EVALUATION OF IMAGE RECEPTOR ANGULATION DURING MEDIOLATERAL OBLIQUE POSITIONING FOR OPTIMISED PRESSURE AND AREA DISTRIBUTION IN MAMMOGRAPHY

MUNIRATU ALIU OSMANU

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Evaluation of image receptor angulation during mediolateral oblique positioning for optimised pressure and area distribution in mammography

Student name: Muniratu Aliu Osmanu

University of Salford

School of Health and Society,

University of Salford

Manchester, UK

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Name of student: Muniratu Aliu Osmanu **Student ID number:** @00407845

The following academics supervised this PhD thesis:

1. **Dr Claire Mercer – 1st Supervisor**
   Head of Radiography
   University of Salford
   School of Health and Society
   Address: L614,
   6th Floor, Allerton Building, Manchester, M6 6PU
   T: 0161 295 3865
   email: c.e.mercer@salford.ac.uk

2. **Dr Katy Szczepura – 2nd Supervisor**
   Senior Lecturer
   University of Salford
   School of Health and Society
   Address: L617, 6th Floor, Allerton Building, Manchester, M6 6PU
   T: 0161 295 2192
   email: k.szczepura@salford.ac.uk

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List of Abbreviations

ACRONYM	DEFINITION
AGD	Absorbed glandular dose
AU	Area uniformity
BMI	Body mass index
CC	Cranio-caudal view
CI	Confidence interval
DAN	Decanewton
DBT	Digital breast tomosynthesis
FFDM	Full field digital mammography
FSM	Film screen mammography
FP	Flexible paddle
FSCM	Force-standardised compression mammography
IMF	Inframammary fold
IR	Image receptor
MLO	Medio-lateral oblique
MQSA	Mammography Quality Standards Act
N	Newton
NHS	National Health Service
NHSBSP	National Health Service Breast Screening Programme
PSCM	Pressure-standardised compression mammography
PU	Pressure uniformity
RP	Rigid paddle
SD	Standard deviation
UK	United Kingdom

Terminology

Term	Definition
Clients	Breast screening and symptomatic patients
Experimental angle	Sternal angle of participants obtained from inclinometer reading of the sternum
Practitioner	Assistant practitioners, radiographers trained in mammography (mammographers), an advanced practitioner specialising in mammography
Reference angle	Image receptor angle at 45^0
University	University of Salford

ABSTRACT

Background

Mammography is the gold standard diagnostic tool for the screening and diagnosis of breast cancer; however, it is associated with pain and discomfort. The pain and discomfort are mostly due to positioning and the compression applied during the procedure. Currently there are variations in the way clients are positioned for mammography and the amount of compression applied during the procedure. In addition, there are sparse guidelines and published literature on mammographic positioning and the application of compression. It is suggested that for the medio lateral oblique (MLO) position, for an effective compression force balance and increased breast footprint, the sternal angle and the image receptor (IR) be parallel to each other. This aim of this research is to evaluate the angle of IR during MLO positioning for optimised pressure and area distribution; this in turn may help reduce pain and discomfort associated with the procedure.

Method

The experimental work described in this report is in two phases.

Phase one was an anthropomorphic phantom study to establish a structured and reproducible method of using the angle of the sternum to measure the correct angle of the IR for MLO projection. An inclinometer was used to measure the sternal angle of phantom model used. Six sets of compressions were made on the breast phantom with the IR at different angles ranging from 40^0 to 70^0 at 5^0 angle increments. Contact pressure and contact area footprint readings between breast phantom/paddle interface and breast phantom/IR interface were recorded using Xsensor pressure mapping system. Pressure uniformity (PU) and area uniformity (AU) between phantom breast/paddle interface and phantom breast phantom/IR interface were then calculated.

Phase two was a human study with participants to investigate contact pressure and area balance on MLO compressions using two angles. A digital inclinometer

was used to measure the angle at which the sternum for each participant. This angle was referred to as the ‘experimental angle’. The other angle was a ‘reference angle’ of 45^0. Compression at the ‘experimental angle’ may result into a better distribution of pressure through the breast and juxtathoracic structures, this may reduce the pain associated with the procedure. In addition to this, compression at this angle may increase breast surface area.

The hypotheses set out to ascertain if there is no significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and it is positioned at a reference angle.
An Xsensor pressure mapping system was used to record and analyse pressure distribution and surface area for compressions at the ‘experimental angle’ and the ‘reference angle’ (45^0). Pressure and area balance between the IR and compression paddle on both of these angles were compared and T-test conducted to accept or reject the hypotheses set out.

In addition, participants were asked to score their pain experience after each compression, that is, compression at the ‘reference angle’ and the ‘experimental angle’.

Results

The results from *phase one* indicated there was greater balance of pressure between breast/IR interface and breast/paddle interface at IR angle 60^0 compared the rest of IR angles investigated. PU of zero indicated equal distribution of pressure from the IR and the paddle. IR angled at 60^0 recorded a PU value of 0.21 which was the closest to zero from the PU recorded for the various angles. AU of zero indicates equal distribution of area footprint from the IR and the paddle. IR at 60^0 (Sternal angle for phantom model) produced the greatest area footprint balance compared to the other angles with AU of 0.05. An IR angled at 60^0, being parallel to the sternal angle of the phantom model which was recorded at 60^0 on the inclinometer, was the angle which produced the greatest balance of pressure and area footprint.

The results from human study indicated there was no significant difference between contact pressure and area distribution when the IR is positioned parallel to the experimental angle or positioned at a reference angle.

Conclusion

For the phantom study it has been shown that positioning the IR parallel to the angle of the sternum produces a more balanced contact pressure distribution and improved breast surface area footprint.

The human study demonstrated no statistically significant difference between pressure and area balance on the reference angle and the experimental angle.

For pain experienced score, although there was a 95% chance that the actual pain score for the compression on the reference angle fell within 3.81 and 5.76. and that of the experimental angle fell within 3.02 and 4.79, there was no statistically significant difference between pain experienced from compression on both angles.

Chapter One - Introduction

1.1 Chapter Overview

This chapter aims to introduce and evaluate the key themes and issues surrounding mammographic positioning and compression. It also provides a structure to the report, providing orientation, outlining the research question and aims and objectives of this study. The significance of this research will also be highlighted. For consistency purposes, the word client used in this report refers to breast screening clients while also at times referring to a symptomatic patient.

1.2 Introduction

Breast cancer is the most common form of cancer among women in the developed and less developed world accounting for about 30% of all female cancers globally (Ashkar & Zaki, 2017; Badu-Peprah & Adu-Sarkodie, 2019; Da Costa Vieira et al., 2017; Sung et al., 2021). According to Sung et al. (2021), it has now surpassed lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases. Breast cancer remains the leading cause of death among women (DeSantis et al., 2019; IARC, 2016; Labrie et al., 2020; Vaidya, 2014). Breast cancer incidence continues to increase worldwide (Ohuchi et al., 2016; WHO, 2018) and in the United Kingdom (UK), it accounts for 15% of all new cancer cases (Cancer Research UK, 2016), and around 11,500 women die from the disease every year, equivalent to 32 deaths every day (Breast Cancer UK, 2021).

Mammography is the radiographic imaging of the breast (Dumky et al., 2018; Jalalian et al., 2013; Seely, 2017) and the gold standard tool for screening and diagnosis of breast cancer (Schulz-Wendtland et al., 2009; Suhaimi et al., 2015; Sulieman et al., 2019; Viegas et al., 2021). It is the preferred method as it has a high sensitivity (75.8%- 93%) and specificity (88%-96.9%) for less density breast (Ohuchi et al., 2016). Mammographic sensitivity however can decrease to less than 50% in dense breast parenchyma (Drukteinis et al., 2013; Li et al., 2017). According to Drukteinis et al. (2013), the sensitivity of mammography could go as low as 36% in women with dense breasts limiting its usefulness in this category of

women and in high-risk younger women. Mammogram is relatively quick examination (approximately 5 minutes) being comparatively inexpensive compared to imaging modality like magnetic imaging resonance (MRI). (Dumky et al., 2018). It is the only investigative method that has evidence supporting mortality reduction for breast cancer (Henderson et al., 2015; Ohuchi et al., 2016). The ultimate goal of mammography is to obtain an optimum image along with maximum breast tissue visualisation (Kopans, 2007) and to enable early and best personalised treatment of breast cancer, improve survival rates as well as to reduce the need for aggressive treatment (Sardanelli et al., 2017).

One of the limitations of mammography is that the procedure is associated with pain and discomfort (Davey, 2007; Moshina et al., 2020; Nelson et al., 2020; Papas & Klassen, 2005). The pain/discomfort is primarily due to the compression applied to the breast (De Groot, Broeders, et al., 2015; Ng et al., 2017; Papas & Klassen, 2005) and patient positioning (Uchiyama et al., 2012).

Correct positioning plays a crucial role in reducing pain and discomfort and this has to achieved before the applied compression will be effective (Pal et al., 2018). A reliable positioning protocol is required so images can be reproduced with the minimum discomfort experienced by the client. There are sparse guidelines on mammographic positioning and the amount of compression to be applied during the procedure. Public Health England (2020a) National Health Service Breast Screening Program (NHSBSP) guidelines for mammographers do not state how positioning should be carried out during the procedure, though provide guidelines on evaluating the quality of images produced. Regarding compression, it states that “Compression should be applied slowly and gently to ensure that the breast is held firmly in position”(Public Health England, 2020b, p.19). Similar recommendations are made in the European guidelines, which state that “compression of the breast tissue should be firm but tolerable”(Perry et al., 2008, p.76). These guidelines lack detail as well on the amount of compression required for the procedure. Though the National Breast Screening Programme (2006) recommend that compression force should not exceed 200N (National Breast Screening Programme, 2006).

The guidelines rely on practitioners to use their discretion, training and experience to decide on the amount of compression to apply and how to position individual client. This flexibility allows for inconsistencies in the amount of compression applied during the procedure. Though there are general protocols to follow when it comes to positioning and compression (Perry et al., 2008; Public Health England, 2020b; Skills for Health, 2013), ultimately the decision lies with the practitioner, for instance, selecting the height and angle of the image receptor (IR) on the cranio caudal (CC) and medio lateral oblique (MLO) respectively. There is therefore a large amount of subjectivity, Dumkey explained, "positioning and compression still depend on the practitioner's perception of how the steps are performed" (Dumky et al., 2018, p. 42).

The other factor that entirely relies on the practitioner is the amount of compression to apply to the breast. The amount of compression applied during mammography is subjective therefore, this could lead to inconsistencies in the images produced and on client experience. Research has demonstrated that there are variations in the application of compression between institutions and among practitioners (Mercer et al., 2013), as such images may not be reproducible between attendances and clients are likely to have varying experience on each attendance for breast screening. The same clients could receive different amount of compression force each time they attend for mammography screening. Due to this variation in positioning and compression, reproducing the images for the same client over time is unlikely.

The introduction of a standardised positioning and compression protocol may be an important step towards a consistent and reproducible procedure for clients. The importance of reproducibility and consistency with regards to compression and positioning could improve client's experience which could increase the rate of re-attendance for breast screening. Research has shown that clients' experience influences their decision to honour subsequent invitation for breast screening (Poulos & McLean, 2004; Sapir et al., 2003; Sterlingova & Lundén, 2018).

The visualisation of the compression pressure together with the compression force, currently used in mammography, may help decrease the variability and improve consistency, which will in turn may give clients a better experience. De Groot, Branderhorst, et al. (2015, p. 390) stated that “by providing a pressure-standardised compression, pain during mammography is reduced, especially severe pain”. They suggest that standardisation of pressure improves standardisation in terms of physiological conditions in the compressed breast (blood pressure) as well as reducing discomfort and pain, particularly the number of severe pain complaints.

Currently, work undertaken in the United Kingdom (UK) with regards to mammography positioning was initially conducted by Hogg, Szczepura, et al. (2013); Smith (2013). In Smith’s (2013) MSc dissertation work, the impact that the height of IR in CC position had on the pressure balance was investigated with 16 participants. However, it is worth noting that only the standardisation for the CC projection was published by Smith, Szczepura, et al. (2015), the MLO projection was not published due to the limited data set included within the unpublished MSc dissertation. Smith’s (2013) MSc dissertation was a follow-up human research study from a phantom study by Hogg, Szczepura, et al. (2013). The phantom study, focused only on the CC projection and described a method for measuring pressures applied to the breast from the IR and the paddle and simultaneously measuring the breast footprints on the IR and paddle. This current study intends to follow on from this work, using a phantom study followed by a human study.

Phantom studies are imperative and are conducted to ensure the tools and equipment used, together with the study design are robust and can be replicated. They fundamentally allow for changes and adjustments to be made prior to human studies.. Qin et al. (2013) states that phantoms have been used extensively in the validation of medical imaging techniques and conducting a phantom study before moving on to a human study is common practice. This study builds on earlier work by adapting similar approach of first undertaking a phantom study and then a human study to investigate the effect of IR angle on distribution of pressure and area footprint.

1.4 Research Question

Is there a significant difference between contact pressure and area balance when individuals are positioned with the IR at a reference angle of 45^0 and the sternal angle (experimental angle)?

1.5 Anatomy of the Breast and Sternum

The breast is a mobile organ and varies in size and morphology for each individual. To be positioned for mammography, the breast has to be eased away from the chest wall and moved from the mobile margin to immobile margin for inclusion of maximum tissue (Popli et al., 2014). It is an epithelial organ that develops in the embryo from the ectodermal primitive milk streak, or 'galactic band'. This ridge of tissue extends from the axilla to the groin, and is responsible for the supernumerary breasts or just nipples occasionally seen in humans, and familiar in other mammalian species (Vaidya, 2014). It is composed of glandular and adipose tissue in varying proportions. The glandular tissue consists of 15–20 lobes containing numerous lobules, linked by ductules **(Figure 1.1).** The ductules combine to form the lactiferous ducts, which open into the lactiferous sinuses and empty through the nipple. The proportions of glandular and adipose tissues in the breast play an important role in mammography. Dense breast which are commonly seen in young females consist of more glandular tissue than fatty tissue. (Manning et al., 2013). Mammographic breast density itself is an independent risk factor for developing breast cancer, with estimates of relative lifetime risk ranging from 2.8 to 6.0-fold increased risk of breast cancer compared with women with less dense breast (Boyd et al., 2007; McCormack & Dos Santos Silva, 2006; Ursin et al., 2003). With dense breast, the sensitivity of mammography in detecting breast cancer is limited. Brem et al. (2015) reported that, sensitivity is as low as 48% in women with extremely dense breast compared to 85% for those with less glandular tissue.

The breast is enclosed in two layers of fibrous tissue connected by Cooper's ligaments, which give it its characteristic shape: a superficial layer, and a thicker deep layer overlying the chest muscles (Vaidya, 2014).

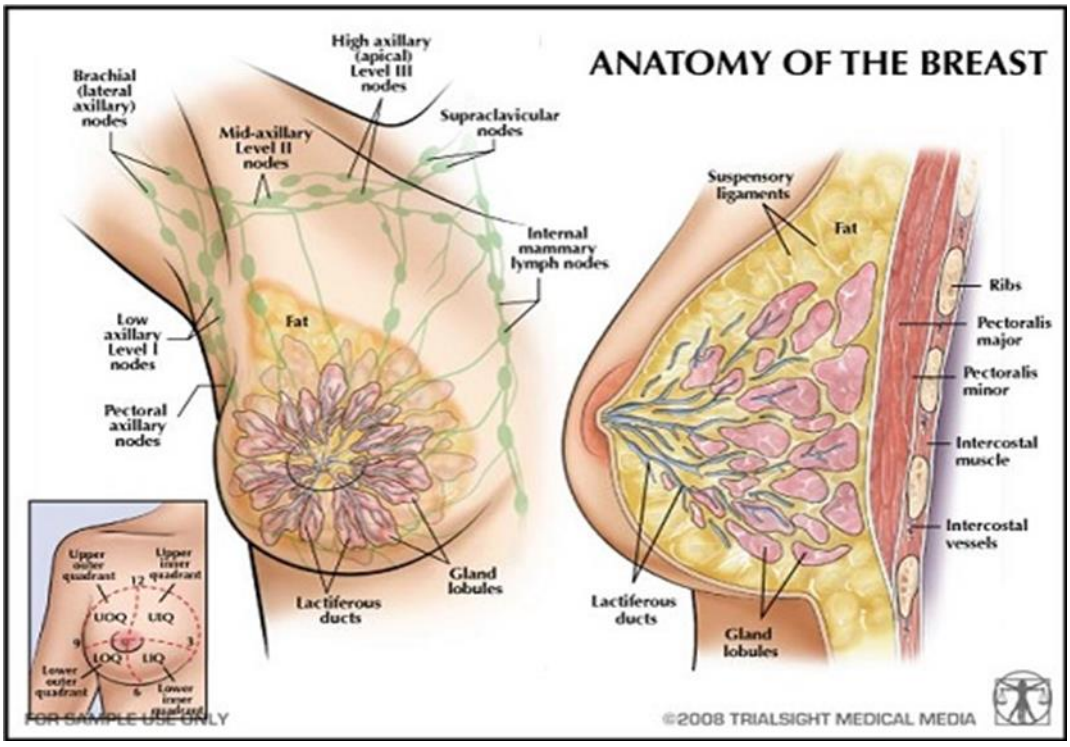

Figure 1.1 Anatomy of the female breast.

(Trialsight Medical Media, 2007)

The pectoralis major has been identified as a key posterior anatomical structure to establish optimum breast tissue inclusion on both CC and MLO projections (Sweeney et al., 2018b). According to Sweeney et al. (2018b, p. 6) "visualisation of the pectoralis muscle on CC view implies that no tissue along the chest wall has been excluded". On the MLO projection, the pectoralis major margin should be well visualised with the lower edge at the level of the nipple.

The sternum, located just beneath the skin between the breasts, can be used as reference point when positioning for MLO projection (Mercer, Hill, et al., 2015). It is a long narrow bone located along the body's midline in the anterior wall of the thoracic region. The sternum consists of three parts, the manubrium, the

body/gladiolus and the xiphoid process and articulates on either side with the clavicle and the upper seven costal cartilages. The average length of the sternum for an adult is 17 cm (Gray, 2000). There is a suggested relationship between the breast and the sternum where mammography is concerned; Mercer, Hill, et al. (2015) are of the view that, for an effective compression force balance on MLO position, the sternal angle and the IR should be parallel to each other. For the purposes of this research, the sternum will be the focal point in establishing the correct IR angle for individuals during MLO positioning.

1.6 Mammography as a Standard Tool for Diagnosis of Breast Cancer

Mammography is the radiological examination of the breast using ionizing radiation and is routinely taken in two projections, CC and MLO (NHS England, 2019). The examination is relatively quick, inexpensive, reliable and can detect tumours as small as a few millimetres in diameter (Dumky et al., 2018). Vaidya (2014) mentioned that, mammography increases the likelihood of detecting a relatively small cancer in patients who have dense breast as well as locate a non-palpable cancer accurately for breast excision biopsy. In addition, it reveals in women with palpable lump, a non-palpable lump in the same or contra lateral breast.

Mammography has evolved over the decades. According to Zackrisson and Houssami (2016, p. 323), substantial technical developments have witnessed an evolution from screen-film mammography (SFM) to full-field digital mammography (FFDM), and more recently to digital breast tomosynthesis (DBT) as a potential screening modality. SFM in breast cancer screening has been proven to reduce mortality in women older than 40 years (Fletcher et al., 1993; Haas et al., 2013; Vinnicombe et al., 2009). Furthermore, SFM and FFDM has been shown to be effective for both routine screening and symptomatic breast diagnosis (Hambly et al., 2009; Michell et al., 2012b). SFM was the standard technique in breast cancer screening for many years, but currently FFDM is modality of choice (Fischer et al., 2002; Skaane et al., 2013). According to (Michell et al., 2012b, p. 977), the accuracy of SFM is limited by anatomical noise resulting from the superimposition of normal structures, this could affect both sensitivity and specificity as a result cancer detection may be limited, particularly in younger women. FFDM has been

found to have similar accuracy to SFM overall however, it provides improved visualization of the skin and subcutaneous fat, which are often not readily apparent on FSM (Harvey, Gard, et al., 2013). Additionally, FFDM has greater accuracy for three subpopulations: women < 50 years of age, pre- or peri-menopausal women, and women with mammographically dense breast tissue (Fuller Mackenzie S., 2015). SFM is increasingly being replaced with FFDM (Karssemeijer et al., 2009) with FFDM used in most Western screening mammography programmes (Nederend et al., 2014). Public Health England (2020a) adds that, mammography systems have transitioned from using film-screen mammography to FFDM with the National Health Service Breast Screening Programme (NHSBSP) in the UK now utilising only FFDM as SFM is no longer approved. In very recent years, DBT which is essentially a quasi-three-dimensional mammogram, has become available (Zackrisson & Houssami, 2016).

Mammography can be performed in two settings, screening and symptomatic. Screening mammograms are acquired from non-symptomatic women for the purpose of diagnosing cancers at an early stage when there may not have caused any symptoms (Sardanelli et al., 2017). It is offered periodically, for example every two or three years and high-risk groups may have screening more frequently than the general population, for example yearly or every 18 months.

Symptomatic mammography is offered to those with clinical symptoms such as palpable lump, nipple discharge and retracted nipple and are referred to the symptomatic clinic by their GP. Those who present to symptomatic clinic represent a higher risk group and the incidence of mammographically demonstrable carcinoma is much higher in this group than the screening population (Biggs & Ravichandran, 2006).

In the UK, 2.12 million women had screening mammograms in the year 2019-20, an 18.3% increase over ten years (Public Health England, 2021a) and mammography is expected to remain the primary breast examination modality for many years (De Groot et al., 2015). Other imaging modalities such as ultrasound, magnetic resonance imaging (MRI), contrast-enhanced spectral mammography

(CESM), microwave imaging (MI) and positron emission tomography (PET) scans are used as adjunct for detecting the nature and location of suspicious lesions demonstrated on mammogram.

MRI is more sensitive (89% to 100%) for breast cancer than standard mammography or ultrasound when using dynamic contrast-enhancement methods regardless of radiographic breast density (Cardenosa, 2017; Ikeda & Miyake, 2016b). Drukteinis et al. (2013) is adds that an additional 14.7 cancers per 1000 women were detected when MRI is used as a supplement to mammography and whole breast ultrasound. Although MRI is more sensitive than mammography, it has not yet been shown to reduce mortality (Drukteinis et al., 2013; Moore et al., 2009) meanwhile, it is used as a screening tool together with mammogram for high-risk groups such as women with strong family history of breast cancer. Public Health England (2017) guidelines recommends annual mammography and MRI screening for these women. The limitations of MRI are that, it is not good at diagnosing ductal carcinoma in situ, the procedure is slow (30 min to one hour), and more expensive modality compared to mammogram (Sree et al., 2011).

Ultrasound is widely available, does not involve ionising radiation and is generally performed for further evaluation of mammographic findings (Drukteinis et al., 2013; Sree et al., 2011). The procedure also provides real-time evaluation of mass shapes, borders, orientation, and internal characteristics to determine whether the mass is malignant or benign (Ikeda & Miyake, 2016b). It is well tolerated by patients and is the initial imaging modality in women 30 years old or younger (Cardenosa, 2017; Drukteinis et al., 2013). Several studies have shown that mammography with adjunctive ultrasonography increased screening sensitivity and detection rates and lowered the frequency of interval cancers in women with dense breasts (Chae et al., 2013; Corsetti et al., 2011; Hooley et al., 2012; Ohuchi et al., 2016; Scheel et al., 2015). The limitation of ultrasound is the inability to reliably detect and characterize calcifications prospectively and the high degree of operator dependence of the hand-held studies (Cardenosa, 2017).

