have risen globally, with the western countries reporting the highest rates. The causes of this include change in reproductive patterns, increased screening, dietary changes and decreased physical activity. Other risk factors and more common causes in Kenya include:

- Female sex
- Advanced age
- Family and personal history of breast cancer and breast diseases.
- Prolonged duration of effect of estrogen e.g. in nulliparity, early age at menarche, late age of menopause, late age of first term pregnancy >30 years.
- Use of combined estrogen/progesterone hormone replacement therapy.
- Oral contraceptive use
- Lifestyle factors such as alcohol, smoking, obesity.
- Gene mutations such as BRCA1 and BRCA2 are familial and are associated with high risk of developing breast and ovarian cancers. Patients with these gene mutations may be offered prophylactic breast mastectomy.

Screening for early cancer detection is recommended as cancer in the early stages has a high cure rate.

There is no established breast cancer screening program in Kenya, however the Kenya National Guidelines recommends that screening be done via self-breast examinations, clinical breast examination and breast imaging through ultrasound, mammography and MRI(4).

Ultrasound is recommended for women <40 years, mammography for women >40 years of age and MRI may be used in patients with high risk factors such as the BRCA1 and BRCA2 gene mutations(4).

Most researchers agree that early detection of breast cancer saves many lives and therefore screening is fundamental in each and every society in the world.

Worldwide, breast screening is done by use of a mammography machine which uses ionizing radiation of low photon beams to detect abnormal breast tissue. As with any other examination using ionizing radiation there is a risk of stochastic effects of radiation on biological tissues.

The mammography machine uses ionizing radiation of low photon energy, the doses are small and do not reach the threshold of deterministic effects. Instead it has a small probability

of radiation stochastic effects and due to screening programs and routine screening, the probability of stochastic effects increases. Hence the importance of the ALARA principle that dictates that we should keep the radiation dose as low as reasonably achievable.

The breast is one of the most radiosensitive tissues especially during the reproductive age(5). The ICRP 2007 recommends a tissue weighting factor of 0.12 for the breast(6). It is therefore important to know the risk of radiation dose offered to the breast during screening or diagnosis by use of mammography machine.

Diagnostic reference dose values have been introduced by the International Commission on Radiological Protection in ICRP Publications and by the European Directive for assisting the optimization of radiological investigations. A diagnostic reference level (DRL) is a dose level for a typical X-ray examination of a group of patients with standard body sizes and for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied. The recommended diagnostic reference levels are 2mGy by the ICRP(6)2.5mGy as by the UK(7) and 2mGy as by the European guidelines(8).

There have been previously reported studies done to determine the AGD during mammography examinations using screen-film mammography units(9). Several studies to accurately determine the radiation dose to the breast by measuring the average glandular dose in mammography. Most studies have been done on the screen-film mammography machine. The glandular tissue is the most radiosensitive part, therefore the mean glandular dose is the best measurement to quantify and evaluate the risk of radiation to the breast. The AGD is measured by 2 methods, estimating measurements on Patients or breast phantoms. The AGD cannot be measured directly and it is influenced by x-ray tube target/filter material, breast composition (ratio of fat: glandular tissue), breast compression thickness and kVp.

The normalized glandular dose (D_{gN}) is required to calculate the AGD. It represents the dose delivered per unit of entrance surface exposure(X_{ESE}), for a given HVL, kVp, breast compression thickness and breast composition(8,9). The D_{GN}also varies according to the target/filter material of the x-ray tube used in the mammography machine and various values have been charted by Dance for reference(11). Most digital mammography machines automatically calculate and display the AGD value for each Patient.

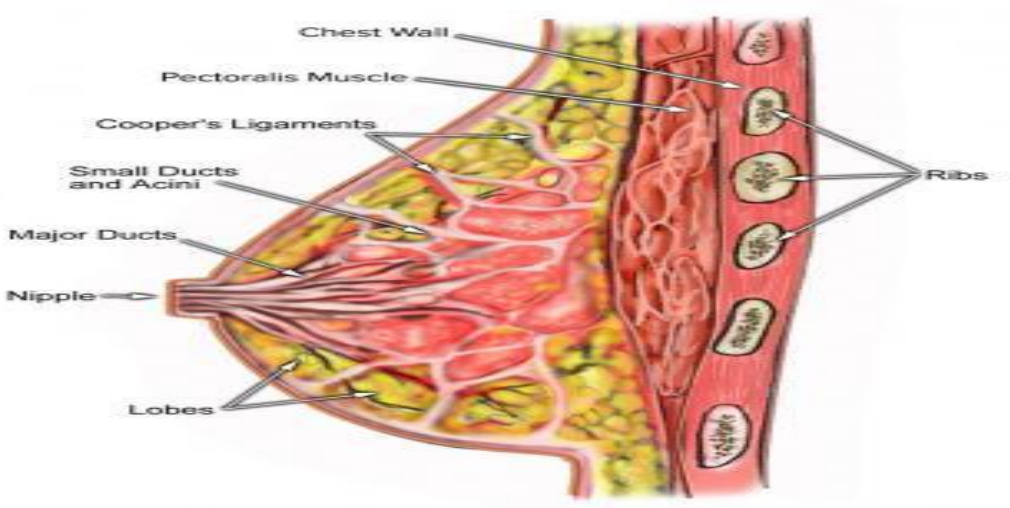
This research analyzed the AGD values as given by the GE digital mammography unit to find the AGD value for the patients coming to KNH for diagnostic mammography. The AGD value was per exposure in the cranio-caudal and MLO views in 2D mammography and breast tomosynthesis. The breast compression thickness was determined and correlated to AGD values.

1.2 Literature Review

1.2.1 Breast Anatomy and Radiosensitivity

It is important to understand the breast anatomy in order to know how it is affected by ionizing radiation. The breast overlies the 2nd to 6th ribs on the anterior chest wall and it is made up of fat and glandular tissue. It is attached to the anterior chest wall by cooper's ligaments. The glandular tissue is made up of 15-20 lobes, lobules and acini, all which drain via lactiferous ducts that open at the nipple. The glandular tissue makes up the breast parenchyma while the surrounding fat will constitute the stroma. This internal structure is the same in all females but the amount varies according to age, parity and other factors.

Younger women tend to have more glandular tissue compared to fat, therefore have denser breast. The glandular tissue is influenced by hormones during the menstrual cycle and pregnancy. As women grow older they tend to have more fat than glandular tissue. A study done in Uganda showed that most women between the ages of 35-50 years had scattered fibroglandular breast tissue, BI-RADS 2 on mammography(11,12).



(Medscape-Article on Breast Anatomy June 2016)

Figure 1: Breast Anatomy

The glandular tissue is the most sensitive part of the breasts and it is affected by ionizing radiation. Ionizing radiation can therefore lead to development of breast cancer. A link has been established between radiation and breast cancer in the Hiroshima Atomic bomb victims. Patients as young as 15 years who were exposed to radiation were noted to develop breast cancer(14).

The UNSCEAR 2012 report concluded that there was strong evidence of effect of ionizing radiation on breast cancer risk. The risk was consistent with a linear dose response(15).

The report also concluded that the ERR (excess relative risk) per unit dose had a strong dependence on age at exposure. Therefore the largest risk was for those exposed as children and young adults(15).

Table 1: Effect of Ionizing Radiation on Breast Cancer Risk

CANCER	RISK QUANTITY ON WHICH TRANSFER IS BASED	EXTRAPOLATED EXCESS RATE PER UNIT DOSE(CASES PER 104 PY Gy0)
Breast cancer	ERR per unit dose EAR per unit dose	36(23,54) 9.2(6.8,12)

Adapted From UNSCEAR 2012 Report(15)

ERR- Excess Relative Risk. EAR- Excess Absolute Risk.

*The risk projection applies to age 70 after exposure at age 30

1.2.2 Mammography

Mammography is considered to be the gold standard technique in breast cancer detection.
It uses ionizing radiation to show the fibrous, fatty and glandular tissue of the breast.
There are 2 types of mammogram exams:

1. Screening –the recommended age is 40 years up to 75 years. There are many societies that have come up with similar recommendations for screening(16).

Table 2:Some of The Recommendations By Various Organizations(16).

	COMPARISON OF BREAST CANCER SCREENING GUIDELINES2016					
RECOMMENDED	ACOG	ACR/SBI	ACS	AMA	NCCN	USPSFT
AGE TO START MAMMOGRAPHY	40	40	40 INDIVIDUAL CHOICE 40-45	40	40	50
AGE TO STOP MAMMOGRAMS (75+)	ANNUAL AS LONG AS WOMAN IS IN GOOD HEALTH	WHEN LIFE EXPECTANCY IS <5-7 YEARS	WHEN LIFE EXPECTANCY IS <10 YEARS	WHEN LIFE EXPECTANCY IS <10 YEARS	UPPER AGE LIMIT NOT ESTABLISHD	74
INTERVAL	ANNUAL	ANNUAL	ANNUAL 45-54 YEARS. 1-2 YEARS 55+	ANNUAL	ANNUAL	2 YEARS
TOMOSYNTHESIS 3D MAMMOGRAPHY	STUDIES ONGOING TO DETERMINE COST EFFECTIVENESS REOLACEMENT OVER 2D	REPRESENTS AN ADVANCE IN BREAST IMAGING AND USED WITH 2D	IMPROVEMENT IN DETECTION AND LOWERS CHANCES OF RECALL	SILENT	DEFINITIVE STUDIES ARE ONGOING	INSUFFICENT EVIDENCE TO SUPPORT ROUTINE USE
NOTES		TOMOSYNTHESIS HAS IMPROVED SCREENING				

ACOG-American Congress Of Obstetricians And Gynecologists. **ACR/SBI**- American College Of Radiology and Society Of Breast Imaging.

ACS- American Cancer Society. **AMA**- American Medical Association.

NCCN- National Comprehensive Cancer Network. **USPSTF**- United States Preventive Services Task Force.

According to the Kenyan national guidelines on management of cancer 2013, screening is recommended every 2 years for asymptomatic women age 40-45years (4).

2. For diagnosis post clinical assessment.

1.2.3 Evolution of Mammography

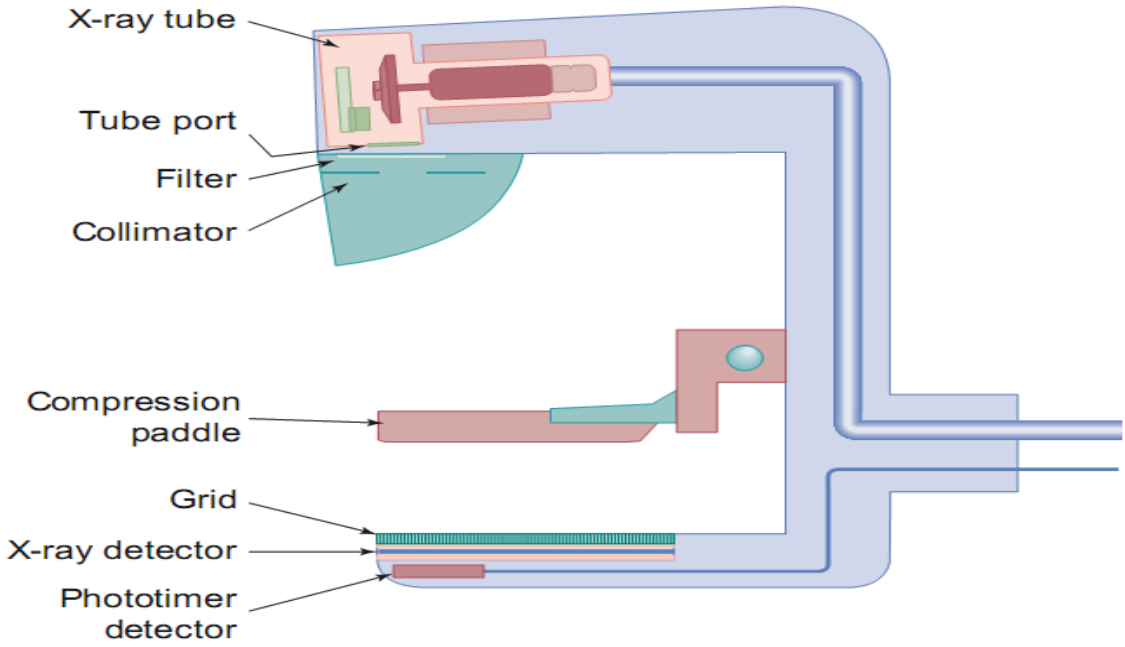
Over the years there has been evolution in the technology of mammography. The technology has moved from:

- Industrial non-screen film: fine-grain emulsion gave good image quality but Patient dose was high (about 20 mGy per view).
- Electrostatic image receptor (Xeromammography): amorphous selenium plates employed principle of photoconductivity. Special feature of edge enhancement provides high local contrast at tissue boundaries.
- Screen-film receptor: Single film emulsion with single screen has reduced Patient dose to about 2 mGy per view.
- Digital image receptors (Prof Tole physics notes)(17).

1.2.4 Physics of Mammography

The objective of the mammography machine is to detect both normal and abnormal breast tissue at low doses of radiation, therefore optimization is the key to good quality images. Mammography uses low photon energy beams of 25-35 kV in order to maximize photoelectric effect interactions that improves image contrast. The mammography machine has 2 important parts the x-ray tube containing the target and filter material, and the compression paddle.