PET scan is a nuclear medicine imaging technique which is used to produce three dimensional images. It detects a pair of γ rays, which are emitted from the radionuclide that is introduced into the human body (Sree et al., 2011). PET detects the movement of molecules in early disease cells. PET scan is good at detecting cancers in very early stages and it scans the entire body for recurrence. Although PET can diagnose cancer in the very early stages as it detects the movement of molecules in early disease cells, it tends to have low resolution (Kwon & Lee, 2016).

Microwave Imaging (MI) has been proposed as a promising adjunct modality to conventional breast imaging for the detection of breast cancer, offering a potential non-ionising, non-compressive and as a potential tool in the monitoring of neoadjuvant chemotherapy (Baran, 2014; Moloney et al., 2022; Xu et al., 2012). MI uses electromagnetic radiation at frequencies ranging between 0.5 GHz and 9.0 GHz to deduce the dielectric properties, or to identify the presence of dielectric contrasts, within an imaging domain as it propagates through and scatters from the tissue (Moloney et al., 2022). According to Delbary et al. (2010) MI is a cheaper and much safer technique than traditional modalities for breast cancer detection since it uses non-ionising radiation. The higher sensitivity of MI compared to mammogram in breast cancer detection is based on the fact that breast tumours have considerably higher contrast at the microwave frequencies (Son et al., 2010). Even though MI has several benefits, it has drawbacks that are challenging to overcome. The first is limitation in resolution of fine structures, particularly within the glandular region. Secondly, it has low sensitivity to small and low contrast objects (Zhurbenko, 2011). Lastly, limitations in accuracy of recovered tissue properties hence poor images (Baran, 2014). The limited accuracy of tissue is due to the fact that the number of reconstruction elements far exceeds the number of independent data, leading to tissue properties inaccurately recovered (Moloney et al., 2022).

The advent of FFDM has allowed new techniques to be developed and the foremost of these is digital breast tomosynthesis (DBT). DBT is an x-ray mammography technique in which tomographic images of the breast are

reconstructed from multiple low-dose projection images acquired by moving the X-ray tube in an arc over a limited angular range (Gilbert et al., 2016; Vedantham et al., 2015). DBT has reduced the primary limitation associated with standard FFDM of overlapping breast tissue within the breast which could decrease visibility of malignant lesions or even obscure them completely (Michell, 2012).Several studies concluded this technique has increased sensitivity and specificity and has proven to improve the rate in cancer detection compared with FFDM alone as well as the reduction in false-positive recall (Gilbert et al., 2015; Michell, 2012; Michell et al., 2012a; Rafferty et al., 2013; Rose et al., 2013; Vedantham et al., 2015). The disadvantages of DBT include increased radiation dose, additional time to read images and increased costs associated with using DBT technology.

Contrast-enhanced spectral mammography (CESM) provides low-energy 2D mammographic images comparable to standard digital mammography and a post-contrast recombined image to assess tumour neovascularity similar to MRI (Patel et al., 2018), The technique utilizes the differences in X-ray attenuation between breast tissue and iodinated contrast material at different energy levels (Richter et al., 2017). CESM has been suggested for patients with MRI contraindications such as claustrophobia and MRI-incompatible implants, e.g., pacemakers (Sommer et al., 2015). Because of the requirement for the pre-contrast image to be registered with the post-contrast image, only a single view of one breast could be obtained. Additionally, breast compression, which is required to minimize movement between the mask image and the post-contrast images leads to limited contrast uptake to the breast (Patel et al., 2018).

There are however certain limitations of mammography. It is not usually recommended for pregnant women, and it cannot be performed in breastfeeding women because milk shadows may resemble fine micro calcified opacities (Shah & Guraya, 2017).

Heywang-Köbrunner et al. (2011) discuss that breast screening is designed as a program that combines multiple aspects and represents a measure that applies to the following:

i) Allows the detected of breast cancer early in order to permit mortality reduction and improved therapeutic options.
ii) It is associated with acceptable side effects for the invited population
iii) It yields reproducible results
iv) Can be applied at regular intervals to the population at acceptable costs for the society (Heywang-Köbrunner et al., 2011).

The primary aim of breast cancer screening is to reduce breast cancer mortality (Beau et al., 2017; Pashayan et al., 2018) finding cancers at an early stage when they are too small to see or feel. Early diagnosis can lead to a more successful treatment. Other benefits include a positive psychological effect and a more conservative treatment, for instance undergoing lumpectomy or wide local excision instead of radical mastectomy (Beau et al., 2017). Another benefit of earlier detection of breast cancer due to screening is the lower cost of treatment and consequent reduced financial burden on health care resources (Sitt et al., 2018).

However, there are associated risks with breast screening **(Figure 1.2)** which include missed diagnosis, overdiagnosis, as well as false positive findings (Sung et al., 2021). Additional issues associated with breast screening are unnecessary distress and exposure to radiation (NHS Choices, 2018). Missed diagnosis is when cancer is not picked up to be treated during screening. As a result, an individual may receive a negative (all clear) mammogram result when cancer is present. According to (NHS Choices, 2018, p. 2),” breast screening picks up most breast cancers, but it misses breast cancer in about 1 in 2,500 women screened”.

Myers et al. (2015) commented that overdiagnosis is one of greatest harms of breast screening especially given the frequency of diagnosis of Ductal Carcinoma in Situ (DCIS) and the likelihood that a substantial proportion of DCIS lesions would not have progressed to invasive cancer. Although DCIS cell have the appearance of malignancy, they do not demonstrate invasiveness, it is not in itself a life threatening disease (Marmot et al., 2013). Over diagnosis is defined as the diagnosis by screening of cancer that would not have been diagnosed in the

client's lifetime if screening had not taken place (Duffy et al., 2012; Marmot et al., 2013). Overdiagnosis leads to unnecessary further tests and overtreatment and can cause adverse psychological impact on the individual (Marmot et al., 2013).

A false positive is when the results from screening prompts a recommendation for additional procedures including further imaging or tissue sampling, and the results are found to be negative. This definition only applies to those with no findings of breast cancer within one year of that mammogram (Elmore et al., 1998; Heywang-Köbrunner et al., 2011; Oeffinger et al., 2015). Oeffinger et al. (2015) added that smaller percentage are recalled, then go on to have a biopsy, and a majority of these will have benign findings. Although the majority of women understand that false-positive test results are an inevitable part of screening, it could result in significant short-term psychological distress as well as increased health care utilisation and costs (Smith et al., 2003). Radiation-induced breast cancer is a concern in women who are offered screening. The estimated cumulative risk of death from breast cancer due to radiation from mammographic screening is 1 to 10 per 100,000 women, depending on age and the frequency and duration of screening (Loomis, 2015).

A systematic review by Long et al. (2019) searched eight databases for qualitative research reporting women's experiences of receiving a false-positive screening test result. Eight articles were appraised and synthesised to identify women's experiences of having a false-positive breast screening test result. The results showed that women found being recalled was unexpected, shocking and disempowering. They had to endure uncertainty and stress during screening assessment. Their result was accompanied by relief and welcome feelings of certainty about their health. However, some received unclear explanations of their result, contributing to lasting breast cancer-related worry and an ongoing need for further reassurance. The study concluded that the way results are verbally communicated to women may contribute to long lasting breast cancer worry therefore women need more reassurance and answers to their questions before and during screening assessment, and after receiving their result.

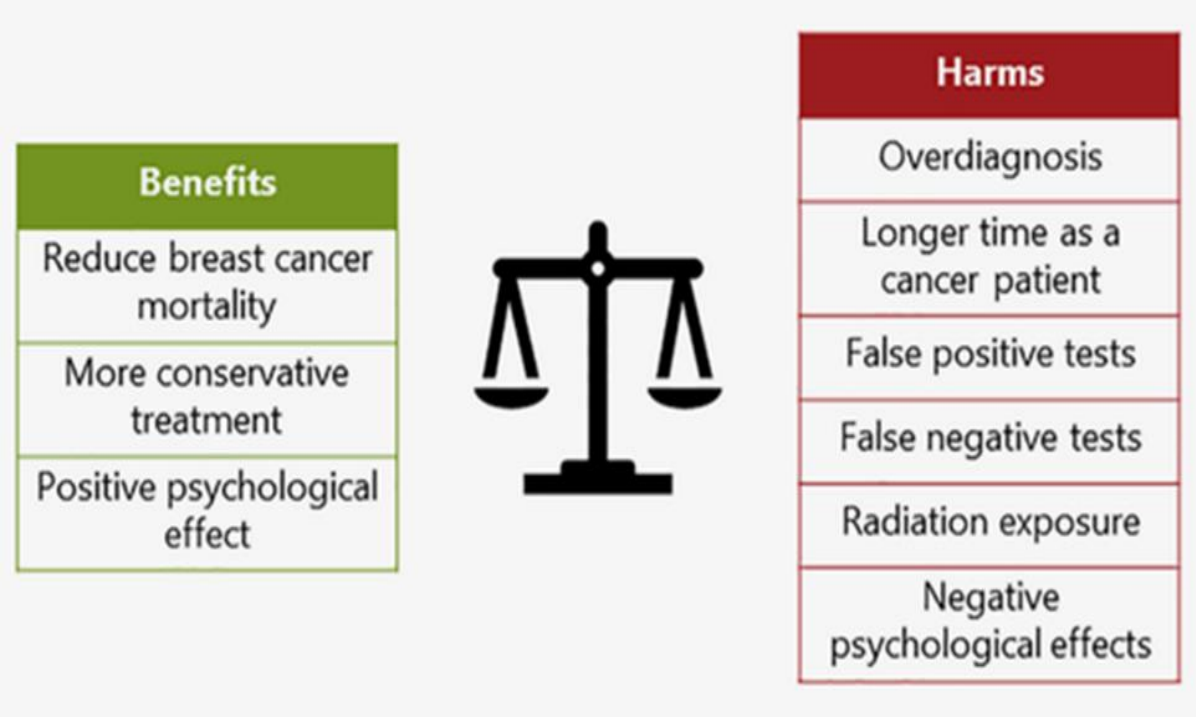

Figure 1.2 The benefit and harm of breast cancer screening.

(Beau et al., 2017)

Figure 1.2 appears to highlight more harms than benefits of breast cancer screening, one large benefit that is apparent is that screening reduces breast cancer mortality. With this in mind, the benefit of breast screening far outweighs the risks. Marmot et al. (2013) added that despite the risks associated with breast screening, there is a 20% reduction in mortality from breast cancer. They concluded in their report that, for every woman whose death was prevented by screening, around three women treated for a breast cancer would not have had their life threatened by the disease.

Most European countries have implemented breast cancer screening programmes (Altobelli & Lattanzi, 2014) that usually provide free mammogram every two years to women aged 50-74 years (Buchmueller & Goldzahl, 2018). This is in line with WHO (2018) guidelines which recommends women aged 50-69 undergo organized, population-based mammography screening. In the UK, screening is offered to women aged 50 to 70 every three years. This age range is being extended to include women between the ages of 47 to 73 through the age

extension trial, AgeX trial (NHSBSP AgeX Trial, 2020). The aim of the AgeX trial is to assess reliably the risks and benefits of extra screening before age 50 and, separately, of extra screening after age 70. Currently, women are randomly selected to take part in the trial and this will continue until 2026 to enable the most extensive analysis possible of the impacts of extending the breast screening programme both in the younger and older age groups (NHSBSP AgeX Trial, 2020).

Trends show a decline in breast cancer mortality due to breast cancer screening (van Schoor et al., 2011). Diagnosis of cancer at earlier stages does translate into prevention of death from breast cancer (Whitman & Haygood, 2012) and this is the reason for the introduction of screening. A study carried out in Germany by Weigel et al. (2009) investigated the epidemiology of breast cancer by comparing the years before breast screening was routinely offered to the years following the implementation. They found out that the average breast-cancer detection rate was 0.29% before screening was implemented. The detection rate almost doubled after implementation of breast screening to 0.53%, and this is due to earlier discovery of cases that would otherwise have lain hidden until being found clinically at a later date.

1.7 Breast Cancer Population Screening.

Breast cancer screening is one of the most popular cancer screening programmes in the UK. Several studies have established evidence that implementation of organized screening through a population-based programme can significantly reduce mortality from cancers (Armaroli et al., 2015; Basu et al., 2018; Schüz et al., 2015; Serwan et al., 2020; Sung et al., 2021; van Schoor et al., 2011). With regards to this, the primary aim of breast cancer screening is to reduce mortality by early detection of the disease in asymptomatic women (Long et al., 2019; Zielonke et al., 2020). Breast cancer screening programs are estimated to result in an approximate annual reduction in breast cancer mortality by 30% (Serwan et al., 2020; Verbeek, 2011).

In the UK, the NHSBSP is the NHS population screening programme that offers routine breast cancer screening to healthy asymptomatic women aged 50 to 70. Following a report by Professor Sir Patrick Forrest (The Forrest report), the NHSBSP was implemented. The Forrest report reviewed all the evidence at that time, 1986, and concluded that mammographic screening had the potential to reduce mortality from breast cancer in the UK population (Harvey, Down, et al., 2013). The basic principles according to Harvey, Down, et al. (2013) of screening for any disease are demonstrated in **Figure 1.3** and breast cancer screening is no exception to these principles. The AgeX trial later introduced randomly selects and screens half the women aged 47 to 35 and 71 to 73. The trial has since ended.

There are some controversies surrounding breast screening and it is whether it is necessary to screen the population for breast cancer. As discussed earlier the issue of missed diagnosis, overdiagnosis and false positive results are a concern.

The Independent UK Panel on breast cancer screening reported that NHSBSP has been shown to significantly decrease mortality, offering an estimated 20% relative risk reduction to women who are screened every three years over a 20-year period and thus saving one breast cancer death for every 250 women invited for screening (Marmot, et al,2013). According to Lind et al. (2010) breast screening in Stockholm, Sweden has reduced breast cancer mortality by 29% and among participants by 52%.

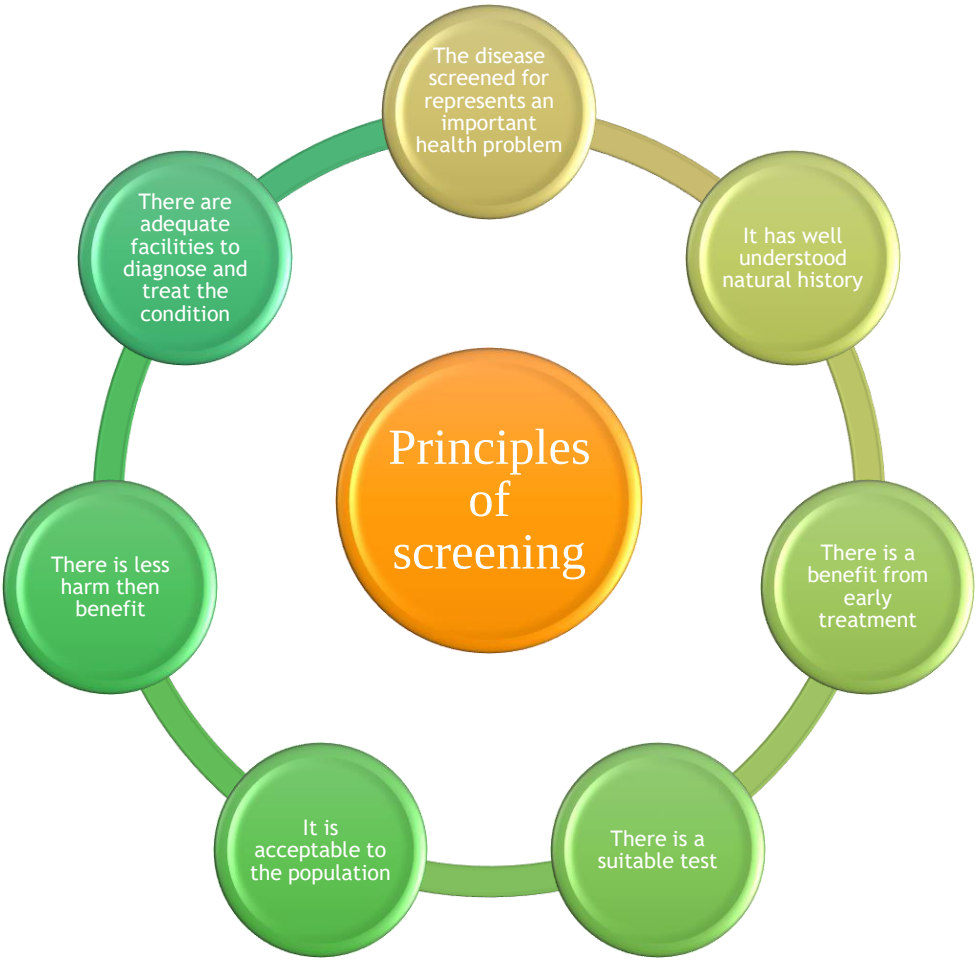

Figure 1.3 The main principles of screening

(Harvey, Down, et al., 2013)(adapted).

The NHSBSP screened 2.12 million in 2019-20 with 17,771 cancers detected (Public Health England, 2021a). Cancer Research UK (2016) emphasised that having breast screening means that about 1,300 breast cancer deaths are prevented each year. These are cancers that are found and treated earlier than they would have been if there was no screening programme. Although there is evidence that breast screening does reduce mortality and the benefit-risk ratio is higher among women, increasing evidence about the harms of mammography screening have generated controversy (Pace & Keating, 2014). Pace and Keating (2014) conducted a systematic review on the risk and benefits of breast cancer screening and concluded that, it does reduce breast cancer mortality but for some

clients, the harms may outweigh the benefits due to the issue overdiagnosis and false-positive results. Some clients could undergo treatment for a lesion diagnosed that would not have progressed to invasive cancer during the woman's lifetime (de Gelder et al., 2011).

The study by (Pace & Keating, 2014)reviewed evidence on the mortality benefit and harms of screening and found out that a 40- or 50-year-old woman undergoing 10 years of annual mammograms, the cumulative risk of a false-positive result is about 61%. About 19% of the cancers diagnosed during that 10-year period would not have become clinically apparent without screening (overdiagnosis). They recommended that better cancer screening tests are required, and more sophisticated tools are required to reduce the burden of overdiagnosis and false-positive results.

The European Commission (EC) programme supported active screening programmes for breast cancer in the period 1990 and to 2002 and in 2003, the European Parliament and the Council of Europe, recommended implementation of organised breast cancer screening programmes (European Union, 2017). Population-based breast cancer screening programmes began in the 1980s in Sweden (1986), Finland (1987), UK (1988), and the Netherlands (1989), with most European countries having implemented screening programmes (**Table 1.1**) According to (Basu et al., 2018, p. 46) screening programmes are offered in 25 out of 28 European Union (EU) member states for nearly 95% of women in the age group of 50–69 years. In these member states, screening is delivered mainly by organised population-based programme recommended by the European Commission. The International Agency for Research on Cancer (IARC) and the European guidelines for breast cancer screening both recommend two yearly mammogram screening for women aged 50-69 (IARC, 2016; Perry et al., 2008).

The American Cancer Society (ACS) recommend the start of routine mammography screening for women aged 40 (Smith, Manassaram-Baptiste, et al., 2015). Yearly screening is recommended until age 54 years; after that age, some women can undergo screening every 2 years (Oeffinger et al., 2015). The US

Preventive Service Task Force (2016) suggest women aged 50–74 years undergo biennial screening mammography and also recommend screening for women aged 40–49 years if the benefits of screening outweigh the risks (United States Preventive Services Task Force, 2016).

Table 1.1 Practices for mammography breast screening programmes in Europe.

(Basu et al., 2018)(Adapted)

Country	Start year	Target age group (Years)	Interval (years)	Percentage of mammograms performed with digital equipment
Austria	2014	45-69	2	100%
Belgium	2001	50-69	2	100%
Croatia	2006	50-69	2	Unknown
Cyprus	2003	50-69	2	100%
Czech Republic	2002	45+	2	100%
Denmark	2008	50-69	2	100%
Estonia	2003	50-64	2	100%
Finland	1987	50-69	2	100%
France	2004	50-74	2	97%
Germany	2005	50-69	2	100%
Hungry	2001	45-64	2	60
Ireland	2000	50-69	2	100%
Italy	1990	45-74	1 (age:45–49); 2 (age:50–74)	80%
Latvia	2009	50-69	2	98%
Lithuania	2005	50-69	2	52%
Luxembourg	1992	50-69	2	100%
Malta	2009	50-69	3	100%
Netherlands	1989	50-75	2	100%
Poland	2006	50-69	2	75%
Portugal	1990	45-74	2	100%
Romania	1015	50-69	2	75%
Slovenia	2008	50-69	2	100%
Spain	1990	50-69	2	95%
Sweden	1986	40-74	1.5-2	100%
United Kingdom	1988	50-70	3	100%

Similar to the recommendations by the European commission, the Australian Government launched a national free mammography screening program for women aged 40 or more years in 1991, the BreastScreen Australia program (Burton et al., 2012). BreastScreen offers screening mammogram to women ages 50-69 every two years. The implementation of screening programmes in Africa is challenging as most African countries do not have the infrastructure, resources, or trained personnel to undertake such programmes effectively (Abuidris et al., 2013). In these countries, breast cancer screening is promoted primarily by advocacy groups and periodic campaigns to promote breast cancer awareness. Loomis (2015) adds that low- and middle-income countries have no established population-based screening but make use of opportunistic screening. Opportunistic screening is a screening tool used by women on their own initiative

or following the advice of their gynaecologist or general practitioner (Eichholzer et al., 2016). It provides screening to women on request and coincidently with routine health care (Loomis, 2015).

Population breast screening services in Asia are highly variable; some have advanced nationwide screening programmes and others have less developed programmes. According to (Sitt et al., 2018, p.170), South Korea and Taiwan are both well recognised for their experience in running such programmes, the former having the highest intake rate and the latter being the most well-structured. South Korea's National Health Service offers mammography every 2 years to women aged 40 or older, and at no cost to 50% of people with the lowest incomes. Population breast screening in Taiwan was implemented in 2004 and invites women aged 50 to 69 years to biennial screen. The programme was expanded in 2010 to screen women aged 40 to 49 years as well. Taiwan's biennial breast screening programme has achieved a 40% mortality reduction from the disease (Yen et al., 2016).

Singapore established its national, population-based screening programme (BreastScreen Singapore) in 2002 and now covers women aged 40 to 69 years. However, participation rate has been noted to plateau at 40% since 2010, short of the target of 70% (Sitt et al., 2018). According to the Health Promotion Board (2014) of Singapore, the greatest barrier to uptake are cultural issues and costs. BreastScreen Singapore is not offered for free as it is paid by an individual's medical insurance account, meanwhile subsidised screening is available to all Singaporean women aged 50 years and above.

China implemented breast cancer screening programme in 2009 for women aged 35-59 years, however this consist of a clinical breast examination as the primary detection method (Song et al., 2015). Breast ultrasound imaging is then undertaken for women with clinical findings highly suggestive of malignancy on the clinical breast examination and women with other high-risk factors. Positive ultrasound findings were evaluated further using mammographic imaging. A second-generation screening program was started in 2012, with modification of the

ages of the women screened and the screening methods (Wu et al., 2019). Screening was offered to women ages 35-64 years and clinical breast exanimation and breast ultrasound were together the primary detection methods. Women with suspicious findings from either examination were recommended to undergo mammography imaging. According to Song et al. (2015), the screening programme chose clinical breast screening and ultrasound rather than mammography for screening for two major reasons. First, the proportion of breast cancer in young and premenopausal women in China is higher, with a peak incidence at age 50. Secondly, the average breast density in Chinese women is higher than that in many Western population.

As with many countries in Africa, no population-based screening has been implemented in Hong Kong, but opportunistic screening has long been practised in the private sector. The Hong Kong breast cancer foundation recommend women aged 40 and above conduct monthly breast self-examination as a measure of raising breast self-awareness. Additionally, regular clinical breast examination and mammography screening is recommended for these women (Hong Kong Breast Cancer Foundation, 2016). The lack of organised population screening in Hong Kong has resulted in a poor screening habit for women as over 60% of women diagnosed with breast cancer have never undergone mammography screening before their cancer diagnosis (Sitt et al., 2018).

Breast cancer screening with mammography has been established in various parts of the world as discussed above. Maximum visualisation of breast tissue in mammography is essential as breast abnormality could be missed if parts of the breast is not imaged. This research evaluated the angle of IR during MLO positioning for optimised pressure and area distribution. Contact surface areas on two IR angles was evaluated. An increase in contact area on any of the angles may imply more breast tissue visualisation on mammogram. Depending on the results of this research, any changes proposed could cause a benefit to all screening services in different countries with the right training and support.

1.8 Mammography Guidelines and Quality Control

There are various set of guidelines for practitioners to adhere to. Quality assurance (QA) programmes in mammography provide a framework for constant improvement through a feedback mechanism and there are strict quality control guidelines for all aspects of mammography. These programmes are essential to make sure compliance with the guidelines, image quality standards, protocols and criteria that guide breast screening and diagnostic mammographic service (Li et al., 2010) To ensure the key goals of mammography are achieved, quality standards should be adopted. Ideally, these should be wide in scope and address the various aspects with impact on the mammography imaging process e.g. technical, clinical and training (Reis et al., 2013).

To guarantee the service provided is up to an optimum standard, there should be a systematic approach for assessing critical performance indicators such as testing of equipment. QA allows the identification of deviations from optimum performance of mammographic equipment, suboptimal clinical practice and training needs (Joy et al., 2005; Li et al., 2010). According to Reis et al. (2013), an effective QA program should be practical to implement in a clinical setting and the testing of equipment should address the various critical stages of the imaging chain (acquisition, processing and display). Lack of proper QA programmes could result in unnecessary exposure due to repeated examination, additional costs of healthcare and in lack of timely diagnosis (Ciraj-Bjelac et al., 2012).

Published national and international quality standards continue to provide differences in described image quality criteria and impact upon clinical image assessment comparisons. According to Sweeney et al. (2018a), one of the differences in described image quality criteria is the inclusion of a classification system by which image quality can be visually assessed and evaluated. The most reported image quality assessment is a system where images are ranked as perfect, good, moderate or inadequate (PGMI) (Hogg et al., 2015). A recent study by Taylor et al. (2017) proposed a new scoring system of perfect, good, adequate or inadequate with new positioning quantitative metrics added for the MLO view. Guidelines from various parts of the world will be looked at to understand

framework put in place regarding image quality and positioning to ensure the goals and targets for mammography are met.

The American College of Radiology provides the following guidelines on assessing image quality. They mentioned that, for CC images, the posterior nipple line of the breast (the distance between the nipple and the posterior edge of the image) should be no more than 1 cm less than that on the MLO view (the distance between the nipple and the anterior edge of pectoralis muscle). The anterior edge of the pectoralis muscle on the MLO view should be convex, and it is desirable for the pectoral muscle to extend to the level of the nipple. The posterior nipple line should be drawn at an angle, perpendicular to the muscle, usually at about 45^0 on the MLO image (Kanal et al., 2013).

In the UK, the guidelines for breast screening for radiographers (2017) with regards to positioning only mentioned the nipple being in profile and images in symmetry (Public Health England, 2020b). These guidelines are in line with the European guidelines for quality assurance in breast cancer screening and diagnosis (Amendoeira, 2013). They indicated specific criteria for CC and MLO images and states what each view should demonstrate when the correct positioning is achieved. These criteria will be discussed further later on in chapter two **section 2.3**.

On the other hand, no mention was made on how this correct position could be achieved. As mentioned in **section 1.2** as far as positioning and compression are concerned, the guidelines by European Society of Breast Imaging (2016) and (Mammography Quality Standards Act, 2018) lack detail.

1.9 Pain Experienced with Mammography.

During mammography, the breast is pressed between a transparent compression plate on top and the image detector underneath as illustrated in **Figure 1.4.**

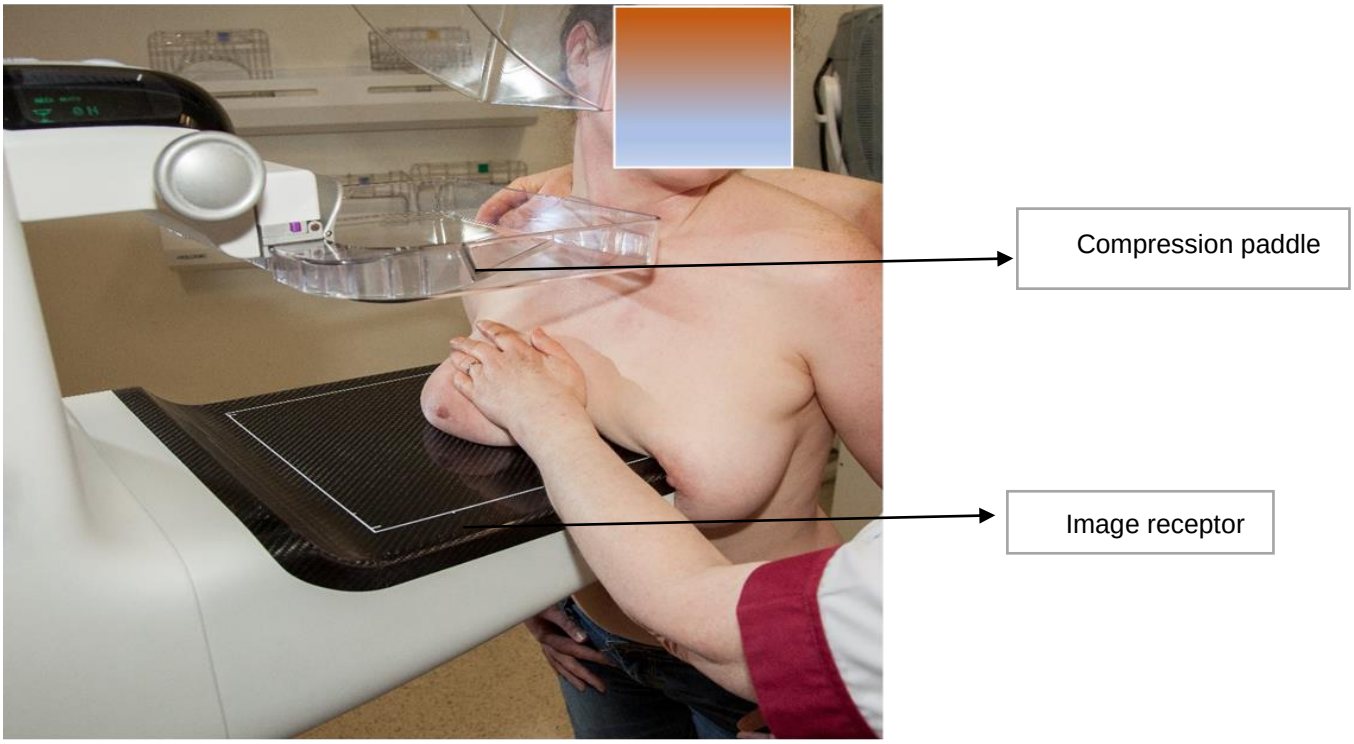

Figure 1.4 Female breast being positioned for mammogram

(Nightingale Centre Manchester University NHS Foundation Trust, 2012).

According to Branderhorst et al. (2015) reduction in thickness of the breast tissue using the compression paddle during mammography, has multiple benefits, these include:

- reduced radiation dose delivered to the breast due to reduced tissue thickness, allowing lower exposure factors to be used
- better image contrast due to a reduction of scattered radiation due to less reduced tissue thickness and lower X-ray energy
- reduced geometric blurring due to the reduced tissue thickness
- better fit of the exposure into the dynamic range of the image receptor due to the reduced attenuation
- reduced overlapping of tissues due to redistribution of glandular tissue within the breast
- reduced risk of motion blurring due to clamping of the breast.

These benefits also apply to compression during DBT examination where multiply projection views are acquired.

Most women associate pain/discomfort with mammography due to the compression applied during the procedure (Katarzyna Feder & Grunert, 2017; Whelehan et al., 2021), with some refusing the procedure due to the pain (Balleyguier et al., 2018; Dumky et al., 2018; Mims et al., 2005; Suhaimi et al., 2015; Uchiyama et al., 2012). Several studies have shown that pain is a significant cause of non-compliance with screening mammography attendance (Andrews, 2001; Ashkar & Zaki, 2017; Marshall, 1994; Papas & Klassen, 2005; Poulos & McLean, 2004; Sapir et al., 2003; Whelehan et al., 2013). The pain and discomfort generally arise from the positioning and compression applied to the breast. Aside from positioning and compression, there are other risk factors that have been associated with pain during mammography (Davey, 2007). Davey (2007) divided these risk factors into three main areas:

1. Biological – breast tenderness, thickness.
2. Psychological – pain expectation, previous painful mammogram, anxiety level.
3. Staff-related – attitude, communication problems.

It is well reported that some women experience pain and discomfort mainly as a result of breast compression (Moshina et al., 2019; Myklebust et al., 2009; Nelson et al., 2020).

Perception of pain and discomfort has been extensively studied but, due to the heterogeneity in the literature, the importance of the problem is still not easily quantified (Whelehan et al., 2013). Clients could experience pain/discomfort if they already have a painful/tender breast or feel anxious about the procedure, more so, those who already experience high anxiety levels could experience increased levels of discomfort and pain (Suhaimi et al., 2015).

The amount of pain/discomfort experienced by individuals is highly variable. A systematic review by Armstrong et al. (2007) appraised 22 publications that

investigated pain/discomfort associated with the procedure from three databases. They also evaluated the evidence about the risks and benefits of mammography screening for women 40 to 49 years of age. The study found a wide range of pain experienced during mammography from as mild as 6% to as painful as 76%. With reference to this, pain experienced during mammography varies on a wide range, from mild to severe.

Asghari and Nicholas (2004) examined the pain/discomfort experienced by 220 Iranian women during mammography. The research found that, up to 92% of clients reported that mammography was uncomfortable/painful. Meanwhile, considerable variability in pain ratings was found, with some women reporting severe pain and others reporting little or no pain. Forty three percent of the women reported having moderate pain while 11% reported having severe pain. Another 6% found the procedure intolerable, with the remainder finding it somewhat uncomfortable but tolerable. Freitas et al. (2006) conducted a qualitative prospective study on 2,164 patients. Patients rated their pain experience after mammography and 90% associated the procedure with discomfort whiles 12% rated it as intense or intolerable.

A recent study by Nelson et al. (2020) measured mammography-related pain in two groups of women undergoing regular surveillance as a baseline for future care and to evaluate any prolonged physical effects from mammography after a week. They recruited two hundred women, half of these were asymptomatic women who had family history (FH) of breast cancer, and the other half had undergone conservative surgery for breast cancer and were currently asymptomatic. The study used pain scale to score the participants' perceived pain before compression based on memory (previous mammogram), immediately after compression and one week later. The finding of the study indicated that physical side effects from mammography can develop and extend beyond the examination period. Patients' prior experience of pain was the only significant predictor of current pain in the study therefore, data on past mammography experiences are essential to improve future pain outcomes.

The pain experienced during mammogram has been known to affect the number of re-attendances for breast screening. In a New Zealand study, Elwood et al. (1998) found out that 46% of previous participants who declined subsequent invitations for breast screening, the major reason was pain. A systematic review carried out by Whelehan et al. (2013) searched 10 databases and reviewed 22 publications supports the fact that pain is a factor that directly affect the rate of re-attendance for mammography. The pain experienced during the procedure is the reason some women do not attend for subsequent screening; therefore, they recommend that more research is needed on effective pain-reducing intervention for mammography. Papas and Klassen (2005) examined mammography associated discomfort among 530 African–American women, and how discomfort influenced rescreening intentions. It was reported that, 76% of the women experienced discomfort of which compression constituted 96% of the discomfort. Intension to reattend for breast screening was significantly reduced as a result.

On the contrary, Moshina et al. (2018) investigated whether compression force and pressure in mammography were associated with re-attendance among screened women in Norway. The conclusion was that compression was associated with re-attendance but not in the way expected. This retrospective cohort study investigated compression force and pressure used on 31,225 women. There was evidence to show that low compression force and pressure at prevalent screening were associated with lower re-attendance compared with medium compression force and pressure. Re-attendance rate was 87% and this was highest for women who received a compression force of 10.0–13.9kg (87.5%) or pressure of 9.0–17.9kPa (87.8%) and lowest for those who received a compression force of<10.0kg (85.0%) or pressure of<9.0kPa (84.7%). This study however has some limitations. Firstly, it assumed experienced pain was the primary reason affecting re-attendance rate for all sample population. Secondly, no information about pain experienced were collected rather, compression force and pressure used at the time of examination were used as a substitute for experienced pain. Lastly, participants views could have been useful as there are other factors that could have influenced re-attendance other than pain such as anxiety and unsatisfactory care at the time of the procedure.

In 2010/11, the NHSBSP recorded a range of between 47,000 and 77,000 women who had chosen not to re-attend for breast screening in that year because of prior pain (Whelehan et al., 2013). This is quite a concern as the breast screening program depends on a high attendance rate so cancers can be diagnosed early when treatment is most effective. The greater the proportion of women who accept the invitation to be screened, the greater the benefit to the public health in terms of reduction in mortality from breast cancer (Marmot et al., 2013). Again, this is all the more important because it is regular screening that diminishes breast cancer mortality by 20% on average for women older than 50 (Independent UK Panel on Breast Cancer Screening, 2012). With regard to this, interventions to reduce pain and discomfort during mammography examinations should be considered to encourage participation in breast screening.

Interventions for relieving pain and discomfort has been investigated. According to a systematic review conducted on interventions to reduce or relieve the pain and discomfort of screening mammography, Miller et al. (2008), found out that giving women written or verbal information about the procedure prior to the mammogram can reduce pain or discomfort of the examination. Additionally, the use of breast cushions also reduced the pain; however, this caused poor quality images in 2% of women screened, which meant that there was the need for further mammogram.

Ashkar and Zaki (2017) recommended psychological approach to reducing pain during mammogram. Practitioners should take the time to speak to the patient, informing them fully and correctly about the procedure while addressing any of their questions and concerns. They could also show more empathy towards the patients and communicate better with them. A study conducted by Lambertz et al. (2008) showed that applying 4% Lidocaine gel to the breast and chest wall around 30 to 60 minutes prior to the mammogram significantly reduced the discomfort experienced. Another way to reduce the pain experienced during a mammogram is patient-controlled compression. Patient-controlled compression may reduce pain and discomfort while causing minimal effects on the image

quality (Ashkar & Zaki, 2017; de Groot, Broeders, Branderhorst, den Heeten, et al., 2013).

Kang et al. (2018) proposed a novel soft-compression mammography based on a weighted l1-norm scatter correction scheme in an attempt to reduce discomfort and pain caused by compression of the breast during the examination. The study result indicated that, the structure of the breast phantom used was much more clearly visible in the scatter-corrected image than in the original scatter-corrupted image. Again, the contrast-to-noise ratio (CNR) for the scatter-corrected image was about 6.3, about 4.1 times larger than that for the scatter-corrupted image, indicating much improved image visibility. They concluded that, the proposed approach seems promising for scatter correction in conventional mammography, thus allowing soft-compression breast examination in clinics.

Apart from pain associated with mammography, there are wide range of other factors that influence breast cancer screening participation. According to Wu et al. (2019), cultural belief, attitude towards breast cancer screening and poor awareness and knowledge of breast cancer appear to be associated with participation in breast cancer screening. The socioeconomic inequalities play a role in adherence to mammography screening.

Women with low socioeconomic status are more likely not to attend breast cancer screening and could present with a more advanced stage cancer than those with high socioeconomic status (Aarts et al., 2011). Eichholzer et al. (2016) is of the view that health-related factors such as poor self-perceived health, serious psychological distress, and non-attendance to cervical cancer screening were associated with non-attendance of breast cancer screening.

On the other hand, it is worth mentioning that the attendance rate for breast screening is one of the highest. The population of women screened has increase by 34% in 10 years (2007-2017) due to the robust screening program (NHS Digital, 2018). The uptake for the year 2016-17 was 71.1%, however there was a declined from 72.1% for the year 2015-16 (NHS Digital, 2018).

For this research study, pain/ discomfort experience was assessed on compression of the breast in two different IR angle for MLO position. Participants were asked to score their pain experience using a validated 11-point numerical rating scale (NRS) (Williamson & Hoggart, 2005) after compression on each breast. This was to ascertain which of the angles provided a more comfortable procedure.

1.10 Significance of the Research

It has been discussed that positioning is the single most important factor in optimising mammographic image quality (Chen et al., 2016; Pal et al., 2018) as it crucially determines the amount of breast tissue included on an image. Without all the breast tissue included on a mammogram all other aspects of the image quality are not relevant (Taylor et al., 2017). Optimum positioning allows for the imaging of all breast tissues to ensure breast pathologies are visualised (Yagahara et al., 2018).

The two main mammographic positioning protocols CC and MLO, are routinely used for the screening and diagnosis of breast cancer. Obtaining consistent optimal breast positioning for these projections are challenging because of inherent patient characteristics, such as variable client mobility, body habitus, and clients' ability to cooperate (Peart, 2014). There are general guidelines to follow during positioning, however it is entirely dependent on the practitioner therefore it is subjective. The subjectivity according to Richli Meystre et al. (2019) leads to a wide range of practice traits and inconsistences.

A study carried out by Taplin et al. (2002) concluded that, there is a correlation between poorly positioned mammography images and the occurrence of interval cancer, that is, breast cancer that occurs between two screening events. Another study carried out by Henderson et al. (2015) reported that that an image reader's accuracy in the diagnosis of breast cancer is influenced by the work of the practitioner conducting the examination.

The MLO is the only projection that must show most, if not all of the breast tissue, in a single view (Dronkers et al., 2001; Ikeda & Miyake, 2016a; Popli et al., 2014). The angle of IR used during MLO projection plays a vital role in the distribution of force on the breast during compression. The selection of IR angle is guided by clients' body habitus; therefore, it is subject to variations from one client to the other. It is recommended that the IR is angled parallel to the sternal angle of the clients (Mercer, Hill, et al., 2015). It is expected that when the IR is parallel to the angle of the sternum, there is an even distribution of pressure through the breast as well the optimisation of breast footprint from both the paddle and IR (Mercer, Hill, et al., 2015). The balance distribution of compression could result into a more comfortable procedure.

The application of compression force is one of the key parts of image acquisition as it immobilises the breast, separate overlapping breast tissue, reduce scattered radiation and ultimately, reduce radiation dose to the breast (Amendoeira, 2013; Balleyguier et al., 2018; Jeukens et al., 2019; Serwan et al., 2021). The application of compression force is entirely controlled by the practitioner therefore, it is subjective.

Several results from evidence-based research have demonstrated a wide variation in the application of compression force (De Groot, Branderhorst, et al., 2015; Mercer et al., 2013; Mercer, Szczepura, et al., 2015; Moshina et al., 2018; Murphy et al., 2015; Nightingale et al., 2015; Poulos & McLean, 2004; Serwan et al., 2021; Waade et al., 2018). Mercer, Szczepura, et al. (2015) discovered that the average compression force for the MLO projection across three sites was 97N, 88N and 132N respectively. There is a wide variation between 88N and 132N and this raises concerns about the consequences of this type of inconsistency. Again, this variability does have an impact on client experience which could in turn influence re-attendance. While it is recognised that the application of compression force is important in mammography, there is sparse and very little guidance available for practitioners as to how to apply compression and to what force. The European guidelines do not provide any indication regarding the required amount of compression force (Amendoeira, 2013). Public Health England (2017, p. 19)

stated “The compression should be applied slowly and gently to ensure that the breast is held firmly in position,” but no mention of how much compression to apply. As a result, the amount of force is subjective and there are inconsistencies and variations even for the same clients as they attend screening over the years. These variations are not desirable, because it suggests unwanted variation in standard of care and brings to question the consistencies and reproducibility of the imaging procedure.

A recent study by Serwan et al. (2021) to determine characteristic compressive forces applied during mammography analysed the parameters of 1972 mammograms from a South Australian diagnostic breast clinic. These parameters included applied compression(force/pressure), breast thickness, breast volume, breast density and average glandular dose. The results indicated that distributions of applied average forces was large, yet distributions of applied average pressures were larger. Regarding force-compressions, 98.6% were >5 daN, 16.6% were >10 daN, while 0.0% were >15 daN. With regards to pressure-compressions, 94.5% were >5 kPa, 36.0% were >10 kPa, and 6.3% were >15 kPa. The conclusion drawn from the work of Serwan et al. (2021) was that there was a high level of variation of applied compression forces in relation to breast/paddle contact area and an even higher variation in applied pressure. This is comparable with existing literature available internally.

Apart from the wide range of compression force variation used in mammography, Dustler, Andersson, Brorson, et al. (2012) found out that the distribution of pressure differed greatly between breasts as well. Two compressions on the left breast were taken on 103 women aged 40.7-74.3 years. One compression was done on standard compression force and the other was done on approximately 50% less force. Pressure reading were recorded using force sensing resistor (FSR) sensors placed underneath the compression paddle. The study concluded that distribution of pressure differed greatly between breasts. On most compression the compression paddle did not provide optimal compression of the breast, as compression force was being absorbed in juxtathoracic structures.

An introduction of a standardised approach to positioning may be an important step towards an individualised, more reproducible and less painful mammographic procedure. It will also help practitioners decrease the variability and improve the predictability of compression which will in turn give those attending for mammography a better experience. In addition to this, if women can trust to have a more pleasant and consistent experience each time they attend for mammography, this has the potential to improve the uptake rate of the breast screening programme.

Understandably, majority of research on intervention development to reduce pain in mammography is focused on compression applied during the procedure (Balleyguier et al., 2018; Jeukens et al., 2019). However, Moshina et al. (2019) is of the view that higher compression is not consistently associated with higher pain levels.

No research has been conducted which directly investigates the effect of positioning technique with respect to IR angulation on levels of pain as well as optimisation of pressure and area distribution. This will be the first study of its kind to study the pressure balance and contact surface area distribution in the MLO projection.

1.11 Purpose of the Research

The overall purpose of this research is to evaluate IR angulation during MLO positioning for optimised pressure and area distribution in mammography.

1.12 Phases of Research

The aim of the research is to evaluate the angle of IR during MLO positioning for optimised pressure and area distribution in FFDM. This will be achieved by an experimental methodology in a clinical setting. The study is clearly defined into two distinct phases:

- Phase one: a phantom study to develop a method of using the angle of the sternum to determine the correct angle of the IR for MLO projection and to investigate pressure and area distribution.
- Phase two: a human study to investigate pressure and area distribution of compressed breast at 'experimental' and 'reference' angles for MLO projection.

1.13 Hypotheses

Three hypotheses were tested in this report:

1. **Null Hypothesis H_0 one:** There is no significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

   Alternative Hypothesis H_1 one: There is a significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

2. **Null Hypothesis H_0 two:** There is no significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.
   Alternative Hypothesis H_1 two: There is a significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

3. **Null Hypothesis H_0 three:** There is no significant difference between pain experienced from compression on the reference angle and the experimental angle.