Figure 1.1



Bushberg et al 2012, pg 240

Figure 2: Mammography Machine

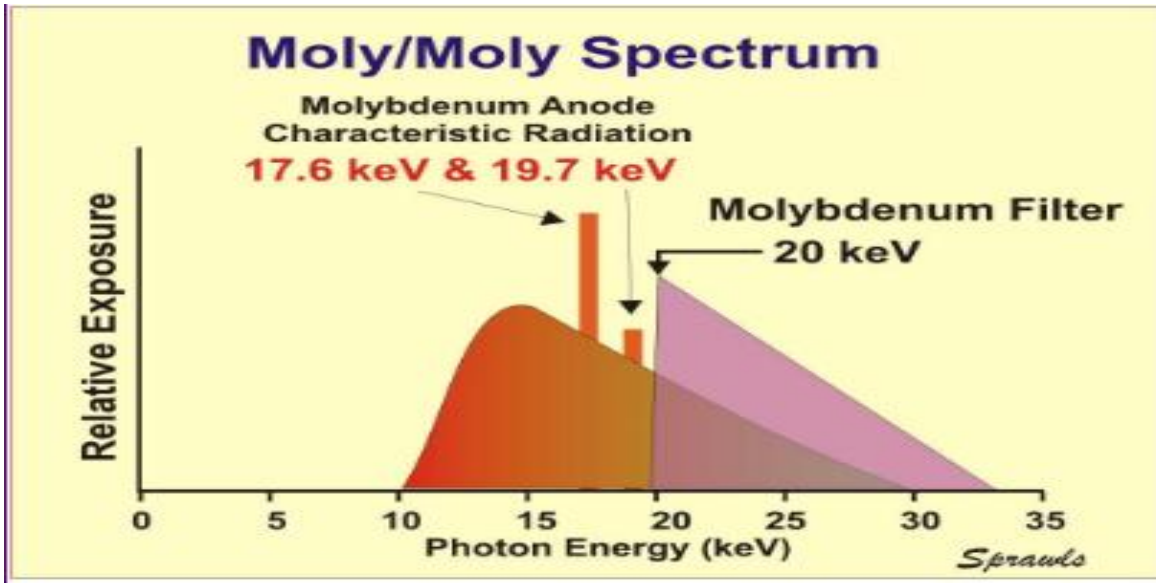
1.2.5 X-ray Tube

Most mammography machines use low kVp generators with molybdenum, rhodium or tungsten target of the x-ray tubes coupled with appropriate filter materials that include molybdenum (Z-42), rhodium (Z-45) and palladium (Z-46). Most combinations are usually Mo/Mo, Mo/Rh, Rh/Rh. Molybdenum and rhodium are the preferred target materials because they have low atomic numbers and therefore will produce suitable low energy characteristic radiation. The filter materials usually remove low energy photons to decrease patient dose and high energy photons to increase photoelectric interaction therefore improving image contrast. Several studies have been done on various combinations of target and filter materials comparing image contrast and average glandular dose on phantom models. Most agree that the Mo/Mo combination has better image contrast however combinations with rhodium tend to reduce patient dose. The combinations also depend on whether the machine is the conventional screen-film or digital.

The Monte Carlo study done by Dance et al (2000) on influence of anode target material and tube potential on contrast, SNR and AGD had several conclusions. The most important for this research is that Mo/Rh, Rh/Rh, Rh/Al offer low AGD values for most breasts at suitable tube potentials compared to Mo/Mo(11) on the digital mammography machine.

The GE Senographe Essential digital mammography machine being used in this research has a dual track anode of Mo and Rh and dual filter of Mo and Rh that can be selected by the operator or automatically by the automatic exposure control system. Molybdenum has an atomic number of 42, produce characteristic radiation energy at17.9 keV and 19.5 keV and its k-edge absorption (K_A) at an energy of 20.0 keV.

The molybdenum filter attenuates and blocks most of the bremsstrahlung spectrum above the energy of 20 keV. This results in a suitable spectrum most often used in mammography, produced with the Mo/Mo anode/filter combination(18).

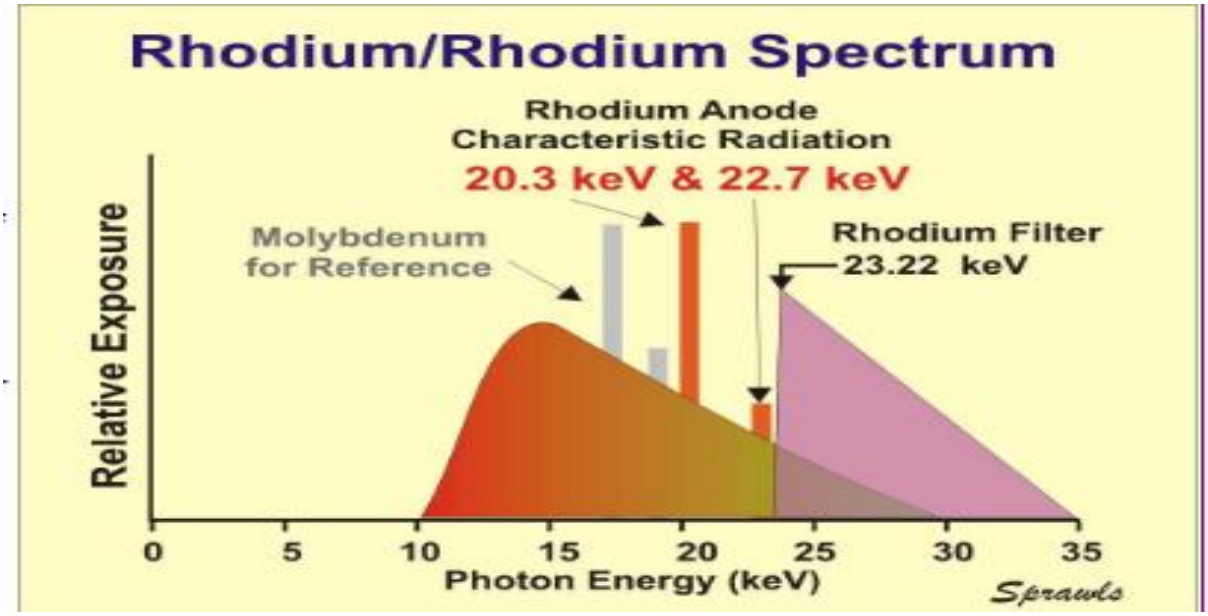


(**Mammography Physics and Technology for effective clinical imaging**)

Figure 3: Molybdenum/Molybdenum Energy Spectrum

Rhodium has an atomic number of 45 with a characteristic energy level of 20.3 and 22.7 keV. The rhodium filter has a K- edge (K_A) at energy of 23.22keV.

The rhodium filter with k-edge energy (23.22 keV) will include the portion of the bremsstrahlung between 20keV and 23, 22 keV to the x-ray beam. This will make the beam more penetrating than when using the molybdenum filter and provides some advantage when imaging thicker or denser breast(18).



(**Mammography Physics and Technology for effective clinical imaging**)

Figure 4: Rhodium/Rhodium Energy Spectrum

1.2.6 Breast Compression

The compression paddle is the 2nd most important part of the mammography machine. It offers breast compression in the 2 views of the breast, these are the cranio-caudal and mediolateral oblique and also in breast tomosynthesis.

Compression has several advantages: It reduces;

- **a)** Patient dose as the breast is thinned out uniformly and hence decreasing volume of tissue being irradiated.
- **b)** Scatter hence improving image contrast.
- **c)** Motional blurring.
- **d)** Geometrical unsharpness.
- **e)** Distortion
- **f)** It enhances the differences in density between normal and abnormal tissue.

Increased thickness will lead to high average glandular dose. Increasing compression decreases breast thickness and reduces radiation dose. A study done by M.A Helvier et al showed that the breast was better compressed on the craniocaudal views than mediolateral oblique views. This difference resulted in increased patient dose, a small distortion and geometrical unsharpness on the mediolateral oblique views (19).

Another study done by Hebrang et al supported the above conclusion and further recommended that in order to achieve better compression the MLO view should be done at an angle of 60 degrees for women with small and pendulous breast(20).

1.2.7 Digital Mammography

Currently most first world nations like the USA and top private hospitals in the country use digital mammographic equipment. Kenyatta National Hospital acquired a Ge Senographe Essential full field digital mammography, early April 2016. The equipment is similar to conventional mammography-system, but film cassette is replaced by digital image receptor and computer.

- Amorphous Se/ TFT solid state detectors are commonly used.
- Digital image receptors facilitate timely display of images (within 1 min of exposure).

Several studies have shown that the digital mammography machines provide better quality images with improved tissue contrast, it is better for dense breasts and younger female Patients who tend to have dense breasts and finally lower radiation doses compared to screen film mammography.(21)

Some previous studies reported no significant difference in cancer detection between screen film and full field digital mammography machines among radiologists(22). However due to the advantage of post-processing manipulation of various factors such as contrast offered by digital mammography, there were few repeat examination retake.

To justify the use of digital mammography in the market, the American College of Radiology Imaging Network did a study that showed that the average glandular dose in digital mammography was significantly lower by 22% compared to screen film mammography per acquired view.(22) The digital mammography equipment has few disadvantages one is cost, price range is between 200-300 thousand USD (20-30 MILLION KES) and inferior spatial resolution.

1.2.8 Breast Tomosynthesis (3D Digital Mammography)

The 2D digital mammogram produces overlapped images in the craniocaudal and mediolateral oblique planes, this can lead to misinterpretation and missing of cancerous lesions especially in dense breasts. Therefore in 2011, digital breast tomosynthesis was introduced as an adjunct to 2D breast imaging. It is an FDA approved technology for both diagnosis and screening and furthermore it overcomes the challenge of tissue overlap.

The digital breast tomosynthesis is a 3D imaging tool, in which the x-ray tube moves in an arc angle of 15-45 degrees,(although this can be varied) while taking a series of images of about 10-20 images. These images are then reconstructed to create a CT like study to enable the radiologist to view the breast in thinner slices of about 1mm. This allows the radiologist to better diagnose lesions that are hidden due to overlapping of tissues and decrease the rate of breast biopsies and repeat examinations.(23)

A research done in Yale university from August 2011 to July 2012(24) concluded that 2D mammography with breast tomosynthesis had a higher cancer detection rate especially in women with dense breasts and reduced patient recall rates and false positives. Currently in Yale university hospital, routine screening includes both 2D and3D mammography. However better image quality comes at higher radiation dose and this has been a major debate surrounding breast tomosynthesis. Most argue that the risk is worth it because of its higher cancer detection rate while other radiologists feel that it should not be part of the screening routine.

Currently there are 3 manufacturers that make breast tomosynthesis units worldwide, these are Hologic, GE healthcare and Siemens. The former 2 have FDA approval while the latter is still waiting on approval. It is reported that the manufactures' dosing parameters more than meet the FDA requirement of 300millirads per exposure and actually range between 150-200 millirads(23). Hologic has further improved its system by adding a C VIEW software that reconstructs 2D images from its 3D images therefore preventing further exposures(25). One study published in Turkey by Olgar et al(10) in 2012 compared radiation doses between 2D mammography and breast tomosynthesis for the Hologic digital mammography machine. They concluded that the breast tomosynthesis had a higher average glandular dose by 34% compared to 2D digital mammography. This was not a direct measurement dose but analysis of data provided by the digital machine and calculations were done using the Monte-Carlo calculation(5,6).

1.3 Breast Dosimetry

The breast is a radiosensitive organ, it is therefore important to quantify the amount of radiation dose it receives and the impact it has on risk of developing breast cancer. The mammography machine uses ionizing radiation of low photon energy, the doses are small and do not reach the threshold for deterministic effects. Mammography has a small probability of inducing stochastic effects. However due to screening programs, the probability of stochastic effects increases. High average glandular dose also increases the probability of stochastic effects. While mammography is an important tool in breast cancer detection, it can also increase the incidence of cancer in the radiosenstive breast.

It is therefore important to evaluate the mammography machines to ensure that they comply with international reference dose values of 2-3mGy to decrease the probability of the stochastic effects. The recent ICRP 2007 guidelines (6) recommend a tissue weighting factor of 0.12 from the previous value following the increased incidence of breast cancer worldwide.

1.4 Average Glandular Dose (AGD)

The average glandular dose or mean glandular dose of the breast is defined as the mean dose received by the glandular tissue during different examinations, mammography included. It is therefore the recommended measurement in mammography to determine the radiation risk to the patient. The term average glandular dose was first described by Karlsson in 1976 in an article he published called the "absorbed dose in mammary radiography",(25,26). He based

his research on the anatomical structure of the breast and the amount of energy absorbed by it.

In 1987, the ICRP and other commissions such as the European Protocol on breast dosimetry supported Karlsson(27), and the term average glandular dose was adopted as the preferred quantity for measuring radiation risk to the breast.

The AGD of the breast cannot be directly measured on patients as it occurs within the breast but it can be determined indirectly by use of 2 methods:

1. A breast phantom
2. Direct surface measurements on the patient, followed by calculations of the AGD using appropriate conversion ratios.

There are currently no standard protocols for breast dosimetry so either method is applicable.

1.5 Methods of Breast Dosimetry

1.5.1 Breast Phantom

A breast phantom is an object that simulates the breast composition and reacts to ionizing radiation the same way a breast would. The FDA approved breast phantom(29) for quality assurance tests of mammography machine has physical dimensions of 8 X 18 cm corresponding to a medium breast for women in their population. It has an adipose thickness of 0.4cm, a fibroglandular layer of variable thickness and composition between fat and glandular layer (30/70, 50/50 and 70/30). The commonly used has a thickness of 4.2 cm which corresponds to 50/50 fibroglandular composition. The phantom is either made of acrylic or BR-12.