Alternative Hypothesis H_1 three: There is a significant difference between pain experienced for compression on the reference angle and the experimental angle.

1.14 Professional Background of Researcher

The researcher qualified as a diagnostic radiographer from the University of Ghana in 2005. She then moved to the UK where she got her post graduate certificate in advanced medical imaging, mammography practice in 2010. The researcher has been working as a mammographer since in both the NHS and private healthcare. She is currently an employee at the NHS Trust where this work was conducted.

1.15 Chapter Summary

This chapter has summarised the key themes and issues surrounding mammography and positioning. It has highlighted the role of mammography in the screening and diagnosis of breast cancer and discussed the benefit and the limitation of the procedure. Variations in mammographic positioning and compression have been discussed as well as the cause of pain and discomfort experienced during mammography.

It has outlined the research question, highlighted the significance and the impact the research may have. The next chapter will address the first aim – a review of the literature on the current mammographic techniques on positioning and compression.

Chapter Two - Literature Review

2.1 Chapter Overview

This chapter will review the key literature in the area of positioning and compression of the breast in mammography. References were made to the guidelines and protocols available to practitioners and literature was reviewed and critiqued This chapter is presented in a narrative format under themes and subheadings.

2.2 Search Strategy

A comprehensive search was conducted using online scientific databases as well as searching for grey literature using general search engines to find relevant literature. Peer- reviewed literature were selected from seven medical journal databases: Medline, ScienceDirect, Google Scholar, PubMed, ProQuest, Web of Science and Cochrane library. To acquire scientific literature for positioning and compression in mammography, search terms used Medical Subject Headings (MeSH), and key words including mammography, positioning, compression, screening, pain, discomfort and breast cancer. There was no date restriction placed on the search; this was to ensure that significant seminal studies were identified. Boolean operators (AND, OR and NOT) were applied to further narrow the results. Search strings specific to each database was developed in line with the stated MeSH. To ensure that the information contained within this literature review was accurate, only submissions from peer-reviewed journals were selected at this stage. Furthermore, only those articles with unrestricted accessibility to their full text were considered eligible for inclusion. Publications that involved other modalities such as ultrasound and MRI instead of mammography were excluded.

The search of grey literature was included in the literature review to identify written material which are not formally published and may not be indexed by major databases. Yasin et al. (2020, p. 36227) defines grey literature as “Information produced on all levels of Government, academics, business and industry in electronic and print formats not controlled by commercial publishing i.e., where publishing is not the primary activity of the producing body”. Grey literature

although not peer-reviewed, is often produced by scholars and scientists of their respective fields and is of high quality and detail (Osayande & Ukpebor, 2012).

Grey literature was searched by using the above databases, however the search for literature was restricted to the following areas: Dissertations and thesis, reports, conference papers and proceedings, Government and official publications and other sources. University of Salford library database,
Conference Papers Index, and UK Government websites were also searched for literature including books, Government policies and guidelines, and unpublished research work.

The next section (**section 2.3**) will discuss the most important findings from the literature search regarding the value of optimal positioning and compression in mammography. Key aspects of articles and literature discussed are summarised in **Table 1 (Appendix I)**.

2.3 Mammography Positioning

Mammographic positioning involves the physical placement of the breast in the mammography machine to create an image. The purpose of mammography is to obtain optimum image quality with maximum breast tissue visualisation for the diagnosis of breast abnormalities (Goldzahl, 2017; Kopans, 2007). It is also to improve survival rate and reduce the need for aggressive treatment (Sardanelli et al., 2017). Positioning has been cited as the single most important factor in optimising mammographic image quality (Pal et al., 2018). However, it is also the aspect of mammography quality that is most frequently suboptimal (De Souza Sabino et al., 2014; Guertin et al., 2016; Rauscher et al., 2013).

According to Taylor et al. (2017), without all the breast tissue included on a mammogram all other aspects of the image quality are not relevant. Optimal breast positioning is a key component to high quality screening mammograms for the diagnosis of breast cancer (Chen et al., 2016). Dumky et al. (2018) added that, there is a correlation between poorly positioned mammography images and the

occurrence of interval cancer, that is, breast cancer that occurs between two screening events.

A high-quality mammogram should exhibit correct positioning, optimal compression, adequate exposure, sharpness, low noise, good contrast and absence of artefact (Popli et al., 2014). Positioning could affect the amount of compression force applied to the breast during mammography. Positioning crucially determines amount of tissue inclusion and correlates with the overall quality of the mammogram (Kwok et al., 2004; Popli et al., 2014).

Mammographic image quality has improved remarkably over the years with the introduction of digital mammography. Popli et al. (2014) mentioned that, with advancements in hardware and software, factors affecting image quality such as exposure, sharpness, noise, and contrast have been addressed. Nevertheless, the two factors that still affect image quality are positioning and compression, both entirely controlled by the practitioner (Anja et al., 2019). As a result, both of these are subjective and without a clear protocol in their application (Poulos & McLean, 2004). Positioning of the breast and the compression applied plays a very important role in acquiring an optimum image. Optimal positioning also maximises the amount of breast tissue being imaged which is a key factor in the diagnosis of breast abnormities. The importance of breast positioning on IR has been advocated for decades by radiologists and researchers (Bassett et al., 2000; Huppe et al., 2017; Tabár et al., 2005) because technical problems and image quality have been found to be responsible for delayed detection in 22% of screening-detected cancers and 35% of interval breast cancers (Baines et al., 1990).

As positioning to a large extent is controlled by the practitioner, Dumky et al. (2018) investigated practitioner's perception on the methodology in mammographic examinations and categorised their results into three main parts, the position of the patients, positioning the IR and compression in their study. This was qualitative research in an interview with 13 practitioners from 6 mammography centres. The conclusion from Dumky et al. (2018, p. 47) study stated that

“practitioners work and think in different manners concerning the methodologies used in mammographic examinations”. The study drew this bold conclusion because from the interview with 13 practitioners, there were vast variation in how they position patient and the amount of compression they apply. Some practitioners mentioned they apply as much compression as the patient can tolerate while others said they use the same compression force for all. This conclusion is reflective of the current standard, as there is a lack of clear guidelines on positioning. However, as this is a descriptive study, the opinions expressed are limited to the individual’s interpretation of the procedure and together with a small sample size of 13 practitioners, this publication is limited and may not imply to the general population.

2.3.1 Cranio Caudal (CC) View

The CC view is acquired with the client facing the mammographic system just a few centimetres back from the IR **(Figure 2.1).** The breast is then positioned on the IR and initially sitting at a 90^0 to the chest wall with the nipple in profile.

Figure 2.1 Patient being positioned for CC projection

(Nightingale Centre Manchester University NHS Foundation Trust, 2012).

An optimal CC image should ideally demonstrate the following (Mercer, Hill, et al., 2015; Public Health England, 2020b)

- Maximum tissue on both medial and lateral aspect of the breast.
- Nipple in profile
- Skin fold artefact free
- Free from blurring
- Symmetrical

Public Health England (2020b, p. 21) guidelines for mammographers further on mentioned that, “the breast should be presented as straight with no lateral or medial rotation and no ‘rolling’ to one side or the other”. The pectoralis major has been identified as a key posterior anatomical structure to establish optimum breast tissue inclusion on both CC and MLO projections (Sweeney et al., 2018b). Even though this is not always visualized on the CC, it is encouraged to image the breast as far back as possible (**Figure 2.2**). In addition, Public Health England (2020b) stated the following specification for CC and MLO projections (**Table 2.1)**.

The height of the IR during positioning for CC projection has been widely investigated. The general consensus is that the image receptor is positioned at the level of the Inframammary fold (IMF) (Lee et al., 2003; Public Health England, 2020b), however several studies have stated otherwise (Branderhorst et al., 2016; Hogg, Szczepura, et al., 2013; Smith, Szczepura, et al., 2015).

Branderhorst et al. (2016) conducted a phantom study to assess the feasibility of implementing an objective and reproducible method of setting the image receptor height on CC projection. The findings of Branderhorst and colleagues (2016) indicated that monitoring the force imbalance and actively adjusting the position of the IR throughout the compression may lead to less pain, better image quality and reduced radiation dose. Although the work proved that even small changes such as adjusting the height of the IR by a few centimetres does have

influence on the procedure, it did not provide the exact height of the IR to be used during positioning with reference to any anatomical structure. The height of the IR was also investigated Hogg, Szczepura, et al. (2013) in a phantom study to measure pressures applied to the breast from the IR and the paddle and to measure breast footprint.

Table 2.1 NHSBSP criteria for CC and MLO images.

(Public Health England, 2020b)

CC Image specification	***MLO image specification***
Medial border of the breast	Whole breast imaged according to local protocol
Some of the axillary tail of the breast	Pectoral muscle shadow to nipple level
Pectoral muscle shadow may be shown on the posterior edge of the breast on some CC views depending on anatomical characteristics.	Pectoral muscle at an appropriate angle in accordance with good practice.
Nipple in profile	Nipple in profile
Correct annotation	Correct annotations
Appropriate compression	Appropriate compression
Appropriate exposure	Appropriate exposure
Absence of movement	Absence of movement
Absence of artefacts covering the image	Absence of artefacts covering the image
Symmetrical images	Symmetrical images
	Skin fold free
	Inframammary angle clearly demonstrated

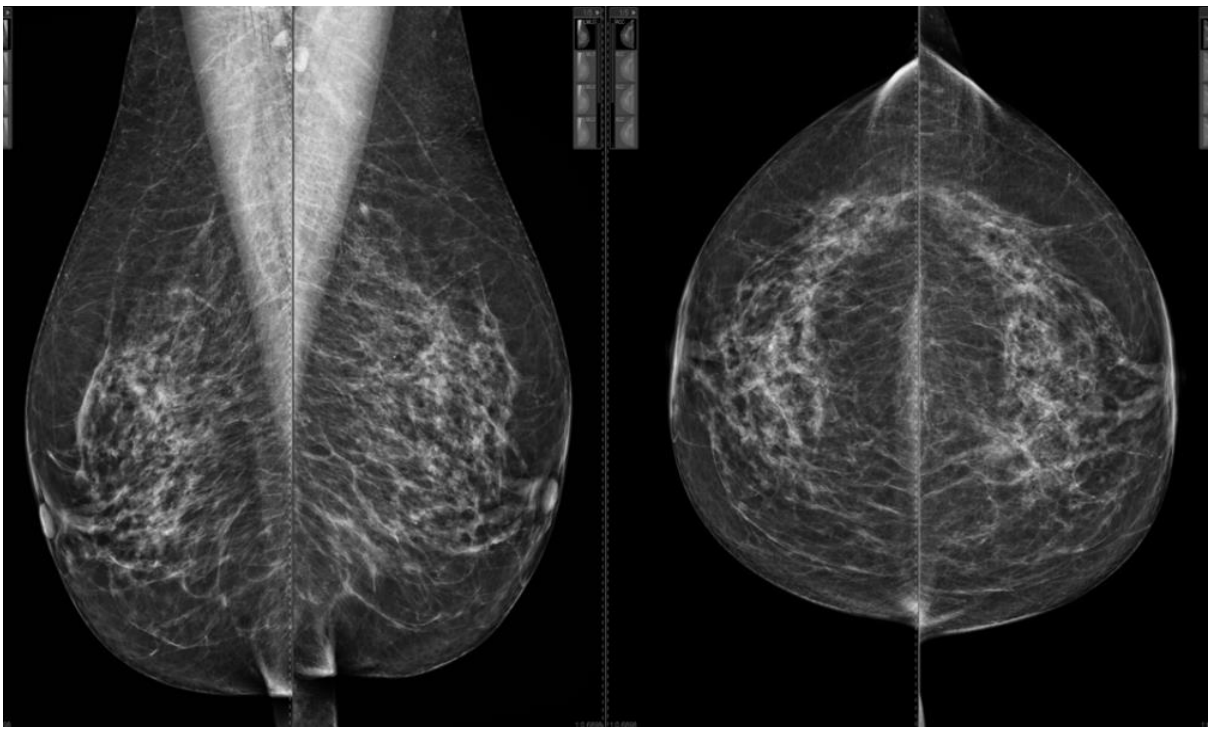

Figure 2.2 The main features of MLO (left) and CC (right) mammographic images (Radiology Assistant, 2013).

The results of the phantom study concluded that the greatest IR footprint was achieved when the IR is raised by 2 cm from the IMF on CC projection. A follow on human study was conducted by Smith, Szczepura, et al. (2015) which confirmed the findings of the phantom study. Smith, Szczepura, et al. (2015) conducted their research to look at ways to optimise the amount of breast tissue imaged on CC projection and to improve pressure balance. The results indicated that there was increased area footprint and better pressure balance of the breast when the IR is at +2 cm relative to the inframammary fold (IMF), in other words, the balance of pressure between breast/paddle interface and breast/IR interface.

2.3.2 Mediolateral Oblique (MLO) View

MLO projection is the most important view and considered to be a more superior projection, in comparison to CC (Anja et al., 2019) as all of the breast tissue is most likely to be included on the image (Kwok et al., 2004). To ensure that the entire glandular tissue is imaged with the best possible compression, correct positioning of the breast is a prerequisite (Fischer, 2002). The MLO is the most important projection and should ideally show all the features on CC as well as demonstrating the pectoral muscle to the nipple level with appropriate width, and the infra mammary angle.

Selection of the appropriate angle for MLO is a skill and an observation of the client's body habitus will provide a rough, but subjective indication on choosing the most appropriate angle. Selection of the appropriate IR angle could have effect on the resultant image and the client's mammographic experience. Anja et al. (2019) and Mercer, Hill, et al. (2015) added that incorrect angle selection could results in excessive compression being applied to the chest wall and axilla. This may cause unnecessary discomfort to the client and result in inadequate compression of the breast.

Positioning the IR at an angle for MLO projection is practice based, not based on evidence and the practitioner decides on the angle of the image receptor according to the patient's habitus (Dronkers et al., 2001; Mercer, Hill, et al., 2015). In practice, a tall, average weight client would be imaged on a steep angle. On the other hand, a shorter, high body mass index (BMI) client will be imaged on a less steep angle (**Figure 2.3).** Dronkers et al. (2001, p. 109) states that, "in tall, slender women the angle from the vertical may be slightly smaller; in smaller, more opulent women the angle from the vertical may be slightly greater".

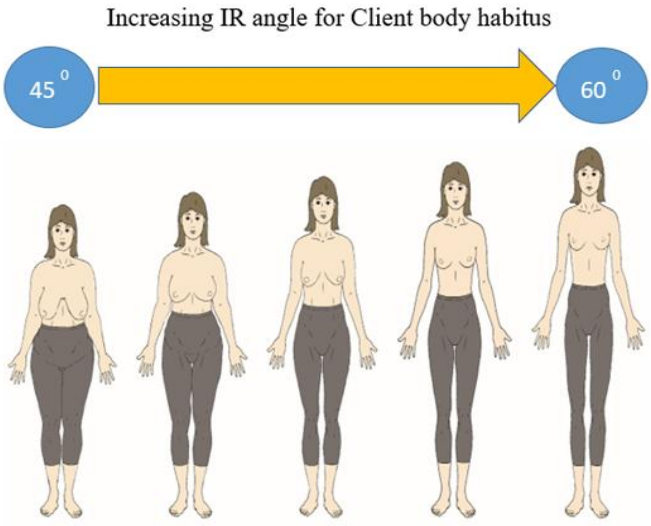

Figure 2.3 Guide to appropriate IR angle selection

(Mercer, Hill, et al., 2015)(Adapted).

As the selection of angle is entirely practitioner dependant, it is highly variable and subjective. Mercer, Hill, et al. (2015) added that to enable effective compression force balance between the IR and compression paddle to with maximum breast footprint, the sternal angle should be parallel to the IR (**Figure 2.4**).

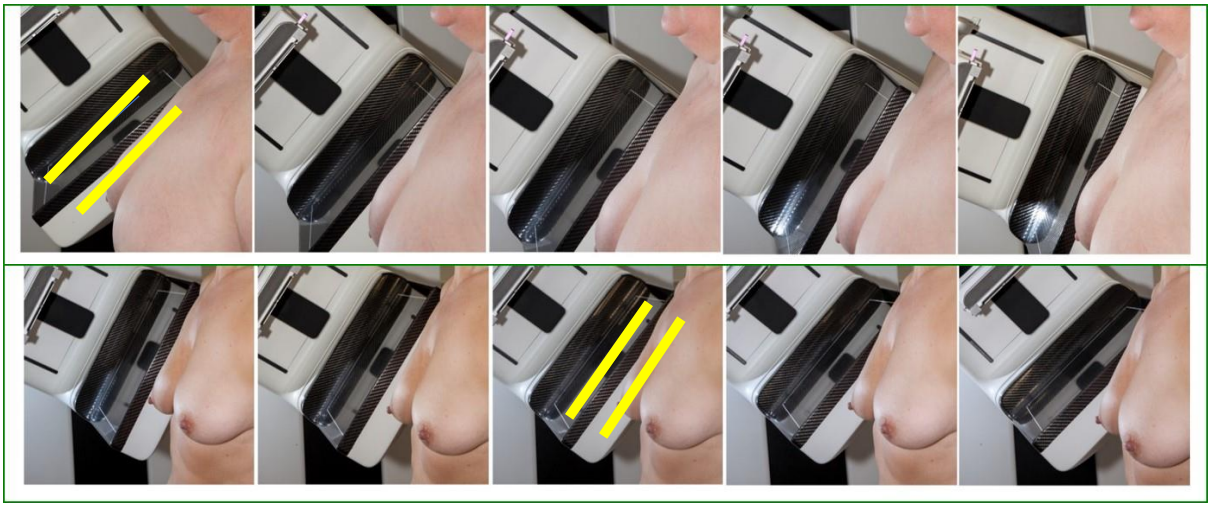

Figure 2.4 IR angle selection for various body habitus on MLO position (Mercer, Hill, et al., 2015).

Compression plays a part in the pain/discomfort during mammography, in addition the correct position of the breast will assist with compression technique. The positioning of the breast plays a very important role in reducing pain and discomfort as when the breast is positioned correctly between the IR and the compression paddle, pressure is evenly distributed throughout the breast and this could result into less pain and discomfort.

In the routine mammographic positioning, imaging is carried out in a fixed posture with the neck in a bent and unnatural position for the MLO projection (**Figure 2.5**). Compression of the breast combined with the often awkward posture required in mammography can cause an unpleasant experience with pain for women undergoing the examination (Uchiyama et al., 2012).

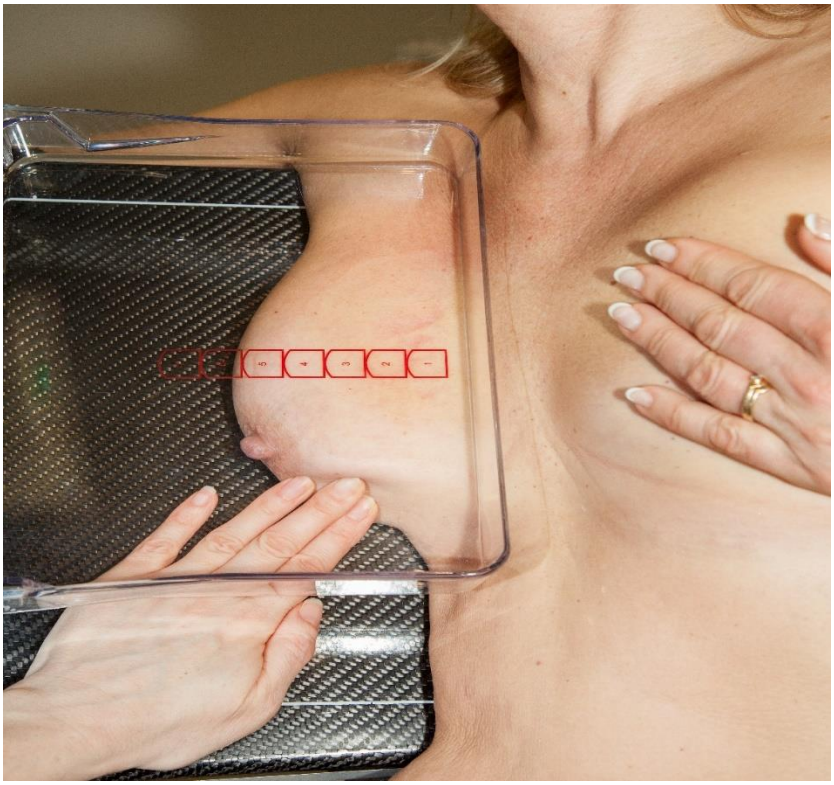

Figure 2.5 Patient being positioned for MLO

(Nightingale Centre Manchester University NHS Foundation Trust, 2012).

Positioning as well as compression is practitioner dependent. The practitioner decides how to position the client for a mammogram. This could result into the tendency of adopting a 'one size fits all' situation which could lead to clients being examined under a fixed practice without any change of technique to suit the individual client. During mammography it is a common practice to modify positioning technique from one client to the other to suit their body habitus so as to make the procedure as comfortable as possible. Moshina et al. (2022) and Popli et al. (2014) are of the view that, modification of technique is done with the aim of producing optimum images and to suit clients' body habitus. Anecdotal evidence suggests that; a small proportion of practitioners do keep the same angle of the IR for the MLO for all clients, this is poor practice and should be discouraged. The body habitus of each client is different, and this demands varying positioning techniques not only to produce optimum images but make the procedure as comfortable as possible for the client as well. Practitioners will have to understand how to modify positioning to suit all body types; small/large breast women, men,

post-surgery, patient with pectus excavatum or barrel chest, wheelchair and stretcher patients (Peart, 2005). Each client will have to be assessed and adjustments made to suite individual needs while still aimed at producing optimum images.

Angle adaptation of the IR is the main adjustment when it comes to MLO positioning. An angle of approximately 45^0 is often described (Brnić & Hebrang, 2001; Popli et al., 2014) and used in practice however, this could range from 40^0 – 60^0 **(Figure 2.4)**. Popli et al. (2014) suggests IR is angled to 45^0 to begin with, then this is personalised to the client as per size of the breast for up to $\pm 10^0$. Public Health England (2020b) states that "This angle varies according to the variations in physical constitution of the individual". It should be at an appropriate angle to enable the axillary tail of the breast to be demonstrated clear of the muscle shadow on the mammogram." Selection of the appropriate angle should be based on the body habitus of the client. Ideally, the IR should be placed at an angle so it is parallel to the sternum of the client (Mercer, Hill, et al., 2015).

Smith (2013) investigated the relationship between IR angle, pressure balance and footprint when compressing the breast in the MLO projection. Compressions were made at IR angles 45^0 and 55^0 on 16 volunteers had 4 MLO compression 2 on each breast (1 on 45^0, the other on 55^0). The study concluded that there was no significant difference observed in pressure balance at IR angle 45^0 and 55^0. There were however few limitations to the study. First and foremost, no justification was made as to why these two IR angles were selected for the study, as in practice there are ranges of IR angles used and this varies for all clients. Secondly, the study found significant statistical difference between the left and right breast, this could be due to the fact that one practitioner consistently performing the compression on the right breast, with another performing the left breast. The method has the potential of generating positioning difference when comparing pressure balance on the left and right breast. Last but not the least, pressure and area data were analysed together. It would have been useful to compare each of these separately to give a real sense of balance on these parameters on their own.