In an article by Dance et al, the calculation of AGD using a breast phantom is based on the formula(7) :

$$\mathbf{AGD=Kgcs.}$$

a) Where **K** is the incident air kerma at the upper surface of the breast phantom, measured without back scatter from the breast. The g,c, and s are conversion factors derived from a simulation of series part of the Monte Carlo Study by Prof Dance et al,(9,29).

b) **g**-stands for glandularity at 50% and is influenced by the target/filtration and KV.

c) **c**- corrects for glandularity and therefore allowing inclusion of breasts with different glandularity.

d) **s**-this accounts for different x-ray spectrum.

The values of g, c and s should be looked up for the breast thickness that is simulated by the phantom as shown by the Dance tables in appendix A- (9,28,30):
For digital breast tomosynthesis, the formula is:

AGD=KgcsT

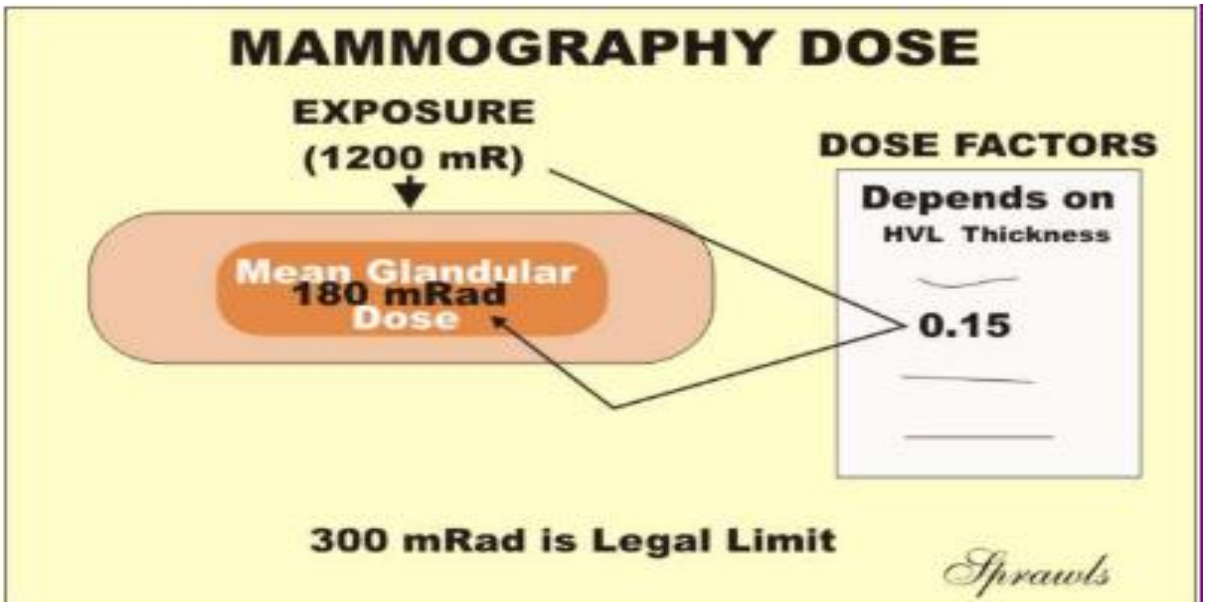
T stands for tomo factors for the individual tomographic projections taken as the xray tube moves in arc angle(15-45 degrees)

1.6 Direct Surface Measurements

The average glandular dose is calculated by multiplying the entrance surface air kerma(ESAK) by conversion factors provided for by Dance(26).

AGD=F.ESAK

The ESAK values can be measured using thermoluminiscence dosimeters (TLD) and ionization chambers(31).
For conversion factors are as provided by Dance et al(26).



(**Mammography Physics and Technology for effective clinical imaging**)

Figure 5: Diagram showing calculation of AGD using direct measurements

Several studies have used this method for example Chevalier et al used information extracted from DICOM reader and measured ESAK values to calculate the AGD values for digital mammography. They concluded that the AGD value per exposure was 1.88mGy and 3.8mGy per examination for CC and MLO respectively(32). Both methods are therefore valid and can be used for the measurement of average glandular dose during digital mammography. Currently all digital mammography machines automatically calculate and display the AGD value for each patient.

1.7 Theoretical Monte Carlo Methods

These are theoretical methods of deriving organ doses using mathematical photon transport models when the radiation beam quality parameters are known.

2.0 CHAPTER TWO

2.1 Study Justification

Mammography has been proven to be the gold standard in breast imaging during screening for breast cancer and confirming the diagnosis of breast cancer. Mammography uses ionizing radiation and the risks are well documented, therefore any exposure needs to be justified and doses need to be kept as low as reasonably possible. Radiation dose is a major concern in the United States and Europe where screening is done. In Kenya and most African countries there is no screening program, instead mammography is mainly for confirmation of clinical diagnosis of breast cancer.

However there is ongoing evolution of healthcare in the country, more and more private facilities are buying the state of art radiology equipment. Kenyatta National hospital acquired a GE healthcare digital mammography machine in April 2016. It is therefore important to establish if the digital mammography machine's radiation dose level is in keeping with international standards of 2-3mGy per exposure(6,7,8,33). Unfortunately there have been very few or no studies done on the digital mammography in Kenya and Africa as a whole. Majority of the reported studies have been done elsewhere in the USA, Europe and other developed countries. Therefore, there is an urgent need to assess the levels of patient doses and equipment performance in our own setting that can inform whether the current practice is in conformity with recommended radiation protection standards.

The knowledge of radiation dose to the breast is of great value and this research gives us a chance to set the standards in Kenya and Africa as a whole. Once a screening program is set in place, many patients with normal breasts will be exposed to radiation and this carries risks.

This research analyzed the AGD values as was given by the GE digital mammography unit to find the mean AGD value for the patients coming to KNH. The mean AGD value was per exposure in the cranio-caudal and MLO views in 2D mammography and breast tomosynthesis. The breast compression thickness was also determined and correlated to AGD values.

2.2 Hypothesis

2.2.1 Null Hypothesis

The average glandular dose received by the breasts during digital mammography and breast tomosynthesis is between 2-3mGy which is in keeping with international dose reference levels as suggested by the ICRP, European guidelines and UK Protocols on mammography(6,7,8,33).

2.3 Aim

- To assess the mean average glandular dose received by the breast during digital mammography exam in the craniocaudal and mediolateral oblique views.

- To assess the mean average glandular dose during breast tomosynthesis. The findings of this study will generate the first data on AGD levels for digital mammography and breast tomosynthesis in Kenya.

- To generate data that will assist in the formulation of a policy on a breast screening program in the country.

- To stimulate comprehensive research in this field that would include breast phantoms whose breast densities can be varied and software models of calculation of AGD values.

2.4 Study Question

a) Is the mean AGD value of the GE digital mammogram machine within international dose reference level?

b) What is the mean AGD value for breast tomosynthesis and is it acceptable for our population?

2.5 Objectives

2.5.1Broad Objective

The objective of the study is to determine the mean average glandular dose offered in digital mammogram and digital breast tomosynthesis.

2.5.2 Specific Objectives:

- To determine the mean AGD in the 2D cranio-caudal view per exposure.
- To determine the mean AGD in the 2D medio-lateral-oblique view per exposure.
- To determine the mean AGD in the 3D breast tomosynthesis.
- To determine the mean compressed breast thickness.
- To determine if CBT plays a role in the reduction of radiation dose in both the 2D and 3Dimaging modes.

3.0 CHAPTER THREE

3.1 Study Design and Methodology

3.1.1 Study Design

This was a cross sectional study carried out in the mammography unit within KNH radiology department.

3.2 Study Area Description

Mammography unit in Kenyatta National Hospital, located in Nairobi County, Kenya. A typical shift in the unit is staffed by a radiographer (technician), consultant radiologist and a resident radiologist. The daily workload comprises approximately five to eight mammography.

3.3 Study Population

The study included patients referred by a medical physician for mammography at Kenyatta National hospital.

3.4 Inclusion Criteria

All Patients referred for diagnostic mammography.

3.5 Exclusion Criteria

- Patients with breast implants.
- Patients who have one breast.
- Refusal of consent.

3.6 Sample Size Determination.

Sample size was calculated using the following formula:

$$n = \frac{Z^2_{\alpha/2} \times \sigma^2}{d^2}$$

Where: n = Sample size.

Zα/2 = Standard normal deviate at 5% level of significance (95% CI) is 1.96

σ = Standard deviation of MGD per exposure 0.61 mGy

d = margin of error (set at 0.085)

Applying the above sample calculation gives a minimum sample size (n) of 200 patients.

A total of 200 patients were sampled.

200 female patients aged between 30-80 years old were randomly selected for this study.

3.7 Study Procedure

KNH uses a Senographe Essential (General electric Company) digital mammography machine. It has a dual anode made up of molybdenum and rhodium and a dual filter made up of molybdenum and rhodium combination with a minimum inherent filtration of 0.0mm aluminum. Other than the radiation dose displayed by the machine, indirect measurements were done using phantom and TLD chip. This is because dosimeters are radio-opaque and when using low kV exposure they will appear on image and may obscure pathology on the breast. Therefore direct dosimetry measurements were avoided.

The patient was exposed first and all patients included in the study had CC and MLO exposures of both breasts. Each patient's age and radiological examination data was recorded as provided by the machine. These included the AGD, ESE,KVP, type of anode and filter material, CBT and MODE.. Once the exposures were made to the breasts, the patient was asked to step aside.

The TLD was placed on top of the phantom and using the same exposure factors as the patient's breast, a second exposure was made. The exposure factors of the phantom were recorded, together with the CBT, AGD as recorded by the machine and ESE. Due to difficulty in firmly fastening the phantom, only the cranio-caudal views were repeated using the phantom.

The patients' films were then evaluated by principal investigator together with a consultant radiologist upon which they decided whether the Patient needed to have a breast tomosynthesis. The breast tomosynthesis and mediolateral-oblique views could not be interrogated due to inability to secure the phantom.

3.7.1 Calculation of the Average Glandular Dose

The formula for calculating the AGD is based on protocols by the European Guidelines and IAEA dosimetry.

The AGD was calculated by multiplying the entrance surface air kerma(ESAK) by conversion factors provided for by Dance(26)-appendix A.

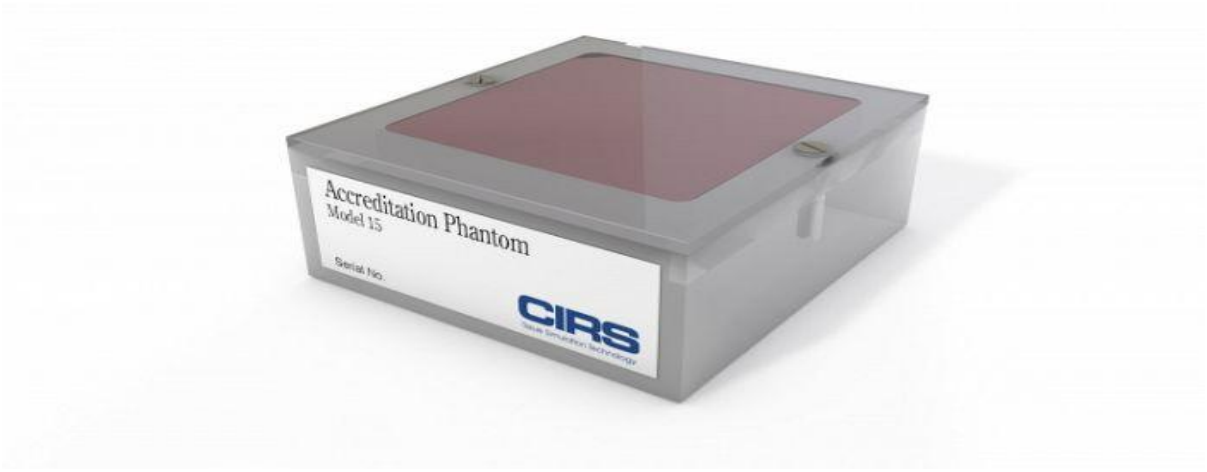
AGD=F.ESAK

The ESAK values were measured using thermoluminiscence dosimeters (TLD)(31).
This was placed on a phantom with a 50% glandular/adipose composition. For conversion factors(F) they are as provided by Dance et al-appendix A-(9,28,30) .The breast glandularity of 50% was assumed.

3.7.2 Evaluation of AGD Using the Phantom

A 62mm PMMA of 50% glandularity was used for simulation. Patients who had a CBT between 50-65mm were selected for the simulation tests. This is because the phantom has a fixed height of 62 mm. The phantom with a TLD attached on top of it was placed on top of the mammogram bucky. The phantom was then exposed using the same exposure factors as the patients. The CBT and exposure factors were recorded. The AGD and ESE were also recorded as given the by machine.

Image of breast phantom



The TLDs were then read using the TLD reader and the light units converted to milligrays to obtain the ESAK.The AGD was finally calculated using the ESAK and conversion factors. Finally a comparison was made among the patients AGD and phantom AGD as provided by the machine and calculated AGD.

3.8 Data Collection Procedures

The data was collected after careful evaluation of the request form, physical examination and proper mammographic examination. The data was recorded on to a questionnaire (APPENDIX F) which was administered by the principal researcher and research assistants.

3.9 Materials

- KNH uses a Senographe Essential (General electric Company) digital mammography machine.
- Data collection tool/questionnaire.

3.9.1 Study Personnel

- Radiographers working at the mammography unit in KNH.
- Biostastician to analyze the data.

3.10 Data Collection Tool

A structured data collection form (appendix C) was completed by the principal researcher and research assistants who were the radiographers present at the time of examination. The data collection tool is provided in appendix C.

3.11 Data Handling

The questionnaires were sorted at Kenyatta National hospital. The filled questionnaires were stored in the department of diagnostic imaging and radiation medicine under lock and key during data collection and entry and later moved for safekeeping at an offsite location. Data were entered into a password protected Microsoft access database. Once entry was completed, the principal investigator compared contents of the database with the hard copy results to identify and correct any data entry errors.

3.12 Ethical Considerations

- Written informed consent was sought from the patients.
- Ethical clearance. The research team obtained ethical clearance to conduct this study from the KNH/UON Ethics and Scientific Review Committee.
- Institutional permission was sought from both KNH and university of Nairobi
- Confidentiality was maintained at all times during the study

3.13 Confidentiality of patients

The principal investigator ensured that there were no identifiers that could link the research data to study Patients. Each study patient was allocated a unique numeric identifier that was used in the data abstraction tool and database.

3.14 Confidentiality of data obtained

Access to the patient data was restricted. No unauthorized persons were allowed any access to patient records. All electronic databases were password protected to control access.

3.15 Beneficence / Maleficence

The results of the study will be used to improve Patient management and set reference diagnostic AGD values. All patients were protected from any health, physical, social or economic harm.

3.16 Data Management and Statistical Analysis Plans

3.16.1 Data management

All data abstraction tools and electronic databases (MS Excel) utilized in this study were protected by procedures which are consistent with applicable laws, policies, regulations and standards in Kenya. Computers used to enter data were password protected at the operating system level using software that is commercially available. The electronic databases were password protected and all hard copies were kept under lock and key.

3.16.2 Data analysis

The Statistic Package for Social Science version 20.0 for Windows® was utilized for statistical analysis of data. Analysis of patients' demographic data was conducted using descriptive statistics. Demographic data were collected as categorical data and analyzed using frequency distribution curves to determine the percentage of patients' with specific demographic traits. The mean AGD was calculated for each of the three imaging modes used: 2D (cranio-caudal and medio-lateral oblique) and 3D breast tomosynthesis. The mean dose for each imaging mode and view was presented along with a standard deviation to show variation in AGD per exposure. The machine readings for breast thickness were used to calculate a mean compressed breast thickness and SD for the sample. Finally, correlations were done between CBT and radiation dose through calculation correlation coefficients.

3.17 Data Dissemination

The results of this study are bound in a Master's thesis book and disseminated to the department of Diagnostic imaging and Radiation medicine. A copy shall be provided to all the involved departments which are; KNH radiology department, the GE healthcare manufacturers, the radiation protection board of Kenya and the Kenya Association of Radiologists. This study will also be disseminated to a wider audience through publications in peer review journals, technical briefs and presentations in Kenyan and international meetings.

4.0 CHAPTER FOUR: RESULTS

The mammograms of 200 female patients were included in this study. The mean age of the patients was 50.4 years (SD ± 9.2) with a range between 30 and 80 years. Figure 6 shows the age distribution of patients.

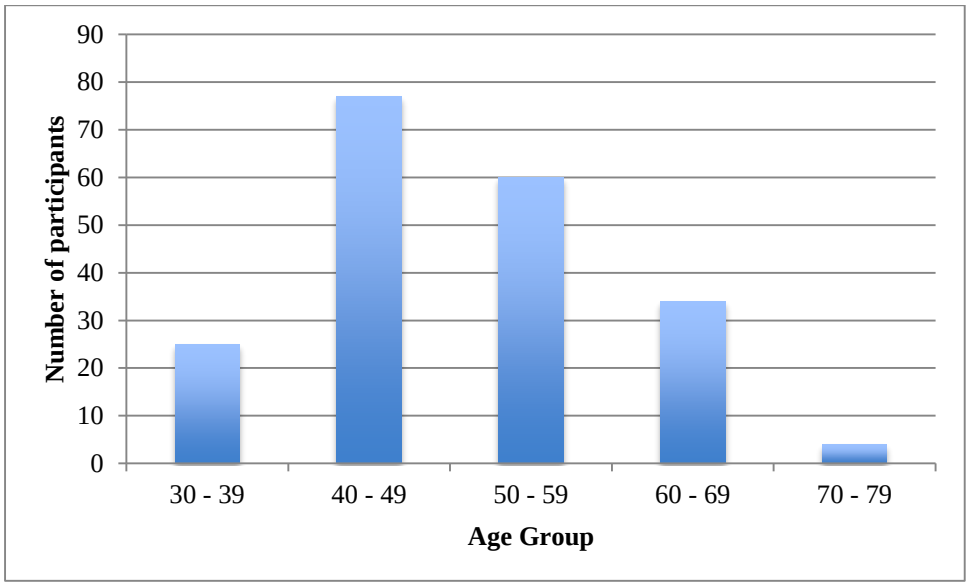


Figure 6. Total number of participants according to Age Group during the study period (Nov 2016 – May 2017).

4.1 Mean Glandular Dose per Exposure View

The AGD values per view of exposure was as follows:

Table 3:Mean glandular dose in breast mammography (mGy)

VIEW	MEAN	SD	MINIMUM	MAXIMUM
RCC	1.2	0.6	0.4	7.9
LCC	1.2	0.8	0.5	7.1
RMLO	1.3	0.5	0.4	6.9
LMLO	1.4	0.9	0.5	7.7

RCC-RIGHT CRANIOCAUDAL LCC-LEFT CRANIOCAUDAL

RMLO-RIGHT MEDIOLATERALOBLIQUE LMLO- LEFT MEDIOLATERALOBLIQUE

Average CC versus MLO Views MGD

There was a significant difference in mean radiation dose between the CC and MLO views ($p < 0.001$). The results of the t-test are shown in Table 4. The MLO views had a higher mean dose of 1.3 ± 0.6 mGy compared to the CC view of 1.2 ± 0.5 mGy . The mean difference in dose between the two views was -0.1mGy (95% CI -0.2 to -0.1)

Table 4: Comparison of mean CC and MLO AGD in breast mammography (mGy)

Mammography View	Frequency (n)	Mean dose	SD	95% CI
CC-MGD	200	1.2	0.5	1.1-1.3
MLO-MGD	200	1.3	0.6	1.2-1.4
Difference	200	-0.1	0.2	-0.2- -0.1

CC-MGD- craniocaudal mean glandular dose

MLO-MGD-Mediolateral oblique mean glandular dose

The MGD for breast tomosynthesis among 11 patients with data was 0.32 (SD 0.46). This was insufficient data for analysis.

4.2 Compressed Breast Thickness and Radiation Dose

The mean CBT for various views are given in table 5 and ranged between 53.1 and 61.5 mm.

Table 5: Mean CBT according to mammography views (mGy)

CBT	MEAN CBT (in mm)	SD	MINIMUM	MAXIMUM
RCC	53.1	13.0	17	120
LCC	53.5	14.2	20	115
RMLO	61.5	15.0	18	116
LMLO	61.5	16.0	22	119

RCC- Right Craniocaudal
LCC- Left Craniocaudal
RMLO- Right Mediolateraloblique
LMLO- Left Mediolateraloblique
CBT-Compression breast thickness

There was a positive correlation between CBT and MDG in all the four views examined in the study (Figure 7 and 8).

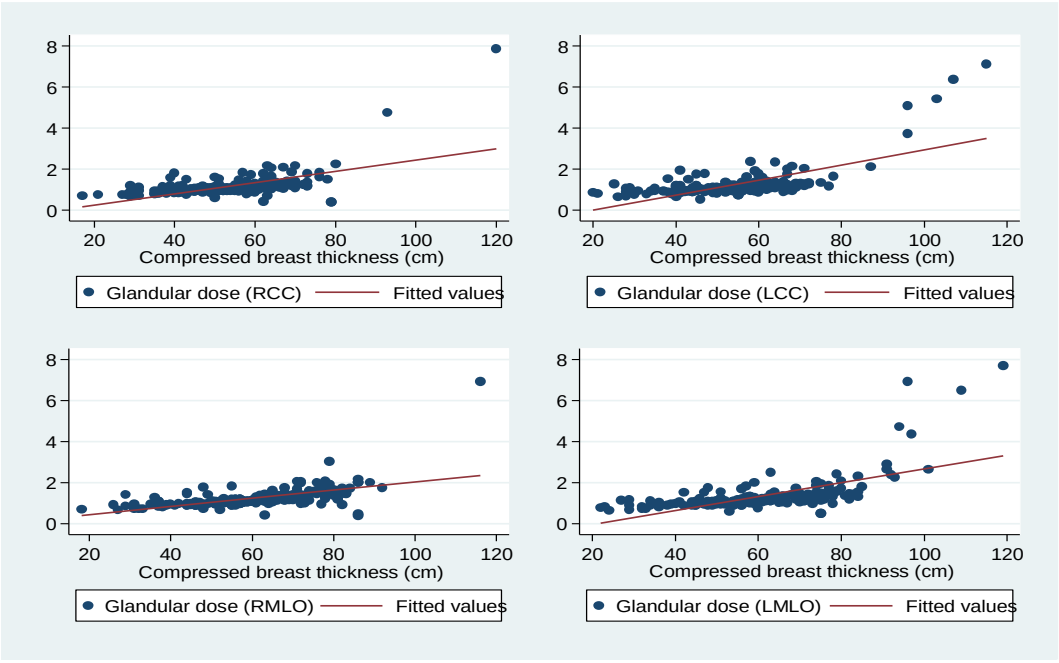


Figure 6: Correlation between CBT and mean glandular dose according to view per exposure

Figure 8 shows a positive correlation between CBT and MGD for combined CC (Pearson's correlation = 0.58) and MLO (Pearson's correlation = 0.58) views.

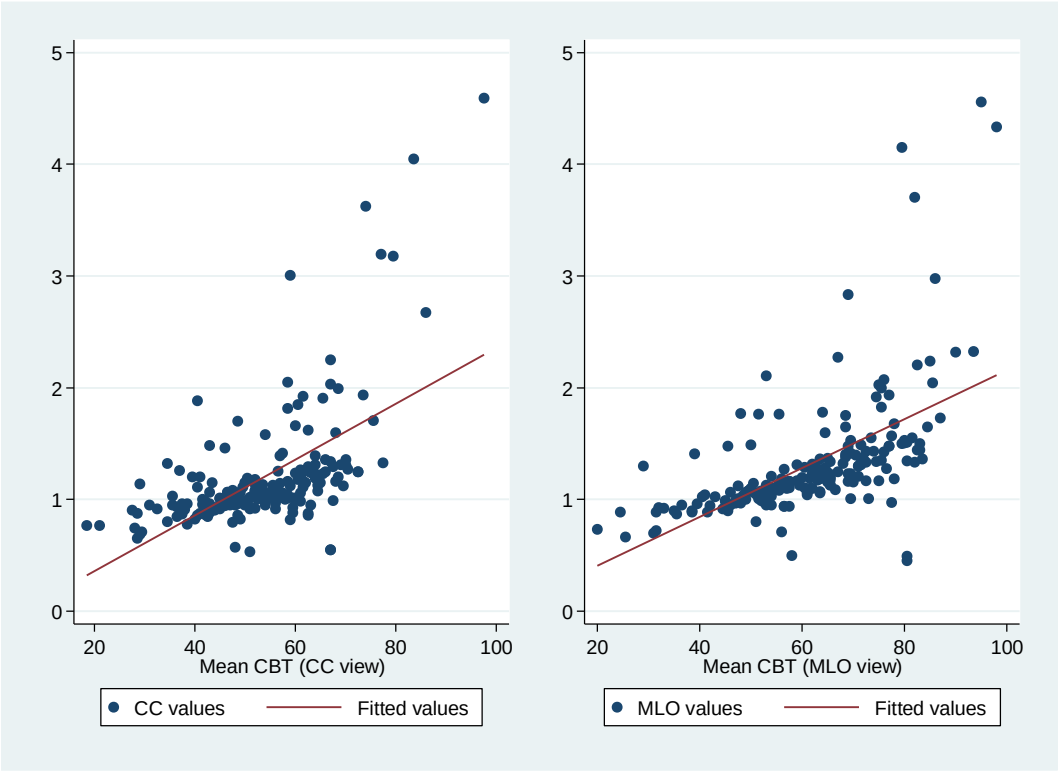


Figure 7: Correlation between CBT and mean glandular dose according combined view

4.3 Target/Filter Material and Radiation Dose

The GE machine has a dual anode and dual filter material. These include Mo,Rh and Mo,Rh. The results show that the commonest selection for most patients was Rh/Rh in all the views.