High quality mammographic images for both CC and MLO are crucial for the success of breast cancer detection. Image quality evaluation is required to assess the diagnostic value of images. The European Commission (EU) guidelines stated the criteria for positioning and image characteristic as follows:

a) Positioning: On a properly positioned medio-lateral oblique (MLO) view, the inferior aspect of the pectoral muscle should come to the posterior nipple line (PNL) and the pectoralis muscle should also be sufficiently wide. The breast is not sagging. Inframammary fold is open. The PNL on the CC view is within 1 cm of its length on the MLO view.
b) Compression: Better compression can be identified by better spreading out of the breast markings.
c) Exposure level: better exposure is evident from better penetration of the denser fibroglandular tissue. Underexposure of the pectoralis muscle may prevent visualisation of underlying structures in the breast.
d) Contrast: Image contrast shall permit differentiation of subtle tissue density differences.
e) Sharpness: Margins of normal breast structures shall be distinct and not blurred.
f) Noise: Noise can be identified by an inhomogeneity in the background.
g) Artefacts: An artefact is any density variation on an image that does not reflect true attenuation differences in the subject.(Wall & Shrimpton, 1998).

2.4 Sternum as a Reference Point for MLO Angle Selection

The practitioner is entirely responsible for selection of IR angle during MLO positioning and it is suggested that the decision should be based on the body habitus of the client (Anja et al., 2019; Brnić & Hebrang, 2001). Due to the configuration of the breast and its variability between individuals correct selection of the IR angle is crucial to maximise the amount of breast tissue demonstrated. However, there is no standardisation within the literature to advice practitioners on how best to determine the correct angle (Spuur & Poulos, 2009). Spuur and

Poulos (2009) added that as a result of this, there is significant variation on the selection of IR angle for the MLO as it is subjective.

There is a wide span of angles that could be used because of varying body habitus of clients. The aim of basing IR angle of the client's body constitution is to demonstrate maximum amount of breast tissue and pectoral muscle and to allow effective compression of the entire breast (Popli et al., 2014).

Several studies have suggested various technique to consider in order to select appropriate IR angle to suit clients' body habitus (Anja et al., 2019; Brnić & Hebrang, 2001; Mercer, Hill, et al., 2015). Anja et al. (2019) based their selection of IR angle mainly on the size of the breast and the size and shape of the chest. They evaluated the impact of alternative angulation and its impact on breast tissue representation with patients of different constitutional type. They aimed to investigate whether the use of alternative (35^0 or 55^0) angulation in MLO projection represents more breast tissue instead of standard projection with a 45^0 angle, for patients with specific anatomy. To do that, MLO mammograms from 491 patients were evaluated. These images were taken with the IR angled at either 35^0 or 55^0 (alternative angles) and the basic angle of 45^0. Angulation of 55^0 was performed when patient had small breasts long-term chest and convex sternum. The IR angle of 35^0 was used for patients with large breasts and concave sternum as well as patients with shorter thoraxes. All the patients who can images taken at either 35^0 or 55^0 had additional imaging carried out IR angle 45^0.

Measurements to evaluate the amount of breast tissue included on the image were based on the width of the pectoral muscle, the retromammary part of the breast, and the inframammary part of the breast for both projections. The results indicated that when comparing the presented tissue of the breasts between 45^0 and 55^0, all the results were in favour of 55^0. The pectoral muscle was on average wider for 4%, basal part of the breast for 1.3%, and inframammary part for 29%. On the other hand, when comparing the presented tissue of the breasts between 35^0 and 55^0, the results for basal part of the breast and the inframammary part of

the breast were in favour of 35^0. However, there was no statistically significant difference between the width of the pectoral muscle in the examined projections, the basal part of the breast was wider by 3.3% and inframammary part by 32.4%. The study recommends the use of IR angle 55^0 as an appropriate angle to use for patients with longer thoraxes and small breasts and the use of a 35^0 angle for those with shorter thoraxes and large breasts.

Although the study by Anja et al. (2019) came out with specific guidelines for selection IR angles to use for different body habitus, the decision still lies with the practitioner. The practitioner has to decide which category a client falls in. It is uncertain what measures are put in place to identify small breast from a large breast, and short-term thorax from long-term thorax. This classification is still very subjective. Clients who do not fall within any of these classifications are not considered, an individual could have medium sized breasts and of average thorax. Clients could present with a large breast but with long thorax and vice-versa. To summarise, this method is still dependant on the practitioner and does not provide a standardised way of choosing an appropriate IR angle for an individual.

A recent study by Moshina et al. (2022) investigated differences in positioning criteria related to the presentation of the pectoralis major muscle (pectoral muscle) for women of different heights using a standardised 60^0 IR angulation MLO projection. They extracted data associated with the pectoral muscle from Volpara on the right MLO of 45,193 women screened in BreastScreen. The positioning criteria used were pectoral muscle length, width and shape. These measurements were considered adequate or inadequate depending on the degree of fulfilling the criteria. Height information of women collected were divided into three groups, $\leq$163 cm, 164-170 cm and >170 cm. The study concluded IR angulation of 60^0 might suit most female offered mammographic screening in Norway, but women of a relatively low height (163 cm or lower) might benefit from IR angle less than 60^0.

Popli et al. (2014) evaluated the mistakes of improperly positioned mammograms that need to be avoided in order to ensure a high-quality mammogram and recommended the IR is positioned according to the size of the

breast. They suggested that the IR is angled to 45^0 to begin with during MLO positioning, then this is personalised to the client as per size of the breast for up to $\pm 10^0$. This method again is practitioner dependent and could result into inconsistencies.

Brnić and Hebrang (2001) also used the size of the breast to determine an appropriate IR angle for use during MLO positioning. They compared the efficacy of breast compression between two different mediolateral view angles- 45^0 and 60^0, and glandular absorbed radiation doses in the two projections. In 52 women, additional 60° oblique films were carried out after MLO 45^0 projection, with the same kVp and positioning technique. Breast thickness, time–current products (mA s) and absorbed doses were compared between IR angles 45^0-and 60^0. Subgroups of women with large, small, prominent and pendulous breasts were analysed separately.

Their results indicated that mAs was 11.5% lower and compression 7% better with an angle of 60^0 than with 45^0. In the subgroup of women with small breasts, mAs values were 13% lower and compression 9% better with 60^0 than with 45^0, while in the subgroup with large breasts, mAs was 9% lower and compression 5% better. In the subgroup of patients with pendulous breasts, mAs values were 12% lower and compression 10% better with 60^0 than with 45^0, while in the subgroup with prominent breasts, mAs values were 4% lower and compression 3% better. Absorbed glandular dose was estimated to be approximately 20% lower when an oblique mammogram was done with 60^0 instead of 45^0. They concluded that breast compression and mAs were more favourable in women with pendulous breasts, and that MLO be done with an angle of 60^0, especially for small and pendulous breasts. The study by (Brnić & Hebrang, 2001) does not provide enough evidence for standardisation for the selection of IR angle as it is limited to only certain types of breast and it still comes down to the practitioner to decide on the classification of such breast in order to choose the appropriate angle. And the study compared it to radiation dose instead pressure distribution investigated in the current study.

There is a suggested relationship between the breast and the sternum where mammography is concerned; Mercer, Hill, et al. (2015) are of the view that, for an effective compression force balance on MLO position, the sternal angle and the IR should be parallel to each other. Different body habitus presents with different sternal angle therefore if the sternal angle of an individual could be established, then the IR could be positioned at that angle so it is parallel to the sternum. It would not depend on the practitioner to establish the appropriate IR angle to use therefore could reduce inconsistency. This method could be much reliable and could offer a standardised positioning protocol. There is no research work that has looked into the role of the sternum in mammographic positioning and pain/discomfort reduction. The sternum was chosen for this reason as it is a novel approach. Additionally, the sternum was the point of reference made by Mercer, Hill, et al. (2015) to aid in effective force balance on MLO position. This theory was however not tested hence, the reason to use the sternum to ascertain its effect on MLO positioning, force balance and pain/discomfort.

The sternum unlike other body structures is relatively unchanged in an adult. Other studies recommend IR angle depending on body habitus and breast size (Anja et al., 2019; Bedene et al., 2019; Brnić & Hebrang, 2001; Popli et al., 2014). Body habitus and the breast have the tendency of getting bigger or smaller and the breast could also change shape overtime therefore IR angle selection ultimately falls on the discretion of the practitioner. The sternum on the other hand will be easier and more accurate to measure as it does not change much in the life of an adult. This will provide a more consistent and reliable form of reference for standardisation.

For the purposes of this research, the sternum will therefore be the focal point in establishing the correct IR angle for individuals during MLO positioning.

2.5 Compression

While there has been continues advances in image acquisition for instance from analogue to digital, one aspect of mammography that has not changed in 50 years is the need for the breast to be compressed for imaging (Balleyguier et al., 2018).

Compression is one of the important factors that affects mammographic image quality (Kopans, 2007; van Lier et al., 2021). Breast compression is achieved by pressing the breast against using a flat transparent compression paddle at one side against the IR at the other side. It is applied until an adequate thickness of the breast is achieved.

The right amount of compression when applied should improve the quality and detail of a questionable anomaly and separate overlapping breast tissues. Under-compression can lead to blurred images due to motion, more retakes and a higher average glandular dose (AGD), while over-compression causes discomfort and unnecessary pain to the patient (Chen et al., 2012; De Groot, Branderhorst, et al., 2015; Heine et al., 2010). Compression is the main source of pain in mammography. In a study carried out by O'Leary and Al Maskari (2013), they found that 96.6% of the pain experienced by women during mammography was due to compression. Mammographic image acquisition processes are subject to quality standards of Europeans Guidelines Perry et al. (2008) and Mammography Quality Standards Act (MQSA) (Mammography Quality Standards Act, 2018).

Nevertheless, the instructions for the application of compression appear vague to provide any sort of standardisation. National Breast Screening Programme (2006) publication 63 recommends that compression force should not exceed 200N. European guidelines states “compression should be firm but tolerable” (Perry et al., 2008, p. 76) equally, MQSA only provides requirement for testing compression devices but made no mention of how much compression force to use in clinical practice.

As a result, mammographers control the amount of compression applied and this is very subjective and varies from one practitioner to the other. A way of reducing variability is required to enable clients to get a more consistent experience over time. To help reduce this variation, the use of pressure instead of force could give a more reliable and constant compression for each individual (Holland et al., 2017). Compression pressure unlike compression force take into

consideration the surface area of the breast and this guides the practitioner to give an appropriate magnitude of compression.

In the UK, Public Health England (2020b) guidelines for breast screening mammographers, only mentioned that compression is applied until the breast is firmly in position. In addition, Skills for Health (2013, p. 2) states that "the breast should be compressed to ensure the whole breast is included". Various institutions have local guidelines on the range of compression force to be used, this would usually state the minimum and maximum compression force. Mammography quality assurance guidelines worldwide only mention subjective compression criteria such as "until the skin is taut at the sides" (Perry et al., 2008; Poulos & McLean, 2004). Some radiology departments and breast units prescribe a range of compression force to be applied emphasising on the minimum force in an attempt to maximise image quality.

The European guidelines for quality assurance in breast cancer screening and diagnosis state that "the breast should be properly compressed, but no more than is necessary to achieve a good image quality" (Perry et al., 2008, p. 172). As these guidelines do not specifically provide how much compression to use or recommend a range of values, there are varying protocols among screening programs across Europe. The Norwegian breast cancer screening programme recommends in their quality assurance manual that, the compression force for FFDM be between 108- 177 N. (Vee et al., 2011). This compression force values are similar to the range given across board. The research conducted by Mercer (2015) on compression demonstrated that within an individual client screening pathway, the clients could receive significantly different compression force levels over time. This was carried across three breast screening sites and it demonstrated practitioners behave differently in the application of compression force.

In an effort to reduce pain/discomfort, digital mammography systems are often equipped with different types of compression paddles, including RP (rigid paddle) and FP (flexible paddle) (**Figure 2.6**). The RP remains approximately parallel to

the detector during compression, whereas the FP remains parallel to the detector at first, tilts towards nipple side and ends with the highest point at thorax level.

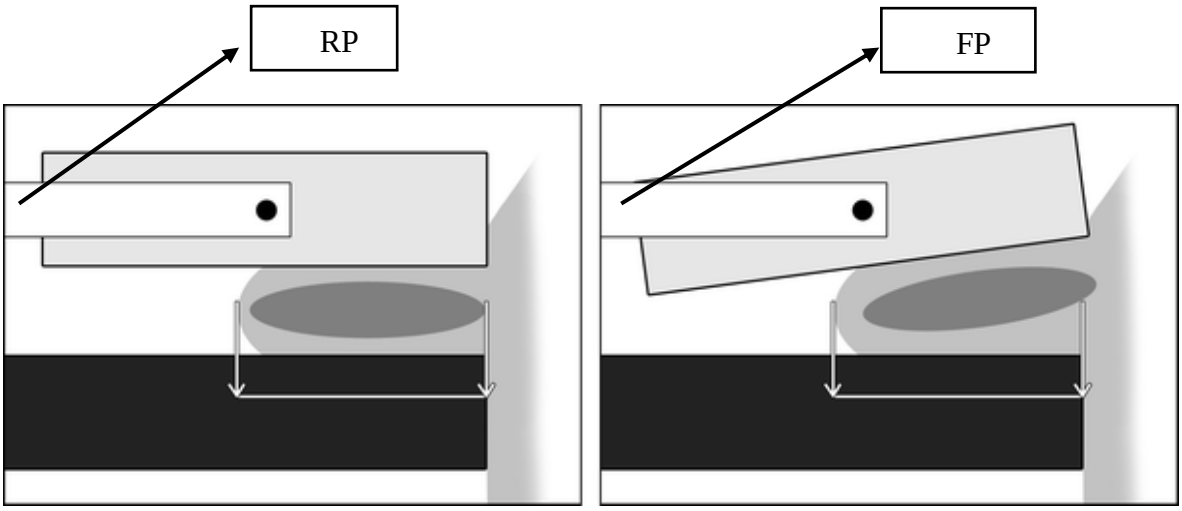

Figure 2.6 Compression of the breast with RP and FP

(Broeders et al., 2014).

Moshina et al. (2019) adds that, FP allow for various tilting angles and were introduced to decrease pain for women. However, no evidence exists to support this claim and the effect of these paddles on image quality has been questioned (Broeders et al., 2015). Broeders et al. (2015) compared pain radiation dose and image quality between flexible and rigid breast compression paddles. They concluded that pain experience showed no difference between the two paddles. In addition, FP performed slightly better in the projected breast area, however, it moved breast tissue from the image area at chest wall side. On the other hand, RP showed better contrast, especially in the retro glandular area therefore they recommended the use RP for standard CC and MLO views. For image quality, research has concluded that flexible paddle tilt has an effect on the accuracy of volumetric breast density estimation (Kallenberg et al., 2012). They suggested that tilt correction is an essential and feasible element in volumetric breast density estimation when images are acquired with a flexible compression paddle.

Dustler et al. (2020a) recommend the use of FP when they investigated whether FP can redistribute force to the central breast and whether this affects perceived pain during mammogram. From their study, they concluded the FP improves pressure distribution by distributing more pressure to the breast and less to areas outside of the clinically relevant parts, such as thick tissue at the chest wall and axillary area.

FP is routinely used for both screening and symptomatic mammography while RP are reserved strictly for QA test contrary to the recommendation of the study. The manufacturers of the equipment (GE Medical Ltd, Little Chalfont, UK) endorse the use of FP for compression during mammograms therefore RP will not be used in this study. Furthermore, only FP is used for mammograms in the breast unit where the study is conducted.

International variability in compression was investigated by Ng et al. (2017) to try and provide uniformly optimal screening for women around the world. A total of 136,752 studies from 17 different countries were processed and by automated volumetric breast density software, VolparaDensity. Patient age and compression force were extracted from the DICOM headers of studies. The study found that a considerable variation exists in breast compression pressure between countries. This variation was due to differences in age, breast composition and especially due to compression forces being applied. Other factors that can contribute to this variation includes population-specific breast differences, differences in compression practice or the reason for mammography.

2.6 Force

The compression used in mammography causes shearing forces within the breast. During mammography the force applied to the breast during compression reduces the thickness of the breast (Ng et al., 2017), and the shearing forces increase the footprint of the breast on the IR (Hogg, Szczepura, et al., 2013; Smith, Szczepura, et al., 2015) .

Measured in Newtons (N) with ten deca Newton (daN) equivalent to one Newton (N) compression force is applied in mammography when the breast is pressed between a flat transparent compression paddle on one side and the IR on the other. Compression force is applied to the breast until an adequate thickness is achieved and the readout is often displayed on the mammographic system. The amount of compression force applied is entirely dependent on the practitioner (Anja et al., 2019). Currently, most often than not, 'force', 'pressure' and 'compression' are used interchangeably by practitioners, however compression force is the correct definition, and was the term used in this work.

The current compression practice for breast screening is based on force-standardised compression (FSCM) in which each breast is compressed within the range of compression force (Den Boer et al., 2018). As FSCM approach does not consider breast size, it may lead to a large variation in applied pressure (Branderhorst et al., 2015). The pressure from compression could be larger for smaller breasts compared with larger ones because the contact area between the breast and the paddle is smaller whilst still being under the same compression force (De Groot, Branderhorst, et al., 2015).

The amount of compression force applied during mammography is entirely dependent on the practitioner therefore Murphy et al. (2015) conducted a qualitative research to investigate compression behaviours of practitioners and to understand 'how' and 'why' practitioners apply compression. They carried out focus groups interviews on 41 practitioners. They reported that some practitioners do not refer to the numerical readout displayed on the equipment for the level of compression being applied during the procedure. In this case they practice purely on "look and feel". This subjective approach is more likely to result in compression force. This reflected in the results of the studies as there was a wide variation in the application of compression force, thus offering a possible explanation for the difference between practitioner compression forces found in quantitative studies.

Compression force was applied in many different ways due to individual practitioner experiences and behaviour. Moreover, the culture and the practice of

the units themselves influenced beliefs and attitudes of practitioners in compression force application. Although results from this study have answered a critical question of compression force variation among practitioners, by seeking practitioner's own perspective the validity of the findings were limited to their interpretation of their compression force practice.

A similar study by Nightingale et al. (2015) looked into the problem-solving process applied to the application of breast compression force from the practitioners' perspective. They found out most practitioners do not utilise any objective measures to assist in their selection of optimum compression, therefore proposed a 7-stage continuum model to be used for the application of compression force. However, this model has not been validated and no record of it been used in any research work as yet. With respect to these quantitative studies, the views expressed by practitioners are limited to their understanding of the procedure.

A retrospective randomised controlled study conducted in Norway investigated the force used in the Norwegian breast cancer screening programme. A total of 17,951 mammographic examinations were examined in 14 breast centres. They investigated the applied compression force on the left breast in craniocaudal and mediolateral oblique views for breast centres, mammography machines within the breast centres and for the practitioners. They found a wide variation in applied compression force between the breast centres. This variation indicates a need for evidence based recommendations for compression force aimed at optimizing the image quality and individualizing breast compression (Waade et al., 2017).

2.7 Pressure

Pressure is measured in kilo pascal which is the total force divided by surface area. The use of pressure in place of force takes into consideration the surface area of the breast to produce standardised pressure to client. Pressure-standardised compression is provided by the Sigma paddle it is in use in the Netherlands (De Groot, Branderhorst, et al., 2015). Pressure has the same unit

(mmHg) as tissue elasticity and blood pressure, whereas force itself is unrelated to any physiological parameter. These three parameters are used to estimate the amount of force per unit area. Therefore, pressure may be more closely related to physiology than force (De Groot, Branderhorst, et al., 2015). The benefits of pressure-standardised compression mammography (PSCM) over force-standardised compression mammography (FSCM) according to (De Groot, Broeders, Branderhorst, Heeten, et al., 2013), are as follows:

1. It improves standardisation across the population in terms of physiological conditions in the compressed breast,
2. It reduces discomfort and pain, particularly the number of severe pain complaints,
3. It comes with a limited effect on image quality and radiation dose. There is no difference in image quality and absorbed dose between images obtained using conventional FSCM and PSCM.

The use of standardised pressure in mammography will take into consideration the size and density of the breast. The Sigma paddle is the first pressure-based compression paddle available provides pressure feedback in real-time (PRWeb, 2016). Based on breast-size and tissue-stiffness the Sigma paddle calculates the pressure to achieve an optimal compression. de Groot et al. (2017) adds that the paddle measures both the force (in decanewton, daN) and the breast contact area (in square decimetre, dm2) and calculates in real-time the contact pressure (in kilopascal, 1 kPa = 1 daN/1 dm2). Sigma paddle has sensors that indicate real-time pressure on the breast. The practitioner is always in control of the compression force and this is a guide to optimise the compression applied. The paddle prevents unnecessary discomfort or pain and the procedure is highly reproducible with the same physical experience, year after year (SigmaScreening, 2018) and pressure standardisation reduces compression variability between exams (Branderhorst et al., 2015).

A more recent study by van Lier et al. (2021) evaluated the use of pressure sensing flexible paddle in digital breast tomosynthesis (DBT). The aim was to measure the effect of a pressure based flexible paddle on compression

parameters and its influence on the radiographer's and patient's overall experience of DBT. Additionally, the study aimed to assess the difference between a remote-controlled, pressure based, patient-assisted compression process on the one hand and a pressure-based, standard radiographer-assisted compression process on the other.

The flexible paddle is capable of performing pressure-assisted compression can be controlled by the radiographer or by the woman during the compression process using a remote-control device. Of the 103 participants, 50 has patient-assisted compression while 53 had radiographer compression. The participants had prior examinations available for data comparison and also successfully completed a questionnaire to evaluate their experience in terms of comfort and overall satisfaction. Compression parameters of contact areas from both the current and previous images were analysed. van Lier et al. (2021) concluded that using this new type of paddle, with or without the involvement of the woman, both the women and radiographers reported an improved experience of the whole compression process, showing the potential of the system to decrease the negative perception commonly associated with breast compression in mammography and DBT. At the same time, compression pressure variability, mean breast thickness, and glandular dose were significantly reduced.

A further study van Schoor et al. (2019), investigated the impact of mammographic compression with Sensitive Sigma in providing a pressure-standardised compression mammography (PSCM). They compared images of hundred participants from Belgian population-based screening who had a prior force-standardized compression mammography (FSCM) and recently introduced PSCM. They obtained compression force, breast contact area, mean compression pressure and mean glandular dose from current (PSCM) and prior (FSCM) mammograms. Participants were asked for their current pain experience compared to the last screening exam. Statistical significance was then tested with a paired t-test. The study showed that when using PSCM, the compression reproducibility within and between technicians improved with less variation. Additionally, a reduction of under- and over-compression was seen, with an

increased number of mammograms in the target pressure range of 8-14kPa. It was therefore concluded that by using a paddle with a real-time pressure indicator in PSCM, the discomfort experienced during mammography was reduced.

De Groot, Branderhorst, et al. (2015) also compared a conventional 14 daN force-standardised compression protocol using Sigma paddle with a personalized 10 kilopascal (75 mmHg) pressure-standardised protocol. The target pressure of 10 kPa was chosen because it is expected to result in a tissue pressure between normal venous and arterial blood pressure. This was done by comparing the compressed breast thickness, average glandular dose, pain experienced, and the proportion of required retakes with respect to a strict implementation of the 14 daN target force compression protocol. The study concluded that, for the majority of women, pressure-standardised compression reduces pain, without compromising image quality and the average glandular dose and retake proportions were similar for both protocols. The limitation of this study was that, in 18% of the women who took part in the study pressure-standardised protocol required forces higher than the force-standardised protocol. This was due to the fact that their breast contact area was larger than 1.4 dm^2 and the design of the study did not allow concluding whether this additional force was beneficial for image quality or AGD.