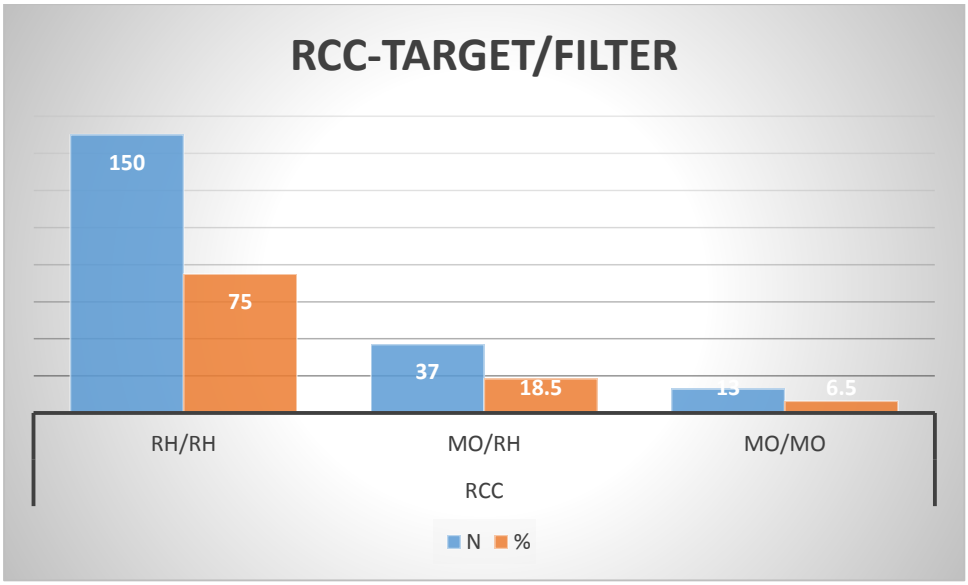


Figure 8: Target/Filter material in RCC view

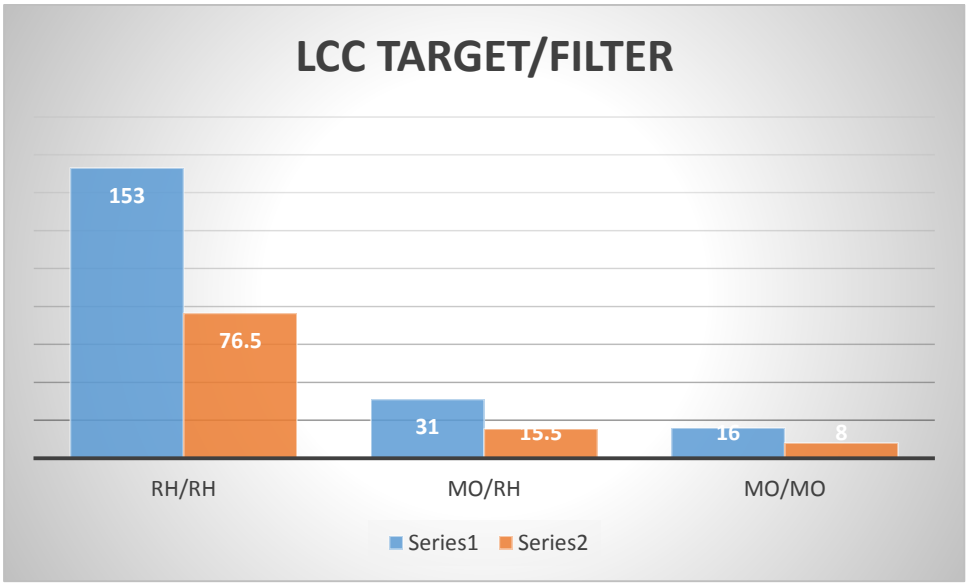


Figure 9: Target/Filter material in LCC view

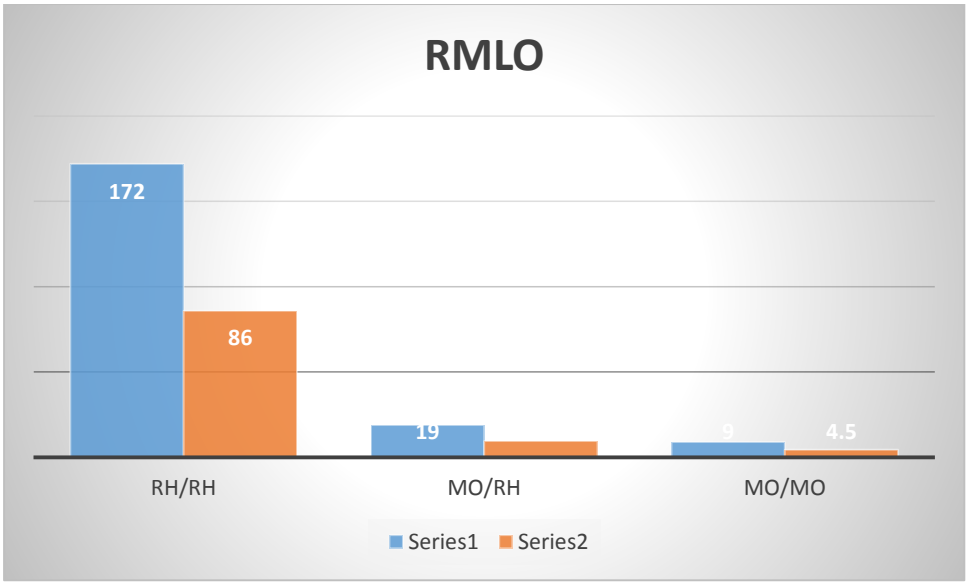


Figure 10: Target/Filter material in RMLO view

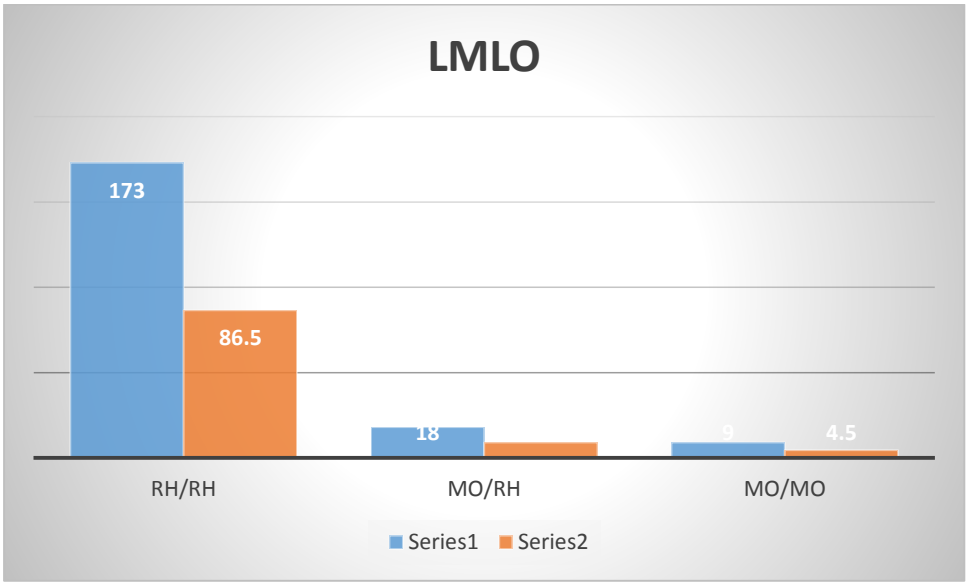


Figure 11: Target/ Filter materials in LMLO

4.3.1 Target/Filter Combinations versus Radiation Dose

The results in Table 6 show that the RH/RH view emits a higher dose compared to the other combinations in all the views per exposure, as shown in the tables below.

However it is important to note that the number of patients who used Mo/Mo and Mo/RH were very few and a confident comparison cannot be made.

Table 6:Target /filter combinations and AGD

A. CC VIEW(mGy)

	RCC			LCC		
	n	**Mean MGD**	**SD**	**n**	**Mean MGD**	**SD**
Rh/Rh	150	1.2	0.7	153	1.3	0.8
Mo/Rh	37	0.9	0.2	31	1.1	1.0
Mo/Mo	13	1.1	0.2	16	1.1	0.2

B. MLO VIEW(mGy)

	RMLO			LMLO		
	n	**Mean MGD**	**SD**	**n**	**Mean MGD**	**SD**
Rh/Rh	172	1.3	0.5	173	1.4	0.9
Mo/Rh	19	0.9	0.2	18	1.0	0.2
Mo/Mo	9	1.0	0.2	9	0.9	0.1

Rh- Rhodium CC-craniocaudal

Mo- molybdenum MLO-mediolateraloblique[1]

The results in Table 7 show the ranges of kV used for various target and filter combinations.

Table 7: Tube Voltage (keV) and Target/ Filter

	Right breast				Left breast			
	N	**median**	**Minimum**	**Maximum**	**N**	**median**	**Minimum**	**Maximum**
CC view								
Rh/Rh	150	29	27	31	153	29	27	31
Mo/Rh	37	27	26	29	31	27	26	30
Mo/Mo	13	26	26	30	16	26	26	29
MLO view								
Rh/Rh	172	29	27	31	173	29	27	31
Mo/Rh	19	27	26	29	18	27	26	29
Mo/Mo	9	26	26	30	9	26	26	29

CC- CRANIOCAUDAL MLO-MEDIOLATERALOBLIQUE

Rh-Rhodium Mo- molybdenum

111

Table 8 below show the mean CBT used for the various target/filter combinations. Rh /Rh combination was used for breast with increased thickness.

Table 8: CBT(mm) and Target/ Filter

	Right breast		Left breast	
	N	**Mean CBT**	**N**	**Mean CBT**
CC view				
Rh/Rh	150	58.0	153	58.1
Mo/Rh	37	39.4	31	41.2
Mo/Mo	13	34.5	16	34.1
MLO view				
Rh/Rh	172	65.2	173	65.3
Mo/Rh	19	39.8	18	38.8
Mo/Mo	9	34.9	9	33.9

CBT-COMPRESSION BREAST THICKNESS
CC-CRANIOCAUDAL
MLO-MEDIOLATERALOBLIQUE
Rh-Rhodium
Mo-molybednum

4.3.2 Phantom Test Results

TLD calculation range kVp = 26 to30

Range mAs 3.27 to 87

Table 9:Phantom machine AGD and calculated AGD (mGy)

	N	Mean	SD	Min	Max
MGD reading (machine)	45	0.9	0.3	0.4	1.8
Calculated MGD (TLD)	45	0.1	0.1	0.001	0.3

MGD-MEAN GLANDULAR DOSE

TLD-THERMOLUMINESCENT DOSIMETER

5.0 CHAPTER FIVE: DISCUSSION

The purpose of this study was to determine the average glandular dose in 2D digital mammography and tomosysnthesis in diagnostic mammography. The recommended diagnostic reference levels are 2mGy by the ICRP(6), 2.5mGy as by the UK(7) and 2mGy(7,8) as by the European guidelines .The American College Of Radiology also recommends that the average glandular dose for the breast should be between 2-3 mGy(33). The mean AGD in this study was 1.2±0.5 mGy for CC and 1.3±0.6mGy for MLO views respectively. This was within the recommended dose and similar to results from other studies(19). There was a significant difference in mean radiation dose between the CC and MLO views ($p < 0.001$), the mean difference in dose between the two views was -0.1mGy (95% CI -0.2 to -0.1). This difference is attributed to the high mAs values used in the medio-lateral views and the difference in the compressed breast thickness. MLO tends to be thicker because of the presence of the pectoral muscles(19).

The mean CBT was 53.1mm in the cc view and 61.5mm in the MLO view. These findings were almost similar to a study done by J B Mccullugah , clinical dose performance of full field digital mammography in a breast screening program, found the mean CBT in CC view was 60.5mm and in the MLO was 63mm (9).In the present study a strong correlation between dose and CBT was found . These findings are similar with a study done by M.A Helvier et al that found increasing compression decreases breast thickness and reduces radiation dose. Secondly, the breast was better compressed on the craniocaudal views as compared to the mediolateral oblique views. This difference might have resulted in increased patient dose (19).

Another study done by Hebrang et al supported the above observation and went a step further to recommend that the MLO view should be done at an angle of 60 degrees for women with small and pendulous breast. This is because better compression is achieved at this angle as opposed to the 45 degrees and hence a reduction in patient radiation dose(20). The mean tube kV and mAs values were on the higher side but within acceptable range. The kV range was from 26-31 and mAs values were 35-335(Appendix C). According to the medical physicists on mammography technology, the recommended kV range is between 24-32 depending on the anode/filter combination used(34). Increasing the kV will increases the efficiency and output for a specific mAs value and shifts the photon energy spectrum upward so that the beam becomes harder and more penetrating.

This is necessary when imaging thicker and more dense breast, although, a more penetrating beam will reduce contrast sensitivity. This, therefore means that compressed breast thickness is the principal factor that determines the optimum kV. The study proved that there was a strong correlation between the kV and CBT in both CC and MLO views (Appendix C-figure 14). This therefore seems to suggest that most women included in this study had thick breasts. It is also important to note that most were patients who undergo breast mammography at Kenyatta National Hospital have existing breast disease at an advanced stage and this tends to increase the thickness of the breast. This could explain the high kV and mAs values with the most common target/filter combination used in the study being Rh/Rh (86%). The other used combinations were Mo/Rh and Mo/Mo. The GE Senographe Essential digital mammography machine being used in this research has a dual track anode of Mo and Rh and dual filter of Mo and Rh, these are selected automatically by the automatic exposure control system.

Molybdenum has an atomic number of 42, produces characteristic radiation energy at17.9keV and 19.5keVand its k-edge absorption (K_A) at energy of 20.0 keV. Rhodium has an atomic number of 45 with a characteristic energy level of 20.3 keV and 22.7keV. The rhodium filter has a k edge (K_A) at energy of 23.22keV. Rhodium has a more penetrating beam than molybdenum filter and provides some advantage when imaging larger or denser breast(18).The study therefore suggests that most of the patients had thick or dense breasts hence the use of Rh/Rh combination. The Rh/Rh combination was selected for breast thicknesses up to 58 mm. The Mo/Rh was selected for 39.4 mm and Mo/Mo for 34.5mm.

The data from the study showed that patients who used Rh/Rh combination received a higher dose compared to the other patients who used other target/filter combinations. This may not reflect a true picture because the number of patients who used Mo/Rh (9.5%) and Mo/Mo (4.5%) were significantly low and therefore affecting calculation in the mean MGD. The Monte Carlo study done by Dance et al on influence of anode target material and tube potential on contrast, SNR and AGD had several conclusions. The most important for this research is that Mo/Rh, Rh/Rh, Rh/Al offer low AGD values for most breasts at suitable tube potentials compared to Mo/Mo(11) on the digital mammography machine.

The selected kV increased with compression breast thickness (CBT) and ranged between 27kV and 31 kV for the Rh/Rh combination and between 26 kV and 30 kV for the Mo/Rh combination. And for Mo/Mo ranged between 26 -29 kV in the CC view. In the MLO view

the range was similar as shown in the result section. Analysis of the results between kV,CBT and target/filter combination indicate a lot of overlap which is expected and is most likely a reflection of the dependence of the Automatic Exposure Control system on both breast thickness and density to select the target/filter combination. Only 11 out of 200 patients had tomosynthesis examination and therefore the data was insufficient for any objective analysis. Forty-five phantom tests were carried out using an approved phantom model 015 with 50/50% composition. This is a digital mammography accreditation phantom used in assessing the image quality in full-field digital mammography (FFDM). The phantom was borrowed from the radiation protection board and is usually used to test the performance of a mammographic system by a quantitative evaluation of the system's ability to image small structures similar to those found clinically.

The results revealed that the machine was significantly giving a low output of radiation. The results greatly differed from the projected machine MGD values of the same phantom. The machine MGD varied from 0.4mGy to 1.8mGy with MGD 0.9mGy and 0.001mGy to 0.3mGy with 0.1mGy by TLD reading. These figures were close to those of a study done in Kuala Lumpar by Kamal et al using breast phantoms showed that the lowest AGD value for the phantoms (20/80) was 2.28 mGy for 2D and 2.48 mGy for 3D, for the 50/50 phantoms the AGD was 0.97mGy for 2D and 1mGy for 3D(35). The range of kV used for the study was 26-30 and mAs range of 8.7 to 80. The kV and mAs values were borrowed from patient data collected. The CBT of the phantom was 62mm.

5.1 Conclusion

This study demonstrated that the AGD values for patients in the mammography unit in Kenyatta National Hospital, were within the international recommended values as per the ICRP and European Protocols on mammography.The AGD values were 1.2 ± 0.5 for CC view and 1.3±0.6 for MLO view. The AGD for tomosynthesis (3D) could not be adequately assessed due to low number of examination requests. The study also proved that the AGD values were higher in the MLO view compared to the CC view, statistical difference of 0.1 and this is reinforced by other studies done in other parts of the world. The CBT also played a big role in the reduction of dose during mammographic examinations.

There is no knowledge of breast density within our population and this hampered a true reflection of the value of AGD. The calculations presented above were not based on breast density of the patient. The data collected strongly suggests that most women in Kenya have

thick dense breast, however it is not clear if the breast density is natural to the Kenyan woman or due to breast cancer which most of our patients in the mammography unit were suffering from. There is the therefore need for research in this area, best conducted during breast screening programs.

5.2 Recommendation

- It is important to know the breast density of the normal Kenyan woman to accurately determine the AGD values
- Breast screening programs should be initiated countrywide.
- Availability of all breast phantom with varying glandular tissue to fat compositions.
- Education of the radiologists and other medical doctors on the use and advantages of breast tomosynthesis.

5.3 Study Limitations

- No direct dose measurements are possible in mammography and the study relies on the machine's automated values whose accuracy is manufacturer dependent.
- Lack of a compressible breast PMMA (polymethyl methacrylate) phantom of the standard breast densities (glandular/fat-30/70, 50/50 and 70/30).
- Lack of knowledge on the population breast density and softwares such as the VOLPARA to determine breast density, these would have enabled accurate estimation of average glandular dose exposed to breasts of different densities. Absorbed dose is a nearly linear function of breast glandular tissue.
- Measurements of the phantom were done in only the craniocaudal view.
- Lack of patients for the tomosynthesis examination.

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APPENDICES

Appendix A: Dance Conversion Tables

TABLE A.1: g-FACTORS FOR BREASTS SIMULATED WITH A BREAST PHANTOM (DANCE 2000.2009, 2011)

PMMA thickness (mm)	Equiv. breast thickness (mm)	Gland. of equiv. breast (%)	*g*-factors (mGy/mGy) HVL (mm Al) 0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.378	0.421	0.460	0.496	0.529	0.559	0.585	0.609	0.631	0.650	0.669
30	32	67	0.261	0.294	0.326	0.357	0.388	0.419	0.448	0.473	0.495	0.516	0.536
40	45	41	0.183	0.208	0.232	0.258	0.285	0.311	0.339	0.366	0.387	0.406	0.425
45	53	29	0.155	0.177	0.198	0.220	0.245	0.272	0.295	0.317	0.336	0.354	0.372
50	60	20	0.135	0.154	0.172	0.192	0.214	0.236	0.261	0.282	0.300	0.317	0.333
60	75	9	0.106	0.121	0.136	0.152	0.166	0.189	0.210	0.228	0.243	0.257	0.272
70	90	4	0.086	0.098	0.111	0.123	0.136	0.154	0.172	0.188	0.202	0.214	0.227
80	103	3	0.074	0.085	0.096	0.106	0.117	0.133	0.149	0.163	0.176	0.187	0.199

TABLE A.2: c-FACTORS FOR BREAST PHANTOMS (BASED ON DANCE 2000, 2009, 2011)

PMMA thickness (mm)	Equiv. breast thickness (mm)	Gland.of equiv. breast (%)	*c* -factors HVL (mm Al) 0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65	0.70	0.75	0.80
20	21	97	0.889	0.895	0.903	0.908	0.912	0.917	0.921	0.924	0.928	0.933	0.937
30	32	67	0.940	0.943	0.945	0.946	0.949	0.952	0.953	0.956	0.959	0.961	0.964
40	45	41	1.043	1.041	1.040	1.039	1.037	1.035	1.034	1.032	1.030	1.028	1.026
45	53	29	1.109	1.105	1.102	1.099	1.096	1.091	1.088	1.082	1.078	1.073	1.068
50	60	20	1.164	1.160	1.151	1.150	1.144	1.139	1.134	1.124	1.117	1.111	1.103
60	75	9	1.254	1.245	1.235	1.231	1.225	1.217	1.207	1.196	1.186	1.175	1.164
70	90	4	1.299	1.292	1.282	1.275	1.270	1.260	1.249	1.236	1.225	1.213	1.200
80	103	3	1.307	1.299	1.292	1.287	1.283	1.273	1.262	1.249	1.238	1.226	1.213

TABLE A. 3: HVL MEASUREMENTS FOR DIFFERENT TUBE VOLTAGE AND TARGET FILTER COMBINATIONS (DANCE 2011).

kV	HVL (mm Al) for target filter combination Mo Mo	Mo Rh	Rh Rh	W Rh	W Ag	W Al (0.5mm)	W Al (0.7mm)
25	0.32 ± .02	0.38 ± .02	0.37 ± .02	0.50 ± .03	0.51 ± .03	0.34 ± .03	0.42 ± .03
28	0.35 ± .02	0.42 ± .02	0.42 ± .02	0.53 ± .03	0.58 ± .03	0.39 ± .03	0.49 ± .03
31	0.38 ± .02	0.45 ± .02	0.45 ± .02	0.56 ± .03	0.61 ± .03	0.44 ± .03	0.55 ± .03
34	0.40 ± .02	0.47 ± .02	0.47 ± .02	0.59 ± .03	0.64 ± .03	0.49 ± .03	0.61 ± .03
37				0.62 ± .03	0.67 ± .03	0.53 ± .03	0.66 ± .03

TABLEA. 4: s- FACTORS FOR DIFFERENT TARGET/FILTER MATERIAL(DANCE 2000,2009,2011).

Target material	Filter material	Filter thickness (μm)	*s*-factor
Mo	Mo	30	1.000
Mo	Rh	25	1.017
Rh	Rh	25	1.061
W	Rh	50-60	1.042
W	Ag	50-75	1.042

TABLE A.5: T-FACTORS OF BREAST PHANTOMS FOR DIFFERENT SCAN RANGES AND THE FULL FIELD GEOMETRY(DANCE 2011)

PMMA thickness (mm)	Equivalent breast thickness (mm)	*T*-factor for projection angular range of (degrees)				
		-10 to +10	-15 to +15	-20 to +20	-25 to +25	-30 to +30
20	21	0.993	0.988	0.981	0.971	0.959
30	32	0.992	0.985	0.976	0.964	0.949
40	45	0.992	0.983	0.972	0.959	0.943
45	53	0.991	0.982	0.970	0.956	0.940
50	60	0.989	0.981	0.969	0.955	0.939
60	75	0.989	0.980	0.968	0.954	0.938
70	90	0.987	0.977	0.965	0.952	0.937
80	103	0.987	0.976	0.964	0.951	0.934

Appendix B: Age and MGD Results

TABLE B.1 AGE AND DOSE

The doses are slightly higher within the younger age groups but still within international range. Mean glandular dose according to age group is shown in Table B.1.

Table B.1: Mean glandular dose according to patient age group (mGy)

Age Group	N	Mean	SD
30-39	25	1.3	0.7
40-49	77	1.3	0.6
50-59	60	1.3	0.5
60-69	34	1.1	0.3
70-79	4	1.0	0.1

Most patients had MGD between 1-1.9 mGy on both CC (61.5%) and MLO (73.5%) views. As shown in table 4.3, there were 6 (3%) and 4(2%) patients receiving MGD above 3 mGy on CC and MLO views, respectively.

Table B.2: Mean glandular dose in breast mammography(mGy)

	CC view		MLO view	
	N	%	N	%
MGD range				
0-0.9 mGy	67	33.5	37	18.5
1-1.9 mG	123	61.5	147	73.5
2-3 mGy	4	2	12	6
above 3mGy	6	3	4	2
Total	200	100	200	100

CC-CRANIOCAUDAL
MLO-MEDIOLATERALOBLIQUE
MGD-MEANGLANDULAR DOSE

A few patients had an AGD above 3 mGY as shown by table 4.3 and this attributed to increased breast density secondary The MGD for breast tomosynthesis among 11 patients with data was 0.32 (SD 0.46).

Appendix C: Exposure Factors and MGD

1. KVP AND DOSE

The kVp values in each view are shown in Table C.1 and Table C.2.

Table C.1: Mean kVp values in breast mammography (keV)

VIEW	MEAN	SD	MINIMUM	MAXIMUM
RCC	28.3	1.1	26	31
LCC	28.4	1.1	26	31
Combined CC	28.3	1.0	26	30
RMLO	28.9	1.1	26	31
LMLO	28.8	1.0	26	31
Combined MLO	28.9	1.0	26	31

RCC-RIGHT CRANIOCAUDAL RMLO-RIGH MEDIOLATERALOBLIQUE
LCC-LEFT CRANIOCAUDAL LMLO-LEFT MEDIOLATERALOBLIQUE

Table C.2: Mean kVp in breast mammography according to age group(keV)

	CC view		MLO view	
	Mean	**SD**	**Mean**	**SD**
Age group				
30-39	28.3	1.0	28.9	1.1
40-49	28.4	1.0	28.8	1.0
50-59	28.3	1.0	28.9	1.0
60-69	28.4	0.9	29.0	0.6
70-79	27.5	1.2	27.6	1.4

CC- CRANIOCAUDAL
MLO-MEDIOLATERALOBLIQUE

Tube Voltage And CBT

There was a strong positive correlation between CBT and kVp values on both CC (Pearson's correlation = 0.74) and MLO (Pearson's correlation = 0.75) views (Figure 14)