Den Boer et al. (2018) confirm in their study that PSCM can reduce the pain and discomfort experience during mammography compared with force standardised compression mammography (FSCM). They conducted a retrospective study and analysed 150 PSCM images and 150 FSCM images. The mean pressure decreased significantly from 17.1 to 12.8 kPa when using PSCM instead of FSCM and the relative number of over compressions were reduced from 26% to 2% benefiting patients with smaller breasts.

(Katarzyna Feder & Grunert, 2017)investigated pain in mammography in relation to compression pressure, in an experimental study and reported that women with larger breasts tolerated greater compression compared to those with smaller breast, therefore the need for individualised examination depending on the size of breast.

The relationship between breast contact area and compression pressure applied by the paddle was investigated by Branderhorst et al. (2017). They assessed the accuracy of two methods of determining the contact area between the compression paddle and the breast. The contact areas between breast and paddle were measured for 300 breast compressions both capacitively using a transparent foil with indium-tin-oxide (ITO) coating attached to the paddle, and retrospectively from the obtained mammograms using image processing software (Volpara Enterprise, algorithm version 1.5.2). Video images obtained from the compressed breast were used as the gold standard. The study concluded that the size of the contact area between the paddle and the breast can be determined accurately and precisely, both in real-time using the capacitive method, and retrospectively using image processing software.

This study however had some limitations. Surface area was only calculated for the breast and paddle contact but not breast and IR contact. As the breast is in contact with the IR during the application of pressure, it would have been useful to determine the relationship between IR contact area and compression pressure. Another limitation was gold standard used. The manual segmentations of the video images recorded were regarded as the gold standard. There is a possibility that a part of the reported variation between the two studied methods and the gold standard is introduced by the process of establishing the gold standard.

In a literature review conducted by Serwan et al. (2020), they discussed the concept of personalised pressure standardisation protocol to help reduce subjectivity and variability that comes with compression force. Eighteen articles that explored existing force- and pressure-standardisation protocols in clinical application were analysed. They concluded that compression pressures of approximately 10kPa aid in image acquisition reproducibility both within and between women; pain levels decrease, with minimal variations to breast thickness, AGD and image quality. This was suggested as mammographic guideline in aid in standardisation of compression.

2.8 Mammography Pain Experience Measurement

It has been established that mammography is associated with pain/discomfort (Chen et al., 2012; De Groot, Broeders, et al., 2015; Heine et al., 2010; O'Leary & Al Maskari, 2013; Uchiyama et al., 2012; Whelehan et al., 2021). Pain experienced during mammography has been investigated by several studies (Armstrong et al., 2007; Asghari & Nicholas, 2004; Ashkar & Zaki, 2017; Nelson et al., 2020; Whelehan et al., 2021).

Armstrong et al. (2007) study was discussed earlier on in chapter one **section 1.9**. They found a wide range of pain experienced during mammography from as mild as 6% to as painful as 76%. Ashkar and Zaki (2017) investigated the association of different factors in mammography related pain perception of women and whether the pain perceived was equal to the pain experienced. They issued structured questionnaires with close-ended questions to 100 women before and after their mammogram asking about their pain perception and whether it had changed after having their mammogram. The results from the research conducted by Ashkar and Zaki (2017) indicated that factors that affected anticipated mammography pain were past mammography experiences, previous breast procedures, and the knowledge that was gathered beforehand about mammography. For pain experienced after mammography, majority of the women who did not expect the mammography to be painful experienced pain during their mammogram whereas the women who thought the procedure was going to be painful experienced what they expected. Finally, most of the women who did not know whether it would be painful or not experienced the procedure as painful.

In an effort to measure the pain/discomfort experienced during mammogram, Kuo et al. (2021) conducted a quasi-experiment and recruited 150 participants for their study. A visual analogue scale (VAS) was used to score pain experienced during mammogram by both the intervention and control groups. In addition to receiving the standard mammography education handouts, the intervention group were also presented with an 8 minutes health education video before their mammogram. The video illustrated the actual procedure of mammography, the benefit of mammography and why compression is applied. The control group only

received the standard mammography education handout. Both groups completed VAS questionnaire after mammogram to rate the pain experienced during the procedure. The study found no significant difference between pain experienced by the two groups.

No research has been conducted to compare pain experience based on different IR angulation. This current study will investigate pain experienced on compression of the breast on two different IR angles for MLO position

2.9 Communication

Positioning and compression are the primary cause of pain and discomfort in mammography as discussed earlier. These two parameters are entirely controlled by the practitioner therefore effective communication between the client and the practitioner before, during and after the procedure is essential.

Communication is a process by which information is exchanged between individuals through a common system of symbols, signs, or behaviour (Storlie, 2015). It is a well-established fact that good communication is fundamental to healthcare, as it serves as a mechanism to ensure safe, effective procedure and treatment. Communication failures can cause not only dissatisfaction but serious adverse events (Hill, 2011) therefore efforts should be put in place to communicate with and involve people in their healthcare management. Good communication skills play very vital role in mammographic examination. The behaviour of the mammography practitioner toward the client is crucial in helping to reduce anxiety, gain compliance and perform high quality mammogram (Mackay, 2015). Brett and Austoker (2001) emphasise that, the experience of women during mammogram can have a detrimental effect on the response rate to a screening invitation. In addition to that, the experience of pain during mammography is also influenced by the communication between the practitioner and the clients (Moshina et al., 2020) therefore effort should be made to communicates information clearly to clients before, during and after mammographic examination. The client is more likely to cooperate and feel at ease if the procedure has been thoroughly explained and they know what to expect. In practice, it is always helpful to inform the client about

compression to be applied on the breast and the possibility that it could be uncomfortable. Papas and Klassen (2005) reported that the friendliness and sensitivity of the practitioner is one of the factors associated with pain, hence the importance of good communication.

To improve mammographic experience, it is the responsibility of the practitioner to develop good communication skills with the client for a less painful/uncomfortable examination.

2.10 Aims and Objectives

The aim of this research is to evaluate the angle of IR during MLO positioning for optimised pressure and area distribution in full field digital mammography (FFDM). The main objectives are as follows:

4. Review literature on the current mammographic techniques on positioning and compression.
5. Develop a method, using the sternal angle, to allow selection of the correct IR angle to use on MLO projection using a breast phantom.
6. Using Xsensor pressure map system, determine the pressure and area balance for MLO position with two different IR angles (one on reference angle of 45^0, and the other on experimental angle measurement derived from the sternum of the participant) on healthy participants.
7. Using a pain score questionnaire to assess pain/discomfort experienced on compression of the breast on both the experimental and reference angles.

2.11 Hypotheses

Three hypotheses were tested in this report:

8. **Null Hypothesis H_0 one:** There is no significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

Alternative Hypothesis H_1 one: There is a significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

9. **Null Hypothesis H_0 two:** There is no significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

   Alternative Hypothesis H_1 two: There is a significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and positioned at a reference angle of 45^0 during MLO projection.

10. **Null Hypothesis H_0 three:** There is no significant difference between pain experienced from compression on the reference angle and the experimental angle.

Alternative Hypothesis H_1 three: There is a significant difference between pain experienced for compression on the reference angle and the

2.12 Chapter Summary

From the literature review it has been identified that positioning and compression are two main sources of pain in mammography and these two parameters are entirely controlled by the practitioner, as a result there is an element of subjectivity in positioning and the application of compression.

There are variations in literature with regards to mammographic positioning and compression. Various guidelines have general rules on positioning and compression however these guidelines appear vague. Most of these guidelines provide extensive quality control measures for assessing diagnostic quality of

images for both CC and MLO projections. Practitioners are guided by these quality control measures during mammographic positioning and compression.

Positioning the IR 2 cm above the IMF on CC projection has been proven to increase breast footprint on the IR as well as provide better pressure balance between breast/paddle interface and breast/IR interface (Hogg, Szczepura, et al., 2013; Smith, 2013; Smith, Szczepura, et al., 2015). This has offered a standardised method of positioning the IR for the CC projection. On the other hand, for the MLO position, there is limited literature regarding IR angulation, therefore it is left to the discretion of the practitioner. Although Smith (2013) investigated pressure balance and footprint when compressing the breast on different IR angles in MLO position, the study did not suggest any standardised positioning for the IR angle. The gap in literature is evident and is the focus of this thesis to evaluate image receptor angulation during MLO positioning for optimised pressure and area distribution in mammography. This session has also started aims and objectives with the hypothesis of the research.

Chapter Three - Method

3.1 Chapter Overview

This chapter will address objective two of this thesis. It involves developing a method, using the sternal angle (experimental angle), to allow selection of an appropriate IR angle for use on MLO projection for optimal pressure and area distribution.

It also highlights the processes to be used to measure the angle of the sternum for the research. Validating of the methods used in this thesis were discussed. It includes the validation of equipment and instruments used and the actual process to be used for data collection.

3.2 Sternal Angle Measurement

The sternum is positioned between the breast and it is thought that the sternal angle plays a crucial role in gaining an even distribution of pressure throughout the breast during MLO (Mercer, Hill, et al., 2015). The sternal angle (angle of Louis) is calculated as the angle between manubrium and sternum y-axes within the sagittal plane (Beyer et al., 2017) (**Figure 3.1)**. The sternal angle ranges from 149^0 to 177^0 with an average of 163^0 in men and 165^0 in women (Ball & Adigun, 2019).

To gain an accurate measurement of the sternal angle, three methods were considered to allow the most reliable and accurate one to be selected for the final experiment. Firstly, a motion capture system (MCS) as was considered, a purpose-built system was developed and investigated and finally a digital inclinometer was assessed.

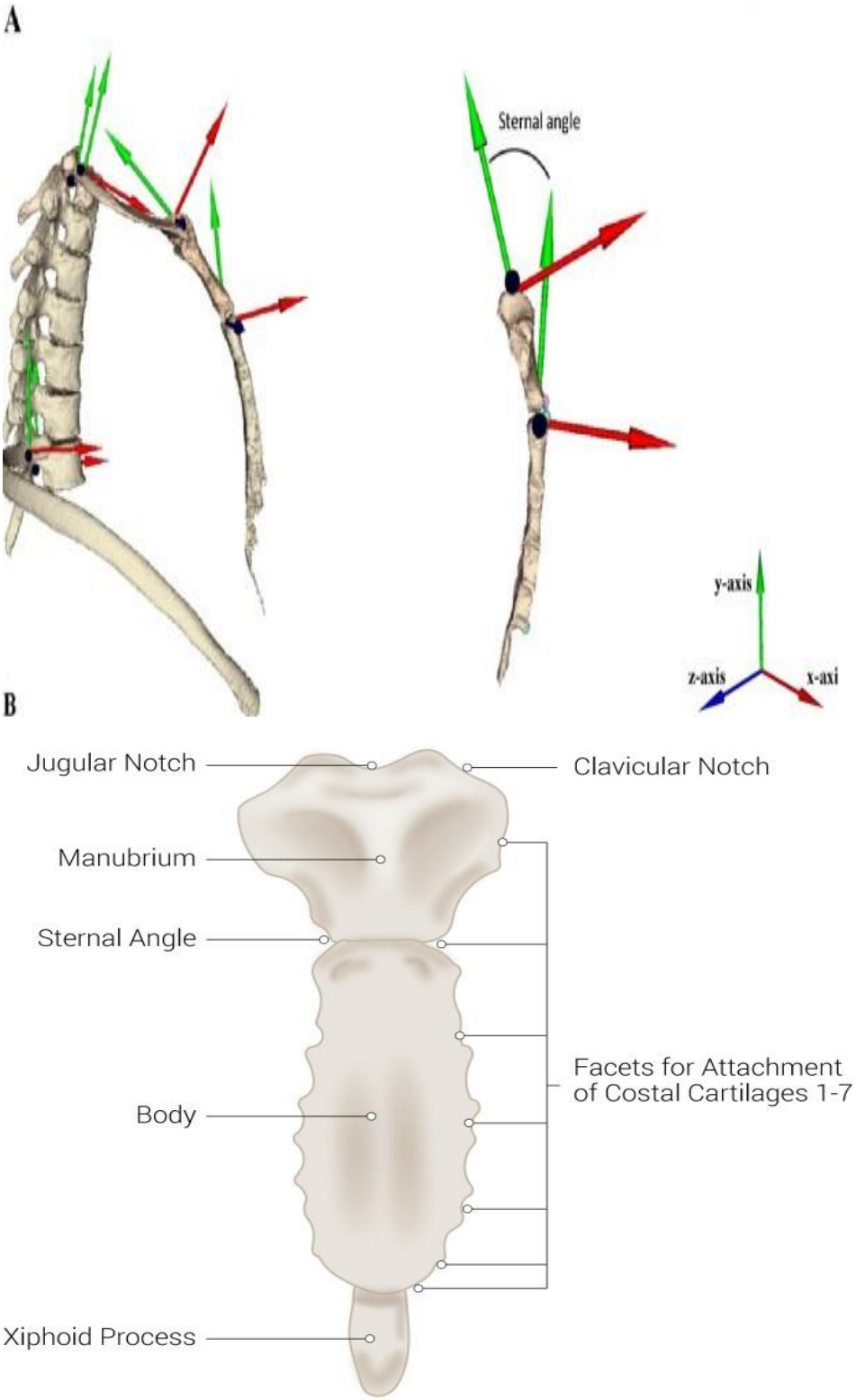

Figure 3.1 Human sternum demonstrating sternal angle

(Beyer et al., 2017)

3.3 Equipment

3.3.1 Motion Capture System (MCS)

MCS can determine the movement of markers in any direction precisely (Park et al., 2015) and it is being used in fields such as sport science, animation and medical treatment (Aurand et al., 2017; Schmitz et al., 2014; Thewlis et al., 2012). In medical treatment for example, there has been growing attention to human motion tracking systems in order to obtain more efficient rehabilitation therapies (Brigante et al., 2011).

For this research, optical MCS method was used to assess the position at which the sternum is perpendicular to the IR. MCS would have employed an active marker method using strobes attached to participants' sternum and the IR. These markers would then emit infrared and visible light. The infrared and visible light reflected would be recorded by a camera and the angle of the receptor adjusted until it is parallel to the participants' sternum. Two or more cameras would have been required as the more the number of cameras the more precise the measurements to be obtained. The key challenge of this system was that, the marker must be within the angle of view of the camera. It is not possible to measure if the field of vision between the markers and the camera gets covered. The issue is that, because the sternum is located between the breasts, it is guaranteed the breast is going to be in the way of the camera. The MCS was reviewed and considered not fit for purpose for this study for the following reasons:

1. Due to the position of the sternum, the breast would have been in the way of the camera therefore the camera could not have read signals from the marker.
2. The marker would have likely picked signals from bone structures (ribs and clavicle) near the sternum as well and this would interfere with readings to be taken. This was realised during a test run on how the system worked.

3.3.2 Purpose Built Sternal Angle Measurement Tool

A tool was specifically designed by the researcher to assess its feasibility to measure the angle at which the IR is parallel to the sternum **(Figure 3.2**). The system was made of a Perspex transparent sheet with studs at one end. Adult sternal length ranges from 12.5 cm to 17 cm with the average being 14.6 cm (Laurin et al., 2012; Tumram et al., 2015). The distance between the two studs was based on the average length of the sternum for an adult. The studs were to be positioned on the gladiolus (the body or the blade of the sternum) with the other end resting on the IR. The aim was to get the sternum and IR parallel.

Figure 3.2 Purposely designed test tool for measuring sternal angle

The purposely built sternal angle measurement tool was not suitable for taking accurate sternal angle measurement because of the following limitations:

1. The studs on the tool which were meant to be positioned on the sternum were flexible so they moved around when positioned. As a result, readings were inconsistent and not reliable or reproducible.
2. The tool was only suitable for use on small breast due to the size of the notch in the centre of the tool.

So far both MCS and purpose-built sternal angle measurement tool discussed were not exactly suitable for purpose hence where no used. Digital inclinometer was next to be explored.

3.3.3 Digital Inclinometer

Digital inclinometers are sensors that measures and display the incline: the angle of slope elevation or depression of an object with respect to gravity's direction. The depression is either depicted in degrees or percentage. Traditionally, electronic inclinometers are used by carpenters, surveyors, and engineers. According to Graham et al. (2013), inclinometers have been recently used clinically in an attempt to improve accuracy in the measurement of incline and slope. It is used in monitoring networks for patients and elderly and to enhance monitoring of patients' exercise (Brigante et al., 2011).

When the digital inclinometer is placed against a solid object, the device compares the angle of the object to the gyroscope and displays the electronic readings on its LCD screen. Inclinometers have probes that use an accelerometer to measure the tilt angle from the true vertical line or horizontal plane with respect to the earth's surface. The accelerometer itself measures the change in acceleration due to gravity felt by it as it rotates about a horizontal axis. The accelerometer experiences maximum acceleration when its sensitive axis is truly vertical and minimum acceleration when its sensitive axis is truly horizontal (Encardio, 2020).

Digital inclinometers are considered to be useful instruments because they are inexpensive and easy to use (Chiarello & Savidge, 1993; de Winter et al., 2004) and able to read angles precisely (Aries, 2017).

To assess validity and reliability, a Powcan digital inclinometer (Powcan manufacturing) was assessed by taking angle measurements at image receptor (IR) angles of a GE Senographe essential mammography unit (ref to manufacturer).

Figure 3.3 The Powcan digital inclinometer demonstrating LCD screen for angle reading (Barbados, 2019).

The Powcan digital inclinometer protractor (**Figure 3.4**) to be used for the research is a 20 cm digital spirit level. It has an LCD digital upright display the following specifications:

- Material: ABS, Aluminium+ Alloy
- Resolution: 0.1°
- Measurement Range: 4×90°
- Working Temperature: 0~40℃
- Power Supply: 2 x 3V CR2032 Batteries
- Base Length: 20 cm
- Weight: 60 g

3.3.4 The Xsensor Pressure Mapping System

The Xsensor is an interface pressure mapping tool is used to measure the distribution of pressure where any two surfaces are pressed together. **(Figure 3.3).** The mat was designed as a conformable, flexible, and durable with highly sensitive sensors for measuring interface pressures in medical applications such as assessing the interface pressure distribution among wheelchair users (Sumed, 2019).

It records, in real time, the interface pressure between two contacting surfaces. The data is used to provide pressure measurements to graphically display the pressure distribution between two interface surfaces. The data from pressure mat reading can also be exported as numerals into Microsoft Excel for analysis.

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Figure 3.4 The Xsensor pressure system (Independent Living Centres, 2011)

The Xsensor pressure mapping tool is comprised of a matrix of capacitive sensing elements with specialised electronics connected to a Windows based computer (Xsensor, 2018). The pressure mat is easily wiped and measures 63.5 cm by 63.5 cm and the active sensing area of 45.72 cm by 45.72 cm sensing points with special resolution of 1.27 cm. The mat is easy to use and data generated could be represented as 2D or 3D image on a colour scale and as numeric data transferred to a spread sheet. The main advantage of this system is its user friendliness and the ability to convert pressure readings into several formats for analysis. It could be easily wiped down for infection prevention purposes. However, there are limitations to the use of the system as well. It can only read a maximum pressure of 256 mmHg, therefore any readings above this level are capped at a reading of 256 mmHg. Again, the mat can only record contact pressure therefore areas of the breast that do not have contact with the mat at both IR and paddle interfaces are excluded from the record.

In addition, the Xsensor mat had been successfully used in similar studies by Hogg, Szczepura, et al. (2013); Smith (2013); Smith, Szczepura, et al. (2015). Hogg, Szczepura, et al. (2013) in their research used the Xsensor mat to read and record paddle and IR footprint of a deformable breast phantom on compression. They gathered area and pressure readings from two mammographic and four paddles at 60, 80, and 100 N with the IR positioned at −2, −1, 0, +1, and +2 cm relative to the inframammary fold. The results indicated that best pressure/footprint balance is achieved at IMF +1 cm.

The Xsensor pressure mat was determined suitable for use for both phantom and human studies as it provided real time pressure readings on contact with surfaces and has the ability to convert pressure data points into several formats for analysis. In addition, data generated by the system were suited to the calculation of contact pressure and contact area footprints.

3.4 Equipment Test and Quality Check

Quality control is a system that maintains a desired level of quality, through service characteristics and implementation of remedial actions, in case of a deviation of such characteristics from a specified standard (Mitra, 2016) To ensure mammographic equipment are functioning as expected routine quality control tests for full field digital mammography systems provided by Public Health England (2013) has outlined in detail the various quality control test and processes to be carried out within the screening programme. These tests include monitor checks, and various daily, weekly and monthly checks on mammography unit. It is important these checks are carried out so any abnormality in equipment function is picked up.

The various equipment and tools used for both phases of this research went through quality control checks to ensure they are in good working order and fit for purpose.

3.4.1 Xsensor Pressure Mapping System

This Xsensor pressure mapping system is routinely calibrated every five years by the manufacturer. It was last calibrated successfully in March 2020. Before being used for data collection for the phantom study, the system was visually inspected for any defect. The power leads, monitor, mat and charging system were all tested before being used for the experiment to ensure they were in good working order. The test carried out on the system involved switching on the system, applying pressure on the mat to visually check the resultant pressure measurements on the monitor to ensure all the sensors are functioning.

3.4.2 GE Senographe Essential Mammography Unit

The GE Senographe Essential (GE Medical Ltd, Little Chalfont, UK) mammography machine undergoes six monthly quality assurance testing by a medical physics service. The equipment is serviced bi-annually by the manufacturer incorporating consistency checked for compression force. In-house quality control tests are regularly undertaken to ensure the unit meets the standards NHSBSP (Public Health England, 2021b) These quality control test include:

a) Perspex block system check (Daily)
b) Contrast to noise ratio, CNR (Weekly)
c) Artefact and uniformity check (Weekly)
d) Image quality test (Weekly)
e) Detector flat-field calibration (Weekly)
f) Automatic exposure control thickness check (Monthly)
g) Mechanical safety and function tests (Monthly) (Public Health England, 2013).

It is essential that all these routine tests are undertaken to ensure the equipment is performing as expected. The mammographic unit had the required quality control tests (Public Health England, 2013) completed prior to data collection and was working within tolerance levels required. For this experiment, the daily Perspex block system check is particularly important as it is designed to

detect any changes in the performance of the unit. This test was undertaken each day data collection was undertaken.

3.5 Evaluation of a Digital Inclinometer

The specific focus of this validation work is to compare the accuracy of the Powcan digital inclinometer to the IR angulation readings of GE Senograph mammography unit. This is to ensure the angle readings of both equipment are comparable and similar.

Various inclinometers have been evaluated in the past (Cawood et al., 2017; Charlton et al., 2015; Kolber & Hanney, 2012; Kolber et al., 2011) to access their accuracy. A similar inclinometer was validated by Cawood et al. (2017). Cawood et al. (2017) used manual and digital compass-clinometer data to compare outcrops generated using terrestrial Light Detection and Ranging (LiDAR), and Structure from Motion (SfM) (both terrestrial Structure from Motion (TSfM) and aerial Structure from Motion (ASfM)) at a fold structure. A compass-clinometer works the same as an inclinometer but with an added function of a compass. The aim was to compare the accuracy of digital outcrop analysis with traditional field data using and compass-clinometer. The results indicate that both compass-clinometers provided similar accuracies. The results from this research work have confirmed compass-inclinometer does give accurate and reliable incline reading therefore the decision was taken to use an inclinometer to read the incline of the IR.

3.5.1 Method of Validating Inclinometer

Prior to the use of the inclinometer, it was physically assessed to ensure it was in a good and usable condition. All functions on the instrument were assessed to make certain it was in good working order e.g., power button, the unit of measure and battery status. For the evaluation of the inclinometer, the IR of the mammography unit was positioned from 0^0 to 70^0 in 5^0 increments and the inclinometer placed at the edge of the IR as demonstrated in F**igure 3.10** to read and record the tilt angle.

For the purpose of repeated measures, the process was carried out 5 times on different days to ensure readings were consistent, reliable and reproducible. To maintain consistency in the readings, the inclinometer was placed at the exact spot on the IR on all occasions. Spots were marked on the IR with permanent ink where the inclinometer was first placed. This served as a guide so the inclinometer was placed in the same location on each occasion.

The readings were acquired 5 seconds after positioning and angle adjustment to ensure the inclinometer reading had stabilised and reached its final calculation, as recommended in the manufacturer's manual.

The inclinometer was used to take readings using the following steps:

1. The IR of the mammography unit was positioned to the desired angle (0^0 to 70^0 in 5^0 increment)
2. Inclinometer placed at the front and edge of the IR (**Figure 3.5**). This position allowed the inclinometer to cover more than half the length of the IR.
3. Readings were recorded 5 seconds after placing the inclinometer on the IR to allow numerals on the display to stabilise before the final angle reading was recorded.
4. Fifteen inclinometer readings were taken from IR at horizontal (0^0) to 70^0 in 5^0 increments.
5. For repeated measure, the above steps were repeated 5 times to generate 75 data points for analysis. Repeated measurements were undertaken to establish the consistency, accuracy and reproducibility of the instrument.

It is important to note that inclinometer readings were recorded to one decimal place while the mammography unit displays IR angle in integer numbers. The reading on the inclinometer was therefore rounded to the nearest integer number to correlate with the mammography machine reading.

The GE Senographe essential allows the IR to be positioned from angle 0^0 to 90^0 in integers. The inclinometer was placed on the IR to read the record the

angulation of the IR (**Figure 3.6**) at various IR angles measurements were recorded from both the inclinometer and the mammography machine.

Figure 3.3 Digital inclinometer displaying tilt angle of IR

The angle reading on the inclinometer was recorded together with the IR angle displayed on the screen at the foot of the unit, these two angles' readings were then compared.

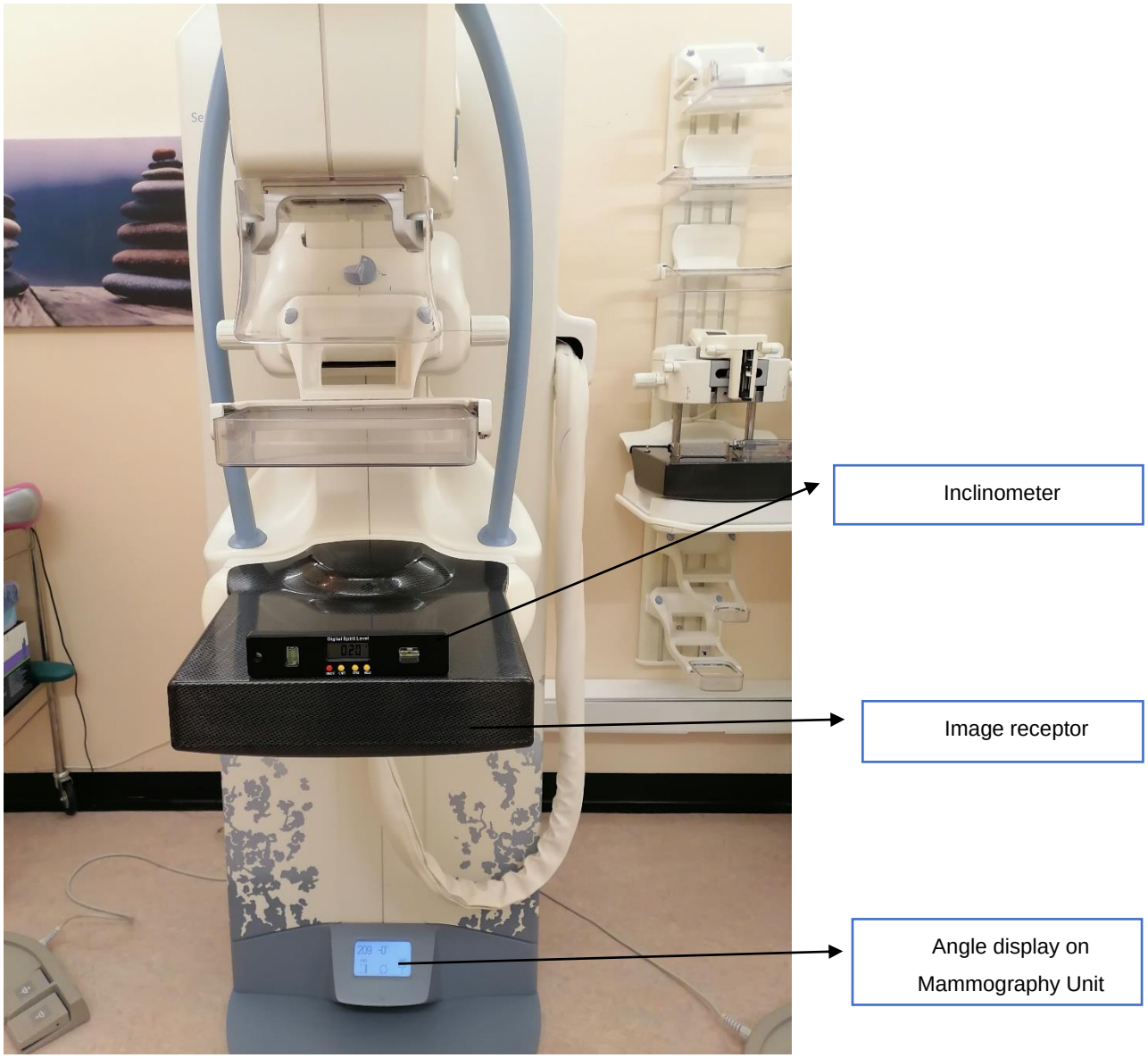

Figure 3.4 Inclinometer displaying tilt angle of IR at horizontal (0^0)

3.5.2 Results

The results of the 75 angle measurements recorded by the inclinometer are shown in **Table 3.1.** The inclinometer readings were all found to be within 0.3^0 of the IR angles.

Table 3.1 Inclinometer reading with of IR angulation.

	Inclinometer reading/^{0}				
IR angle/^{0}	**1st**	**2nd**	**3rd**	**4th**	**5th**
0	0	0.2	0	0	0.1
5	5.1	4.9	5.0	5.0	5.0
10	9.8	10.0	10.0	10.2	10.0
15	15.0	15.3	15.0	15.1	15.1
20	19.8	19.9	20.1	20.0	20.0
25	25.0	25.0	25.1	25.2	25.0
30	30.0	29.8	30.1	30.0	30.1
35	35.2	35.3	35.0	35.1	35.0
40	39.8	40.1	40.0	40.1	40.0
45	45.0	45.0	45.2	45.1	45.0
50	50.0	50.1	50.0	50.2	50.0
55	55.0	55.0	55.1	55.1	50.0
60	60.2	60.1	60.0	60.0	60.1
65	64.8	65.0	65.1	65.0	65.0
70	70.0	70.0	70.1	70.0	70.2

The standard error was calculated using the following equation:

$$Standard\ Error = \frac{SD}{\sqrt{N}}$$

Where:

- SD = standard deviation of protractor angle measurements
- N = number of measurements

Table 3.2 Analysis of inclinometer reading.

	Inclinometer angle/^{0}														
Repeated Measurement	**0**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**50**	**55**	**60**	**65**	**70**
1	0	5.1	9.8	15	19.8	25	30	35.2	39.8	45	50	55	60.2	64.8	70
2	0.2	4.9	10	15.3	20	25	29.8	35.3	40.1	45	50.1	55	60.1	65	70
3	0	5	10	15	20.1	25.1	30.1	35	40	45.2	50	55.1	60	65.1	70.1
4	0	5	10.2	15.1	20	25.2	30	35.1	40.1	45.1	50.2	55.1	60	65	70
5	0.1	5	10	15.1	20	25	30.1	35	40	45	50	55	60.1	65	70.2
Min	0	4.9	9.8	15	19.8	25	29.8	35	39.8	45	50	55	60	64.8	70
Max	0.2	5.1	10.2	15.3	20.1	25.2	30.1	35.3	40.1	45.2	50.2	55.1	60.2	65.1	70.2
Mean	0.06	5	10	15.1	19.98	25.06	30	35.12	40	45.06	50.06	55.04	60.08	64.98	70.06
SD	0.08	0.07	0.14	0.12	0.10	0.08	0.12	0.13	0.12	0.08	0.08	0.05	0.08	0.10	0.08
Standard error	0.04	0.03	0.06	0.05	0.04	0.04	0.05	0.05	0.05	0.04	0.04	0.02	0.03	0.04	0.04

Table 3.3 Difference between the IR angle and the inclinometer angle.

Inclinometer angle/^{0}															
Repeated measurement	**0**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**50**	**55**	**60**	**65**	**70**
1	0	0.1	0.2	0	0.2	0	0	0.2	0.2	0	0	0	0.2	0.2	0
2	0.2	0.1	0	0.3	0	0	0.2	0.3	0.1	0	0.1	0	0.1	0	0
3	0	0	0	0	0.1	0.1	0.1	0	0	0.2	0	0.1	0	0.1	0.1
4	0	0	0.2	0.1	0	0.2	0	0.1	0.1	0.1	0.2	0.1	0	0	0
5	0.1	0	0	0.1	0	0	0.1	0	0	0	0	0	0.1	0	0.2
Average	0.06	0.04	0.08	0.1	0.06	0.06	0.08	0.12	0.08	0.06	0.06	0.04	0.08	0.06	0.06

The maximum standard error was found to be $\pm 0.06^0$ (**Table 3.2**), therefore all angles measure can be assumed to be accurate within this tolerance. The maximum average absolute difference was 0.12^0 and the minimum average absolute difference was 0.04^0 (**Table 3.3**).

The results of the test conducted on the inclinometer suggests the readings to be accurate, reliable, and consistent. The readings are similar to the angle reading of the IR of the mammography unit. The reproducibility of reading as well makes the inclinometer a suitable instrument for the measuring the angle of the sternum. The limitation of this method is that, because the mammography unit displays angle reading in integers, the inclinometer readings had to recorded to the nearest integer.

3.6 Compression of Silicone Breast Prosthesis

A phantom study was conducted as a pilot study to test the reliability, consistency and the reproductivity of the research method, and to ensure optimisation of the human study.

Silicone gel breast implants were used as breast tissue equivalent for this experiment. Silicone gel implants are generally used for reconstructing breasts after mastectomy, correcting congenital or traumatic deformities and remodelling breast shape for cosmetic reasons (Sá Dos Reis et al., 2020; Scaranelo et al., 2004). They are filled with viscous silicone gel and covered with silicone polymer. Silicone gel is a synthetic material inert containing 38% silicon usually in the form of a silicone tetramer.

Silicone has been found to have the same compression characteristics as breast tissue, Hauge et al. (2012) conducted an experiment to demonstrate the compression characteristics of silicone breast prostheses in three sizes, small (220 cm^3), medium (360 cm^3) and large (700 cm^3). They generated compression (N)/thickness (mm) graphs from 40 to 100 N stepping through 10 N. Compressed

thickness data for each prosthesis was averaged and normalized (the data was normalized to 1 for 40 N compression force). These were then compared with normalised average of 29 female human dataset. The normalised compression curve of the large prosthesis was compared with the normalized compression curve of the real breast. The results showed that the compression characteristics between the large prosthesis and real breast tissue had a correlation coefficient of 0.95.

However, using silicone implants does have limitations as it could rupture under compression. Miyake and Ikeda (2017) explained that these silicone implants are not as compressible as breast tissue and can be ruptured if compressed too hard during mammography. Based on this previous work, silicone gel breast implants were deemed appropriate for the phantom study, and a limit of 10 daN was applied during the experiment to limit the risk of rupture.

A selection of silicone gel in different sizes were sourced from Allergan, a breast implants manufacturer (N-TRM685 size 685g, N-TR290 size 290g and N-TRM195 size 195g) (**Figure 3.7**). The three sizes of silicone implants were referred to as large (685g), medium (290g) and small (195g) implants.

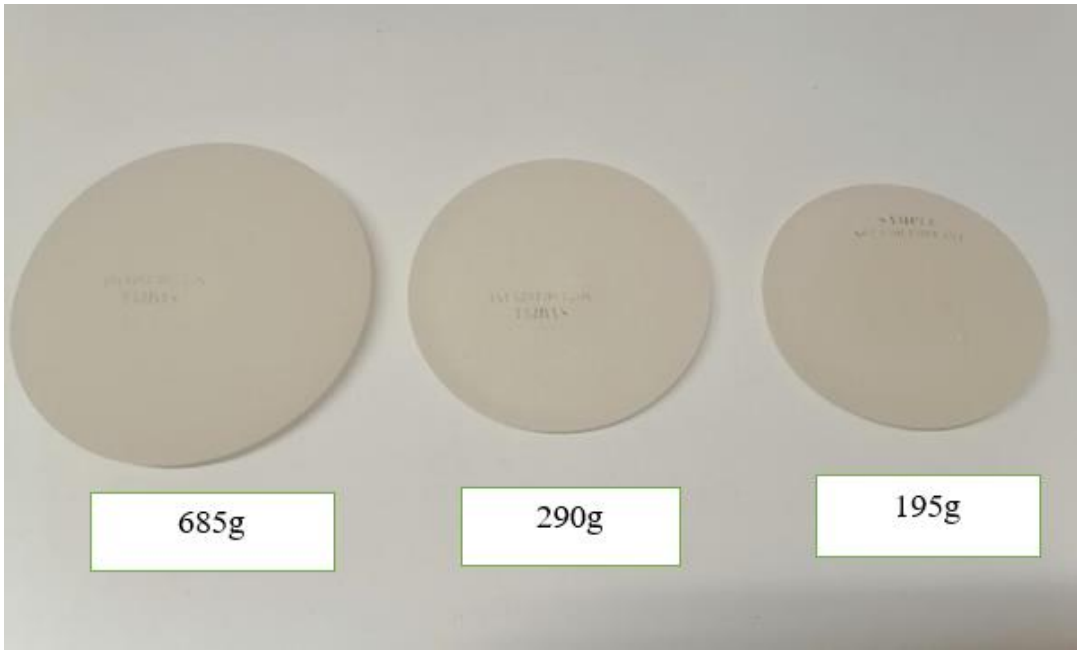

Figure 3.5 Three different sizes of Silicone breast implants used for phantom study.

The X-sensor pressure mat was wrapped around the IR and compression paddle of a GE Senographe essential mammography equipment (**Figure 3.8**). Compression forces of 5 daN to 10 daN at 50degree increment was applied to each implant for 10 seconds. The thickness displayed on the mammography unit and the compression was recorded at each applied compression force. Five repeats were undertaken to ensure reproducibility of the method

To maintain consistency and reproducibility of the process, the following steps were taken for the compression of silicone breast implants:

1. The pressure mat was marked so the mat and the IR /compression paddle aligned in the same way for each series of compressions. This improves consistency and reproducibility of pressure measurements and the same active cells of the mat would be used each time.
2. Each silicone was placed on a marked sport on the pressure mat covering the IR for each of the 5 series. This was done to improve consistency and reproducibility of the method. Compression force was applied for 15 seconds, however only the last 10 seconds of pressure measurements.
3. were recorded for analysis. The reason for this was to allow the compression reading on the mammography unit to stabilise (This phenomenon has been explained in an earlier chapter). The implant thickness was also recorded during the last 10 seconds.
4. Pressure maps, machine measured thickness and the compression force was recorded.
5. Compression was released from the implants after taking pressure reading. A 10 seconds interval was implemented before the next compression force was applied This was to allow the implant to recover to its original composition. For instance, compression force of 5 daN was applied for 15 seconds. However, pressure measurements and implants thickness were only recorded for the last 10 seconds of compression. The plate is then

released for 10 seconds before the next compression force of 10 daN is applied for another 15 seconds.

Figure 3.6 Breast implants positioned on IR for compression

3.6.1 Analysis of Contact Pressure and Contact Area for Breast Implants

Calculation for balance of contact pressure was derived from the work of Hogg, Taylor, et al. (2013); Smith (2013); Smith, Szczepura, et al. (2015).

In this work they developed Uniformity Index (UI), the distribution of average pressure per unit area applied by the IR and by the paddle by using Xsensor pressure mat. IU was calculated as following equation:

Equation 1. Uniformity Index = (A-B)/ (A+B)

Where:

- A = average pressure per unit area applied by the paddle (mmHg/cm^2)
- B = average pressure per unit area applied by the IR (mmHg/cm^2)
- The UI value has the following implications. If UI = 0, there is equal pressure per unit area from the IR and the paddle (equal distribution),
- If 0<UI>1, there is greater pressure per unit area from the paddle on the top of the implant, with 1= all pressure per unit area is applied by the paddle.
- If -1<UI>0, there is greater pressure per unit area from the IR on the underside of the implant, with -1= all pressure per unit area is applied by the IR.

For each compression, thickness displayed on the mammography unit was recorded for each compression force applied. For the 685g breast implants which is the largest prosthesis used, the thickness at 5 daN was 36mm for all 5 series (**Table 3.4**). The thickness reduced to 35mm when compression force was increased to 6 daN for 3 of the series. There was no further change in implants thickness from 7 daN. There was no change in implants thickness on both 290g and 195g grams (**Table 3.5 and 3.6**) with increase in compression force. This could be due to the fact that they were small and thus presented a lot of resistance during compression.

Table 3.4 Large breast implant (N-TRM685 size 685g) thickness with change in compression force.

	Implant thickness/mm				
Compression force/daN	**1**	**2**	**3**	**4**	**5**
5	36	36	36	36	36
6	35	35	36	36	35
7	35	35	35	35	35
8	35	35	35	35	35
9	35	35	35	35	35
10	35	35	35	35	35

Table 3.5 Medium breast implant (N-TR290 size 290g) thickness with change in compression force

	Implant thickness/mm				
Compression force/daN	**1**	**2**	**3**	**4**	**5**
5	20	20	20	20	20
6	20	20	20	20	20
7	20	20	20	20	20
8	20	20	20	20	20
9	20	20	20	20	20
10	20	20	20	20	20

Table 3.6 Small breast implant (N-TRM195 size 195g) thickness with change in compression force.

	Implant thickness/mm				
Compression force/daN	**1**	**2**	**3**	**4**	**5**
5	20	20	20	20	20
6	20	20	20	20	20
7	20	20	20	20	20
8	20	20	20	20	20
9	20	20	20	20	20
10	20	20	20	20	20

The contact pressure and area data in numeric format were recorded on Xsensor pressure mat and exported to a spread sheet. This provided the basis for mathematical analysis. This involved calculating the averages of frames recorded on contact pressure and contact surface area. For each compression, paddle and IR contact area footprints and contact pressure were recorded. The average pressure for recorded on large implant for all series were similar and ranged from 1.66mm/Hg to 2.04mm/Hg (**Table 3.7**). The difference between the average pressure of implant/paddle is 0.39 mmHg while that of implant/IR is 0.46 mmHg.

Table 3.7 Pressure reading from all 5 series of compressions for large implant

Repeated measure	**1**	**2**	**3**	**4**	**5**
Average Pressure implant/mmHg	1.92	1.89	1.75	1.66	2.04
Maximum Pressure	21.12	22.32	20.54	18.24	22.28
Minimum Pressure	1.10	0.50	2.44	1.10	1.04
Average Pressure implant/paddle mmHg	2.13	2.04	1.91	1.81	2.20
Maximum Pressure implant/paddle mmHg	21.12	22.32	20.54	18.24	22.28
Minimum Pressure implant/paddle mmHg	1.10	0.50	2.80	1.10	2.50

Average Pressure implant/IR mmHg	2.05	2.07	1.90	1.80	2.26
Maximum Pressure implant/IR mmHg	18.68	19.84	17.98	16.70	18.94
Minimum Pressure implant/IR mmHg	1.66	1.13	2.44	5.02	1.04
Uniformity Index	-0.007	-0.001	0.0081	0.004	-0.007

Table 3.8 Uniformity Index for all compression for large implants on 5 individual series

Repeated measure	**Uniformity index for large implant at different compression force**					
Series	**5 daN**	**6 daN**	**7 daN**	**8 daN**	**#9 daN**	**10 daN**
1	-0.007	0.020	-0.037	-0.031	-0.030	-0.09
2	-0.001	-0.021	-0.024	-0.002	-0.013	0.012
3	0.008	-0.005	-0.003	0.014	0.090	-0.021
4	0.004	0.037	-0.04	-0.013	0.019	0.004
5	-0.007	-0.016	0.006	0.000	0.025	0.018
Average	-0.001	0.003	-0.019	-0.006	-0.018	-0.015

The average UI for individual compression force were similar for all series from -0.001 to 0.003. The UI of for all 5 compressions were closer to zero indicating there was similar amount of pressure distribution between the paddle and the IR. Two of the five series had UI in the negative, 0.0073 and 0.0077 (**Table 3.8**). This implies that, there was more pressure applied to the phantom from the IR than the compression paddle. At compression force 8 daN on series 5 there was perfect balance of pressure between the IR and compression plate with UI of Zero (**Figure 3.9**).

The average area reading recorded on compression of the large implant is illustrated in **Table 3.9**. The average total area recorded on all 5 compressions were similar with the minimum and maximum area of 49.03 cm^2 and 57.74 cm^2 respectively. The UI for area on compressions 1, 2 and 5 were -.0.007, -0.001 and -0.007 respectively indicating there was more area recorded on the IR to that of the paddle. On compressions 3 and 4, there was more area recorded on paddle than that of the IR hence the UI of 0.008 and 0.004.

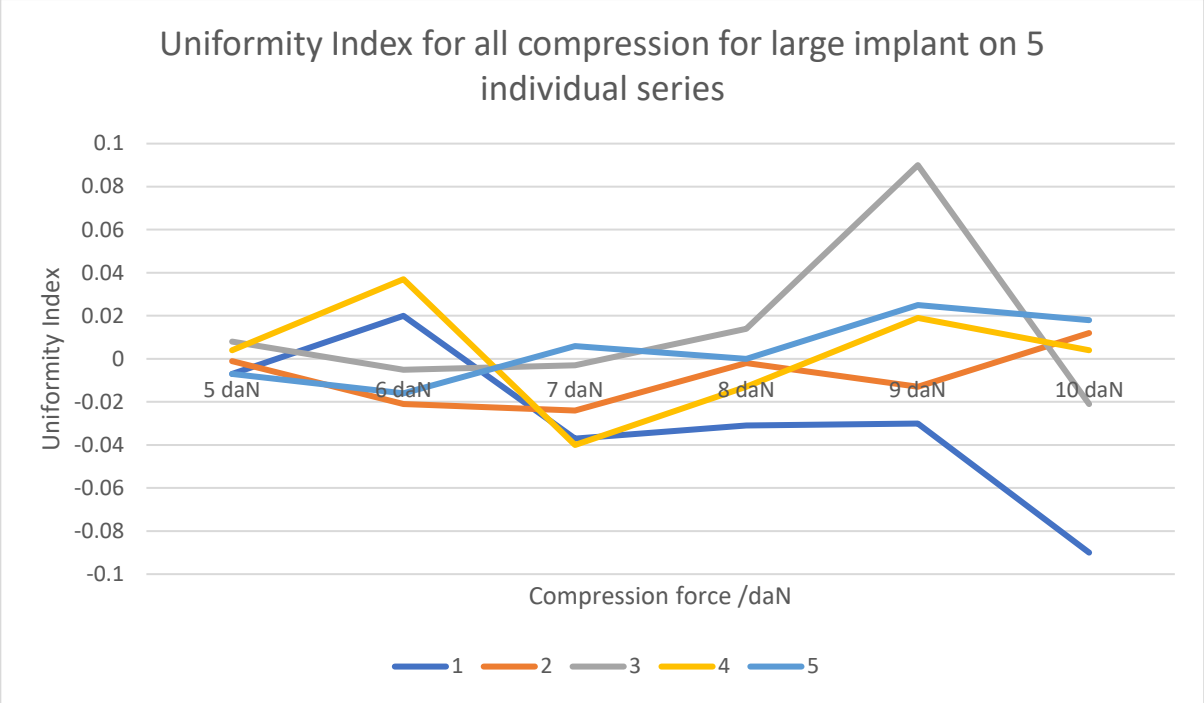

Figure 3.7 Uniformity index for large implant on varying compression force

Table 3.9 The average of all contact area from all 5 series of compressions for large implant

Repeated measure/compression	1	2	3	4	5
Total Area/cm²	57.74	52.58	50.65	49.03	50.65
Area implant/paddle mmHg	29.68	26.13	25.16	24.52	25.16
Area implant/IR cm²	28.06	26.45	25.48	24.52	25.48
Uniformity Index	-0.007	-0.001	0.008	0.004	-0.007

The UI recorded for all compressions on the medium implant were closer to Zero with the highest 0.008 and lowest of -0.001 therefore there is a good balance of area distribution between the paddle and IR.