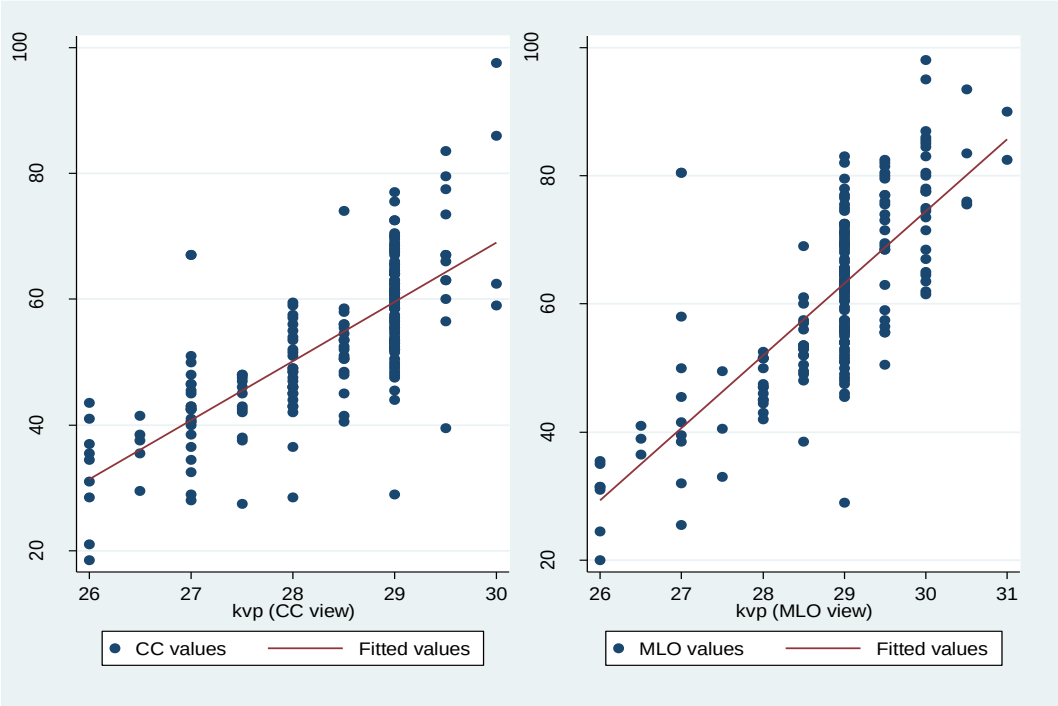

Figure 13: Correlation between kVp and CBT in mammography

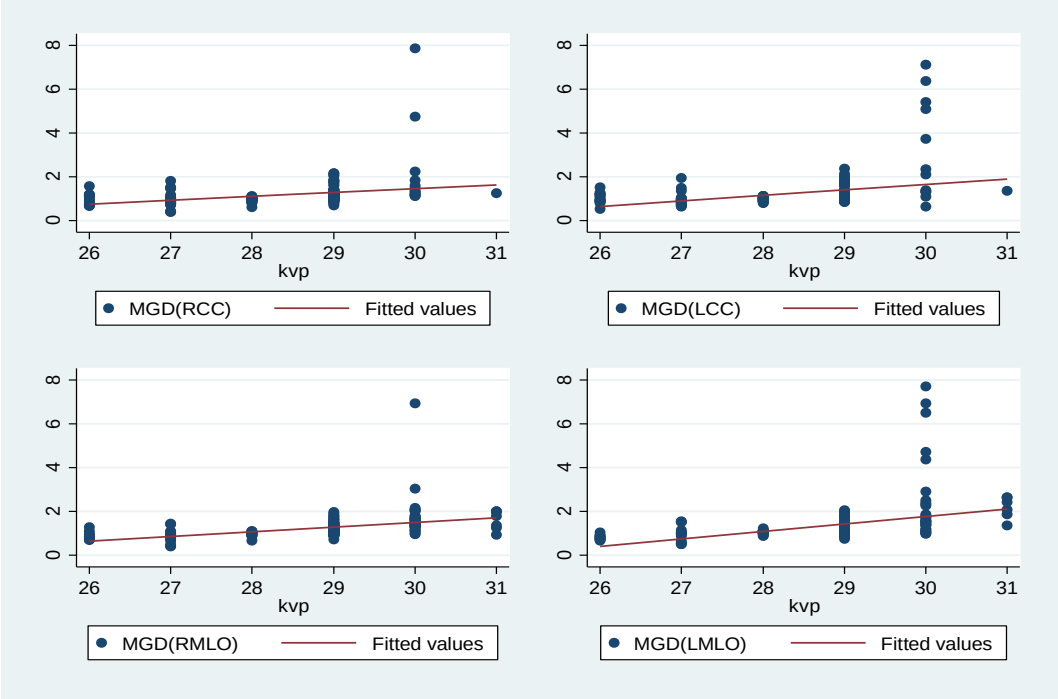

Figure 14:Correlation between kVp and mean glandular dose according to view

There is a weak but positive correlation between KVp and dose.

2. MAS AND DOSE

The MAS values are as follows in table C.3

Table C.3: Tube Current (mAs) values per view

VIEW	MEAN	SD	MINIMUM	MAXIMUM
RCC	57.8	33.3	27	335
LCC	61.1	44.0	29	335
RMLO	63.8	29.1	29	326
LMLO	69.3	46.5	29	335

RCC-RIGHT CRANIOCAUDAL RMLO-RIGHT MEDIOLATERALOBLIQUE
LCC-LEFT CRANIOCAUDAL LMLO-LEFT MEDIOLATERALOBLIQUE

Table C.4: Tube Current (mAs) values per age group

	CC view		MLO view	
	Mean	SD	Mean	SD
Age group				
30-39	64.1	34.6	72.4	33.6
40-49	60.5	33.5	67.3	32.2
50-59	60.5	28.8	67.8	31.8
60-69	53.0	16.9	60.6	18.9
70-79	47.4	5.7	48.1	4.4

CC-CRANIOCAUDAL
MLO-MEDIOLATERALOBLIQUE

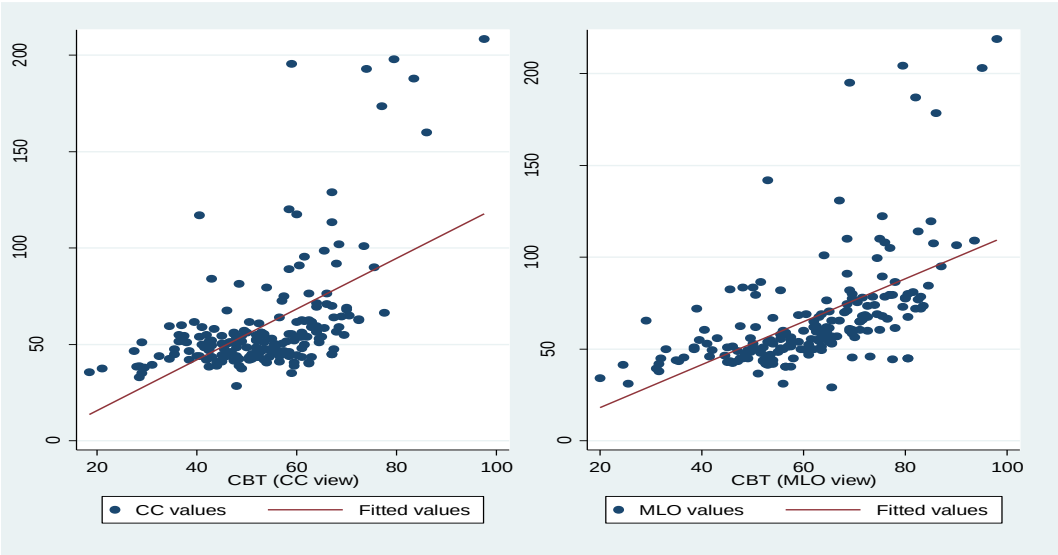

Figure 15: Correlation between MAS and compressed breast thickness

There was a weak positive correlation between the mAs and the MGD as shown the figures below in figure C.4.

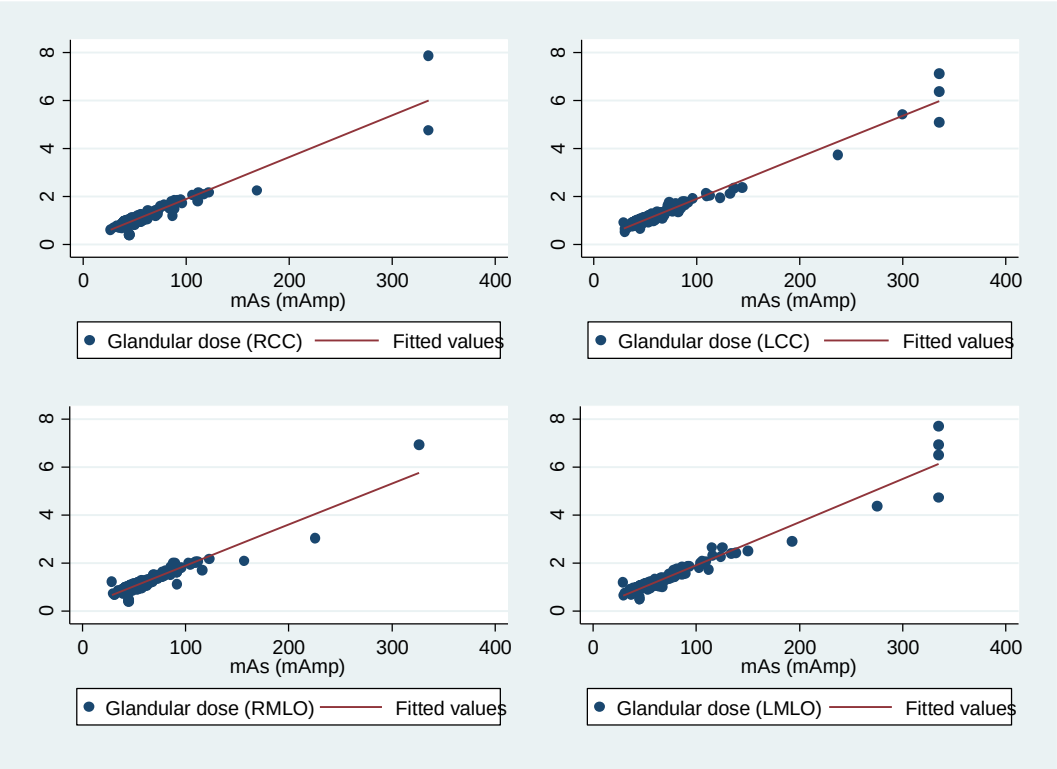

Figure 16: Correlation of mAs to AGD per exposure view

3. ESE AND DOSE

The results of the entrance skin dosage are as follows in Table C.5:

Table C.5: ESE per exposure view(mGy)

VIEW	MEAN	SD	MINIMUM	MAXIMUM
RCC	4.8	3.5	1.7	38.2
LCC	5.1	4.3	2.0	37.5
RMLO	5.8	3.3	2.2	36.7
LMLO	6.2	5.0	2.1	39.6

RCC-RIGHT CRANIOCAUDAL RMLO-RIGHT MEDIOLATERALOBLIQUE
LCC-LEFT CRANIOCAUDAL LMLO-LEFT MEDIOLATERALOBLIQUE

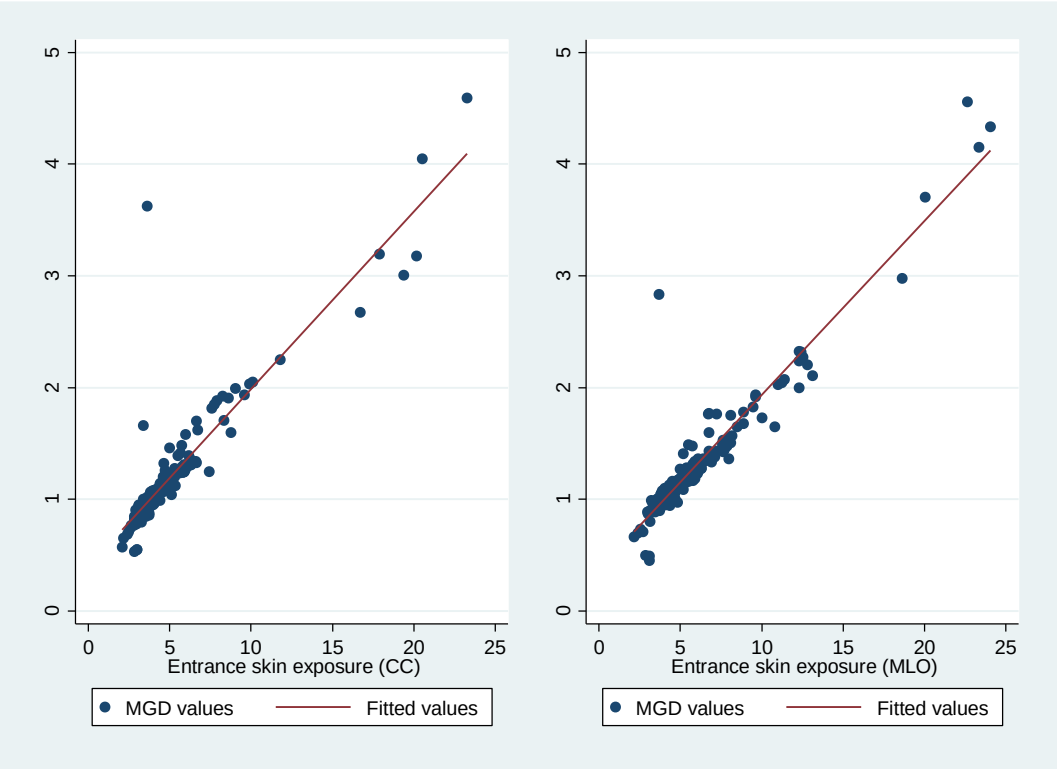

Figure 10:Combined CC and MLO ESE values correlated to AGD

Appendix D: Consent Information Document

THE AVERAGE GLANDULAR DOSE IN DIGITAL MAMMOGRAPHY AND BREAST TOMOSYNTHESIS

BACKGROUND

Imaging is essential for accurate breast diagnosis and the early detection of breast cancer. Population screening with mammography is the only intervention proven to reduce mortality from breast cancer through early detection. Mammography is a type of breast examination that uses a breast examination machine called digital mammography machine.

The breast examination machine uses X-rays called ionizing radiation which may cause other health problems. Therefore any exposure must be justified and doses kept as low as reasonably possible. The aim of this study will be to determine the amount of X-rays (radiation dose) a patient's breast receives during the breast examination**.**

Study Objective

Theobjective of the study is to determine the amount of X-rays (radiation dose) to the breast during breast examination using the digital breast examination machine. The other objective is also to check if the amount of X-rays to the breast during breast examination are the same as in other countries and if they are acceptable.

Voluntariness of Participation

Please note that your participation is voluntary and there will be no financial rewards for participation.You have a right to decline or withdraw from the study.

Benefits

As there is no data available locally on the amount of x-rays the breast receives during the breast examination exam, this study will therefore generate data on the amount of x-ray the breast should receive during the breast examination for this region.

Risks

There are no added risks involved in this study.

Confidentiality

The information obtained from you will be treated with confidentiality and will be used for the purpose of this study only. No information about any other patient shall be revealed to any party. You will be given a study number and no names shall be used.

Consent Certificate

Title of Study

The Average Glandular Dose to the breast during digital mammography and breast tomosynthesis.

Name of Researcher

Dr.Norah Ger, a postgraduate student in the Department Of Diagnostic Imaging and Radiation Medicine at the University of Nairobi.

I hereby confirm that the above named doctor has explained the study to me and I understand fully.

I understand that my participation is voluntary and that I have not been forced to participate.

I understand that I can refuse to participate without giving a reason and my medical care will not be affected.

I understand that I will not receive any compensation,monetary or otherwise for participating in the above study.

I understand that my personal information availed for purpose of this study will be kept confidential.

I hereby consent to take part in the above study.

Patient number:_____ Signature: _____

Date: _____

I certify that the Patient has understood and consented participation in the study.

Dr. Norah Ger

Signature _____

Date _____

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Appendix E: Maelezo Kwa Mwenye Kutoa Idhini Ya Kuwa Mshiriki Kwenye Utafiti Huu

KIWANGO CHA MIALE YA XRAY KINACHOFIKIA MATITI YA MSHIRIKI ANAPOPIGWA PICHA YA DIGITAL MAMMOGRAPHY NA BREAST TOMOSYNTHESIS.

Mhutasari

Mammography ni picha ya matiti ambayo ni muhimu kupima ugonjwa wa saratani wa matiti.

Mammography inaweza kupata saratani wa matiti mapema kabla ya ugonjwa huu kusambaa kwa mwili yote. Lakini mammography hutumia miale ya xray ambazo zinaweza kusababisha ugonjwa wa saratani kwa matiti . Kwa hivyo ni muhimu kujua kiwango cha milae ya xray kinachofikia matiti wakati mgonjwa anapopigwa picha ya mammography. Pia ni muhimu kujua kama hicho kiwango kinafaa kwa mgonjwa. Umuhimu wa utafiti huu ni kujua kiwango cha mionzi ambayo matiti inapata wakati wa kipimo cha picha ya matiti.

Lengo Kuu

Lengo kuu la utafiti huu ni kupima au kukadiri viwango vya miale inayofikia matiti wakati wa picha ya matiti. Baada ya kukadiri viwango vyetu tutaweza kulinganisha na viwango vinavyo kubalika uilimwenguni.

Kushiriki Kwa Hiari

Kushiriki kwako kwenye utafiti huu ni kwa hiari. Hakuna malipo ama zawadi au fidia utakayo pewa au kopokea kwa kuwa mshirika.

Faida Ya Utafiti Huu

Utafiti huu utawezesha kubuni viwango vya miale vinavyostahili kutumiwa bila madhara kwa matiti hapa nchini na sehemu hii ya bara letu.

Hatari Ya Utafiti

Hamna hatari yoyote ama madhara yoyote kwa mshiriki kutokana na utafiti huu.

Siri Kwenye Utafiti

Habari ambayo tutakayo kusanya kutoka kwako itahifadhiwa na kutunzwa kwa siri ya hali ya juu kabisa.Hatutamia majina yako kwenye taarifa zozote wakati wa utafiti. Kwa hivyo utapewa nambari maalum ambayo tutakuwa tukitumia badala ya jina lako.

Uhuru Wa Kutoshiriki Au Kujiondoa

Una uhuru wa kukataa kuweka idhini au kujiondoa kwenye utafiti huu wakatti wowote bila kutoa sababu yoyote. Hamna adhabu yoyote au kupoteza faida wala haki zako unapojiuzulu

Fomu Ya Idhini Ya Mshiriki Kwenye Utafiti

KICHWA CHA UTAFITI

KIWANGO CHA MIALE YA XRAY KINACHOFIKIA MATITI YA MSHIRIKI ANAPOPIGWA PICHA YA DIGITAL MAMMOGRAPHY NA BREAST TOMOSYNTHESIS.

MTAFITI

Jina langu ni Daktari Norah Ger, mwanafunzi katika chuo cha udaktari, Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu kiwango cha mionzi ambayo matiti inapata wakati wa kipimo cha picha ya matiti. Mimi natoa thibitisho ya kwamba daktari amenieleza kiundani kuhusu utafiti amabo kichwa chake kinapatikana hapo juu. Ninakiri nimepewa fursa ya kuuliza mAswali kuhusu utafiti huu na nimeridhika. Ninaelewa kwamba ushiriki wangu katika utafiti huu ni kwa hiyari yangu mwenyewe,sijalazimishwa.

Ninaelewa kwamba sitapokea fidia yoyote iwe ya kifedha au vinginevyo wala sitapewa matibabu ya upendeleo.

Ninaelewa kwamba taarifa zangu binafsi zitakuwa siri. Hata hivyo naelewa ya kwamba taarifa zangu zitatumiwa kwa utafiti huu.

Ninatoa idhini ya kushiriki katika utafiti huu.

Nambari ya mgonjwa: _____ Sahihi: _____

Tarehe: _____

Nimekubali kwamba nimeelezewa kikamilifu kuhusu utafiti huu na nakubali kushiriki.

Jina la muchukua idhini: Dr. Norah Ger.

Sahihi: _____ Tarehe: _____

Mawasiliano

Mtafiti

Dakt. Norah Ger

Mwanafuzi wa shahada ya uzamili katika fani ya radiologia

Chuo kikuu cha Nairobi,Idara ya radiologia

Sanduku la posta 19676-00202

Nambari ya simu: 0723436326

Barua pepe: norahger@gmail.com

Msimamizi

Professor N.M. Tole

Chuo kikuu cha Nairobi,Idara ya radiologia

Sanduku la posta 19676-00202

Nambari ya simu: +254 733617135

Barua pepe: nimrodtole@yahoo.com

KNH-UON Secretariat

Kenyatta National Hospital / University Of Nairobi

ETHICS AND RESEARCH COMMITTEE.

Sanduku la posta 19676-00202

Nambari ya simu: +254-202726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Appendix F: Data Collection Tool-Questionnaire

1. Patient's number……..
2. Age (years)……
3. Sex……...
4. Compressed breast thickness (cm):

   a) CC i)Right ii)Left
   b)MLO i)Right ii)Left

5. Exposure factors: a)kVp (volts) –

   b)mAs(mAmp) –

   c)HVT (cm)-
6. Anode Material-
7. Filter Material-
8. Radiation dose (mGy)
   a. CC i)Right:
      ii)Left:

   b. MLO i) Right:
      ii)Left:

PHANTOM	KV	ESD	HVL	MGD	CBT
LCC					
LMLO					
RCC					
RMLO					

BREAST TOMOSYNTHESIS

1. Breast tomosynthesis indicated Yes or No_____

2. Indication for breast tomosynthesis _____

3. Arc angle used:

4. Compressed breast thickness (cm):

5. Exposure factors: a)kVp (volts) –

   b)mAs(mAmp) –

   c)HVT (cm)-

6. Anode Material-

7. Filter Material-

PHANTOM	KV	ESD	HVL	MGD	CBT
ARC ANGLE					

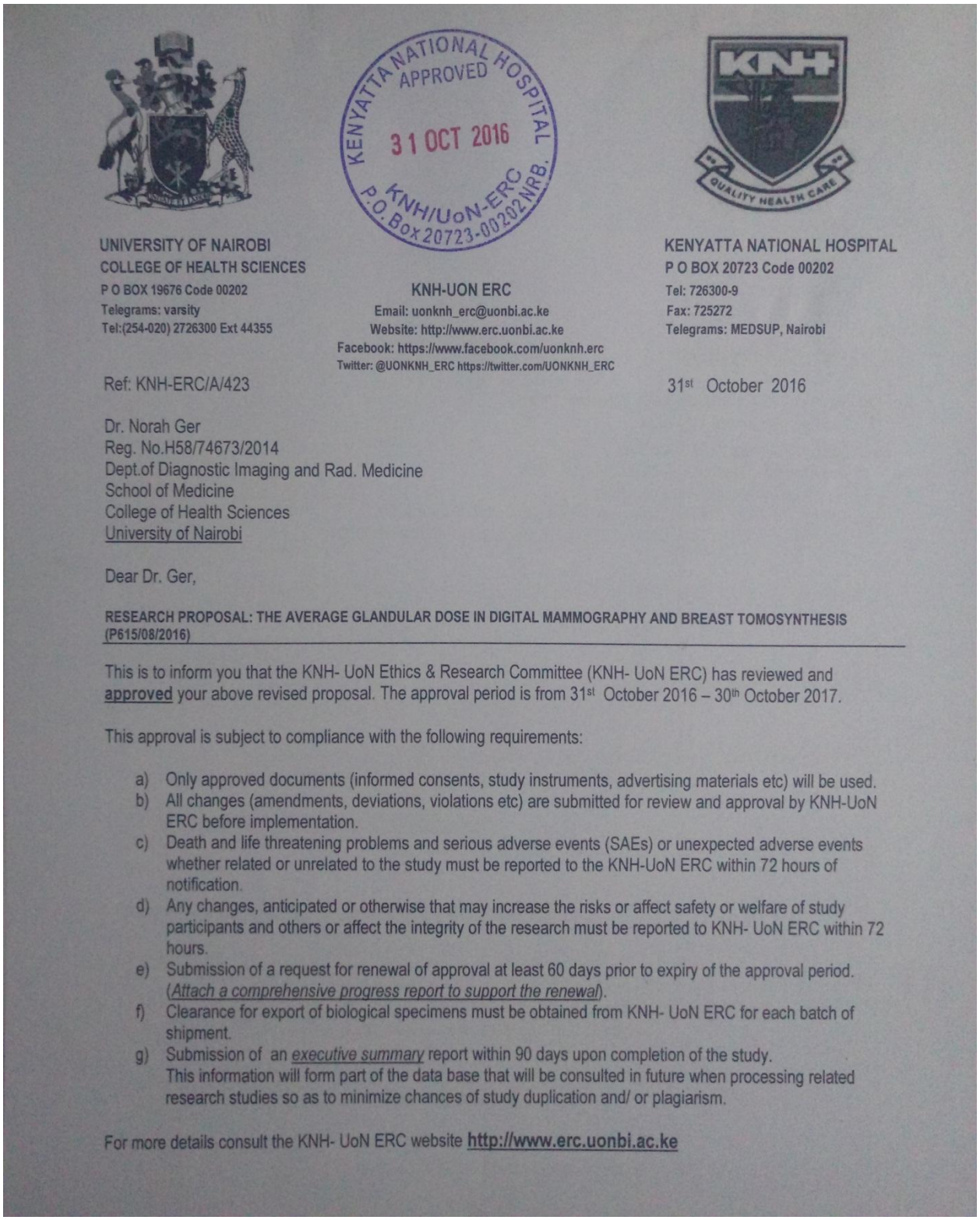
TIMELINE OF EVENTS

	JUL 2016-AUG 2016	SEPT 2016-OCT 2016	NOV 2016-DEC 2016	JAN 2017 – MAY 2017	JUNE-DEC 2017	JAN 2018– MAY 2018
Proposal write up						
Submission to ERC& corrections						
Data collection						
Data entry and analysis						
Report writing and desertion submission						

BUDGET

Item	**Unit cost (Ksh)**	**Number**	**Total cost**
Research assistants	1000.00	2	2000
Biostatistician fee	20000.00		20000
Supplies and equipment			
Printing research proposal	5.00	6(Each with 60 pages)	1800
Printing data questionnaires	5.00	200 (Each with 4 pages)	4000
Printing request form analysis forms	5.00	220(Each with one page)	1100
Printing consent explanation & consent forms	5.00	420 (Each with 2 pages)	4200
Pens	17.00	20	340
Airtime	1000.00		1000
Internet cost	10000.00		2000
Printing report	5.00	10 copies (Each with 30pages)	1500
Miscellaneous			5000
Contingency			10000
Grand Total			**53740**

ETHICAL APPROVAL LETTER



KENYATTA NATIONAL HOSPITAL APPROVED 31 OCT 2016 KNH/UoN-ERC P.O. Box 20723-00202 NRB.

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Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/423

31st October 2016

Dr. Norah Ger
Reg. No.H58/74673/2014
Dept.of Diagnostic Imaging and Rad. Medicine
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Ger,

RESEARCH PROPOSAL: THE AVERAGE GLANDULAR DOSE IN DIGITAL MAMMOGRAPHY AND BREAST TOMOSYNTHESIS (P615/08/2016)

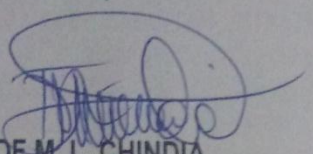
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 31st October 2016 – 30th October 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,



PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairperson, Dept. of Diagnostic Imaging and Rad. Medicine, UoN
Supervisor: Prof. N. Tole, Dept. of Diagnostic Imaging and Rad.Medicine, UoN