The medium implant had recorded UI of below zero for all compression series (**Table 3.10**). This implies that there was more contact from the IR compared to the compression paddle. All UI were close to zero indicating a good balance of pressure between the IR and the paddle. On all 5 series the UI readding were similar varying from -0.058 to -0.096 with the difference between these 2 reading being -0.038. The most balanced distribution of pressure on the 5 series was achieved at compression

force 5 daN with the difference in UI between the minimum and maximum value being -0.013.

Table 3. 10 The average uniformity index for all compression on medium implants on 5 individual series.

Repeated measure	Uniformity index at various compression force					
Series	**5 daN**	**6 daN**	**7 daN**	**8 daN**	**9 daN**	**10 daN**
1	-0.081	-0.064	-0.063	-0.063	-0.064	-0.068
2	-0.084	-0.089	-0.051	-0.058	-0.049	-0.058
3	-0.087	-0.091	-0.087	-0.096	-0.080	-0.075
4	-0.089	-0.095	-0.094	-0.094	-0.066	-0.068
5	-0.0763	-0.083	-0.062	-0.052	-0.052	-0.058
Average	-0.083	-0.084	-0.071	-0.073	-0.062	-0.065

Figure 3.10 graphically demonstrates the relation of UI for all series of compressions on the medium implant with varying compression force. The highest UI was recorded on 8 daN for series 3. The most even distribution of pressure between the IR and the paddle with the lowest UI of -0.049 was on 9 daN for series 2.

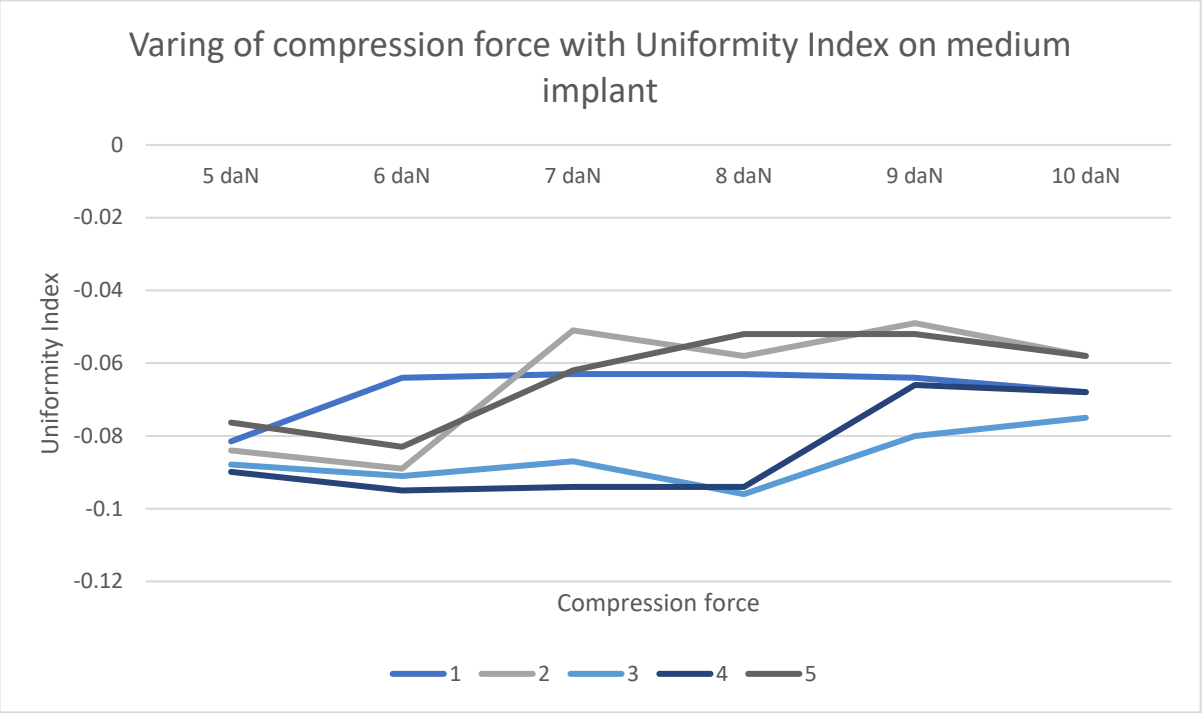

Figure 3.8 Uniformity index with varying compression force for medium implants

Table 3. 11 The average uniformity index for all compression for small implants on 5 individual series.

Repeated measure	Uniformity index at various compression force					
Series	**5 daN**	**6 daN**	**7 daN**	**8 daN**	**9 daN**	**10 daN**
1	-0.080	-0.069	-0.072	-0.070	-0.062	-0.059
2	-0.061	-0.088	-0.075	-0.084	-0.060	-0.054
3	-0.064	-0.056	-0.072	-0.054	-0.061	-0.063
4	-0.048	-0.055	-0.069	-0.061	-0.060	-0.064
5	-0.072	-0.071	-0.076	-0.083	-0.056	-0.051
Average	-0.065	-0.068	-0.072	-0.070	-0.060	-0.058

The small silicone implant (implant size 195g) recorded a good balance of pressure between the IR and the compression paddle. Meanwhile all UI values indicate there was more pressure per unit area on implant/IR interface to that of implant/paddle interface on all compressions (**Table 3.11**). The minimum and maximum average UI for all series was -0.058 and -0.072 10 daN and 7 daN respectively. For the 5 series of compressions on varying compression forces, the difference between the

minimum and minimum UI was -0.038 (**Figure 3.11**). Reading on various compression forces were consistent for all the series.

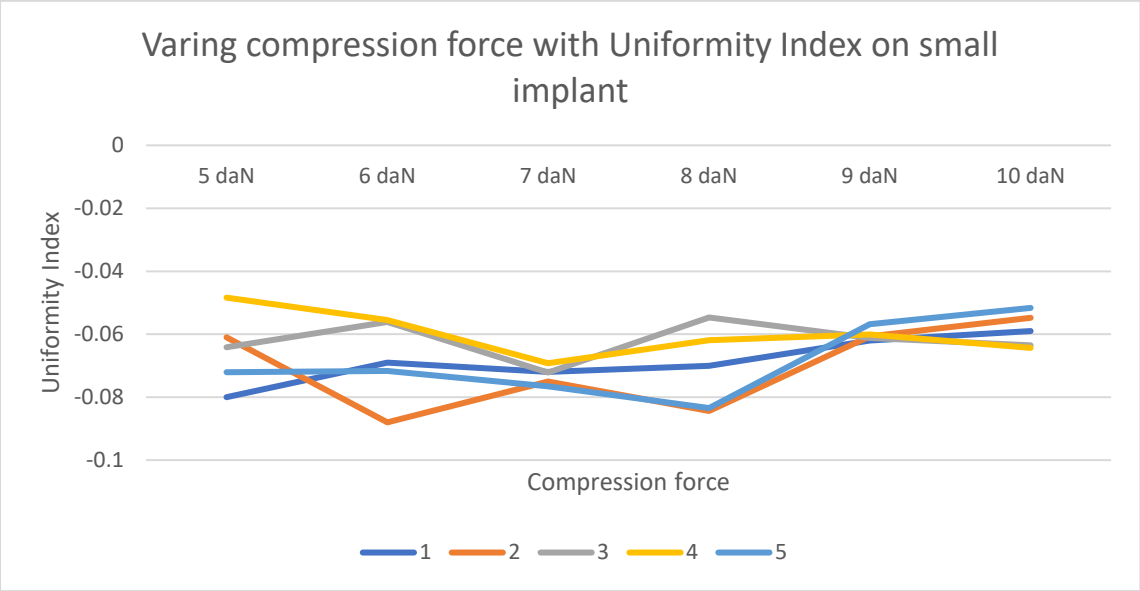

Figure 3.9 Uniformity index with varying compression force for small implants

3.6.2 Conclusion

For the three breast implants, there was minimum difference in implant thickness on compression with increasing compression force. For the large implant there the difference in thickness from the minimum compression force of 5 daN to the maximum of 10 daN was 10mm. The thickness reduced from 36mm to 35mm which is not a large deference compared to the difference in force applied. There was no change in implant thickness when both the medium and small implants were compressed. For both of them, implants thickness remained at 20mm on the minimum and maximum compression forces. These results suggest that breast implants are not as compressible like the breast suggested by Miyake and Ikeda (2017). Meanwhile the experiment has shown thickness readings from the mammography unit are consistent.

The UI calculated on compression of the 3 implants on varying compression force were consistent on all 5 series. For the large silicone implant, the average UI on all compression varied from -0.001 to 0.003 while that of medium implant varied

from -0.083 to -0.062. The minimum and maximum average UI for all series was -0.058 and -0.072 10 daN and 7 daN respectively

The pressure mat produced consistent pressure readings throughout the series of compressions and the method used is reliable and reproducible.

3.7 Ethical Consideration

This experiment was undertaken at the Breast Imaging Unit of Tameside and Glossop NHS Foundation Trust, Manchester. The hospital management has granted the researcher access to the use of their mammography unit for the study.

Ethical application for the research was submitted (**Appendix II**) to the University of Salford ethics board and approval was granted HSR1920-038 (**Appendix III**) for data collection to commence. The management of Tameside and Glossop Integrated Care NHS Foundation Trust gave the permission for the research work to be carried out at the breast unit of the radiology department (**Appendix IV**). The research and development department of the hospital provided confirmation of capacity and capability for the research work (**Appendix V**). The Health Research Authority (HRA) granted approval (**Appendix VI**) before the start of data collection.

3.8 Chapter Summary

In this chapter the various tools and equipment used for the study were discussed in order to understand how they work and why they were chosen. Acquiring the right tool to measure sternal angle was vital as it forms the base of the research. In **section 3.4** quality assurance/control measure were undertaken to ensure standard operating procedures are followed and to make sure ensure the equipment and tools are in good working order. Validating of inclinometer, the tool for measuring sternal angle proved the readings were accurate and consistent.

Study site and ethical consideration was discussed in the final section (**section 3.7**). Ethics approval was granted from the relevant organisations before data collection began.

Chapter Four - Anthropomorphic Phantom Study (Phase one)

4.1 Chapter Overview

This chapter will discuss the methodology for the phantom study. Compression was applied to a phantom breast with the IR at the acquired experimental angle and at set angles. Pressure readings were subsequently read and recorded on Xsensor pressure mapping system. Contact pressure and contact area data from paddle/phantom interface and IR/phantom interface were analysed and comparisons made.

It is to note that standardisation for the height of the IR with regards to the IMF for CC projection has already been developed through the work of Hogg, Szczepura, et al. (2013); Smith, Szczepura, et al. (2015) and Smith (2013) investigated the angle of IR on the MLO projection. This research will build on that methodology and techniques applied to develop skills and knowledge from these previous works.

4.2 Validation of Method for Anthropomorphic Phantom Study

Anthropomorphic phantoms are used to simulate a medical procedure and are built from tissue-equivalent materials to provide a physical representation of the anatomy of the human body (Ramos et al., 2017). Anthropomorphic physical phantoms are the ones in the shape of a human body or part of it, manufactured with materials that are equivalent to human tissues when it comes to size, shape, positioning, density (Staton et al., 2006).

The use of a phantom in a study is essential to ensure that the tools and equipment used together with the study design are robust and to ensure reproducibility within a process. It also ensures that any adjustments in method design are made prior to a human study. Phantoms have been used extensively in the validation of medical imaging techniques (Hubbard et al., 2015; Maksuti et al., 2016; Qin et al., 2013; Ramos et al., 2017).

The aim of conducting this phantom study is to develop a method, using the sternal angle, to allow selection of an appropriate IR angle for MLO projection to optimise pressure and area balance. It was also to understand if and how surface pressure and area distribution altered at a range of IR angles prior to its application on human participants.

Conducting a phantom study allows for greater level of internal validity and control on the study, i.e., the experiment could be repeated as many times as possible, and changes are easier to implement along the way. Phantom studies are also conducted to predict what might happen in human studies. Findings from the phantom study might provide an insight into what could be expected in human study moving forward. The next section (**section 4.3**) will expand on the methods used for collecting and analysing data. The results of the phantom study will inform the development of standardised protocols on positioning and compression for use in phase two (human study) of this thesis.

4.3 Phantom Model Torso

A model torso with breast phantom attachment **Figure 4.1** was designed in conjunction with Leeds Test Objects, a medical imaging phantom specialist. Leeds Test Objects are the manufacturers of high-quality medical imaging phantoms which are used worldwide to ensure the safe use of imaging systems (Leeds Test Objects, 2019). The phantom model was purposely designed for a mammography study with some movement in the upper limb and the neck. The torso served as a support for the attachment of phantom breast and mounted on a detachable and adjustable stand.

Rigid torsos have been used for phantom breast support in research work by Hauge et al. (2012) and Hogg, Szczepura, et al. (2013) (**Figure 4.2**). Both studies mounted a semiflexible backing plates onto a rigid torso in order to simulate how a real breast will behave when it is compressed.

The torso was validated by Hauge et al. (2012) in their phantom study to establish a method to determine breast readout accuracy on mammography units.

This torso was ridged in its design and though useful for the CC projection was not suitable for the MLO projection due to its rigidity. The design of the torso specifically was taken into account in the design of the study. As this study is investigating the MLO projection in contrast with Hauge and Hogg's studies that looked at the CC projection, movable upper limbs and axilla are required to simulate the human torso. The torso used in these previous two studies was not used for the current because upper limbs play a crucial role for MLO positioning. During mammographic positioning, the arm is extended over the top of the IR to allow the axilla area of the beast to be imaged.

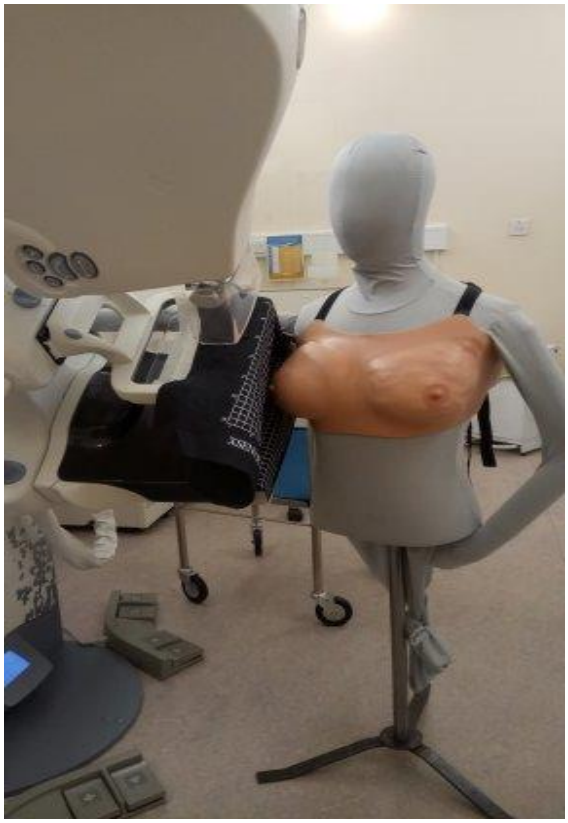

Figure 4.1 The Torso of the model mounted on a stand with breast phantom attachment.

The torso for this work (**Figure 4.1)** was selected because it was specifically manufactured for breast work, has movable arms and readily available. The torso is only a support for holding the breast phantom attachment, therefore there was no requirement to validate it before being used for the experiment. The breast phantom attachment for insertion of breast prosthesis was sourced with the torso from Leeds Test Objects. The attachment is made from rubber and it is designed to simulate the chest wall and pectoral muscle.

The model consists of a detachable breast support that could be filled with breast prothesis of various sizes. The breast prosthetics to be used should ideally be stable, compressible, and moulded into the desired shape of the breast. Silicone breast implants were used for attachment to the breast prothesis used on the model. These implants were chosen because it has similar elasticity and compression characteristics to human breast tissue (Hauge et al., 2012). Visual assessment of the implants was made prior to being used to ensure it was not ruptured or damaged in any way.

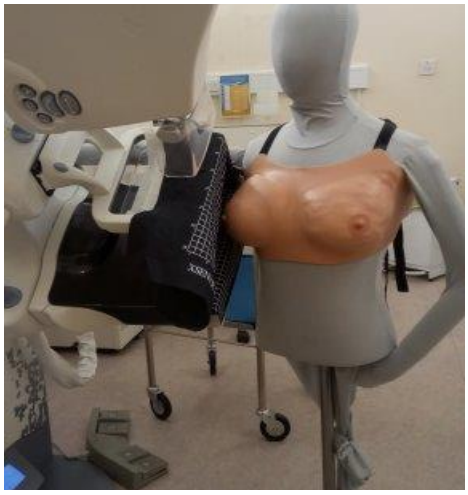

Figure 4.1 The Torso of the model mounted on a stand with breast phantom attachment.

4.4 Study Methodology

The breast department of the Hospital Trust used within this study has a single GE Seno Essential mammography unit which was used for the study. All Covid-19

protocols (**Appendix VII and VII**) were observed before data was collected. The mammographic room, phantom model and all devices used were cleaned down with disinfectant wipes before and after the data collection to help prevent the spread of the virus.

A digital inclinometer was used to take the sternal angle measurement of the phantom model before the model was positioned for compression. The measurement was taken three times and the average and standard deviation of these three was calculated. The sternal angle measurement acquired using the inclinometer was referred to as the experimental angle.

The Xsensor pressure mat was secured to the surfaces of the compression paddle and the IR **(Figure 4.3)** prior to the model being positioned on the unit. A model torso with breast phantom attachment was inserted with large breast implant N-TRM685 size 685g (**Figure 4. 4**) and compressed in the MLO projection.

Several silicone sizes were fitted into the breast support of the model torso in an effort to create a sizable breast phantom to be compressed and silicone breast implant N-TRM685 size 685g was decided on and inserted into the breast support. The above-mentioned size filled in the breast support.

A small flexible paddle (18 x 24) was chosen for the study as the phantom breast will fit this paddle size and it is routinely used at the breast unit.

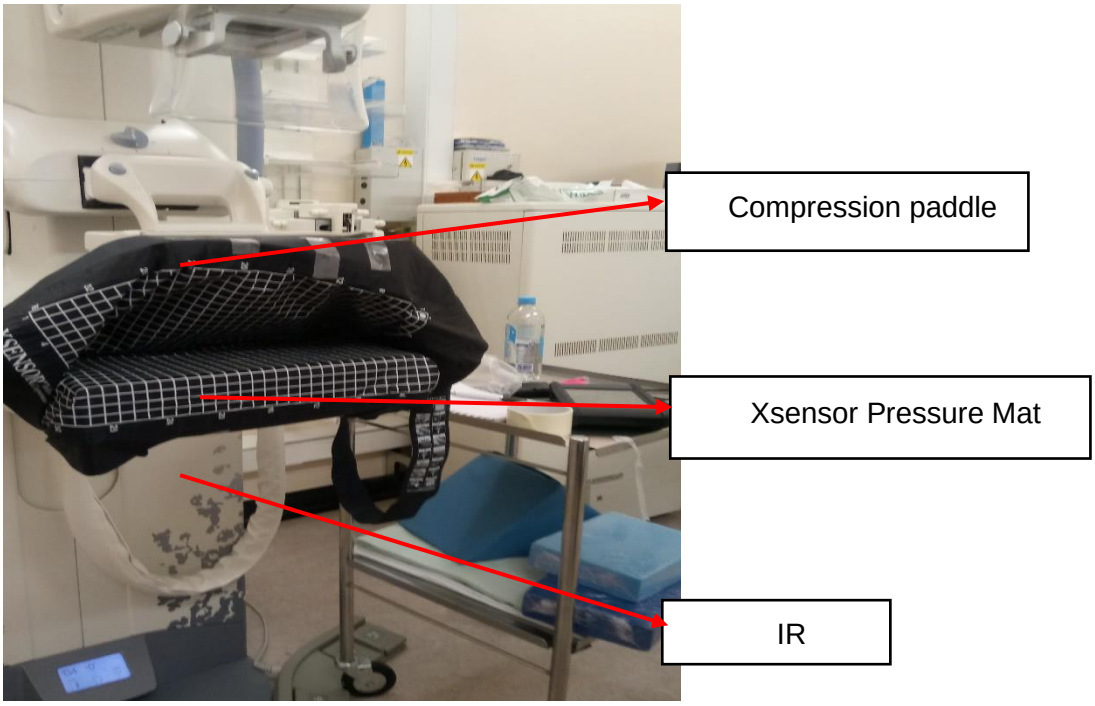

Figure 4.2 Xsensor Pressure Mapping System secured on the GE Senographe Essential mammography unit.

Figure 4.3 Silicone gel breast prosthesis (685g) inserted into breast support of the model.

Positioning of the model with the breast phantom was carried out in six steps:

1. The pressure mat was marked so that when positioning on the IR and the compression paddle, they were positioned accurately and consistently each time for each series of compressions. This was an imperative step and would improve consistency and reproducibility of pressure measurement and the same active cells of the mat would be used each time.
2. Mammography equipment was set to the required IR angle (e.g., 40^0, 45^0, 50^0 etc)
3. IR positioned to an approximate height, at the level of corner of the arm of the phantom, the phantom model was positioned upright, with its upper arm leaning on the lateral margin of the of the IR
4. The breast phantom model was leaned forward towards the mammography unit to replicate the movement with a human participant, the breast phantom was pushed away from the thoracic wall to be positioned on IR
5. The floor was marked so the phantom model was positioned for the MLO projection on the exact spot for each angle to ensure consistency (**Figure 4.5**).
6. Finally, the height of IR was adjusted to the axilla level of the phantom model and compression applied to 10 daN (**Figure 4.6).**

Pressure readings on the pressure mat were recorded with IR angled in multiples of 5^0 from 40^0 to 70^0. Maximum compression force of 10 daN was used for all angles as this was set as the maximum upper limit. Various levels of compression force were tested at the start of the experiment and 10 daN was deemed adequate for the breast phantom This amount of force provided enough compression to allow for surface area of the breast phantom on the pressure mat be comparable to human breast on a normal mammogram. For optimum compression, Hogg, Taylor, et al. (2013) recommend compression force of 9 to13 daN It was aimed to limit compression force within this range and 10 daN provided enough pressure for the phantom.

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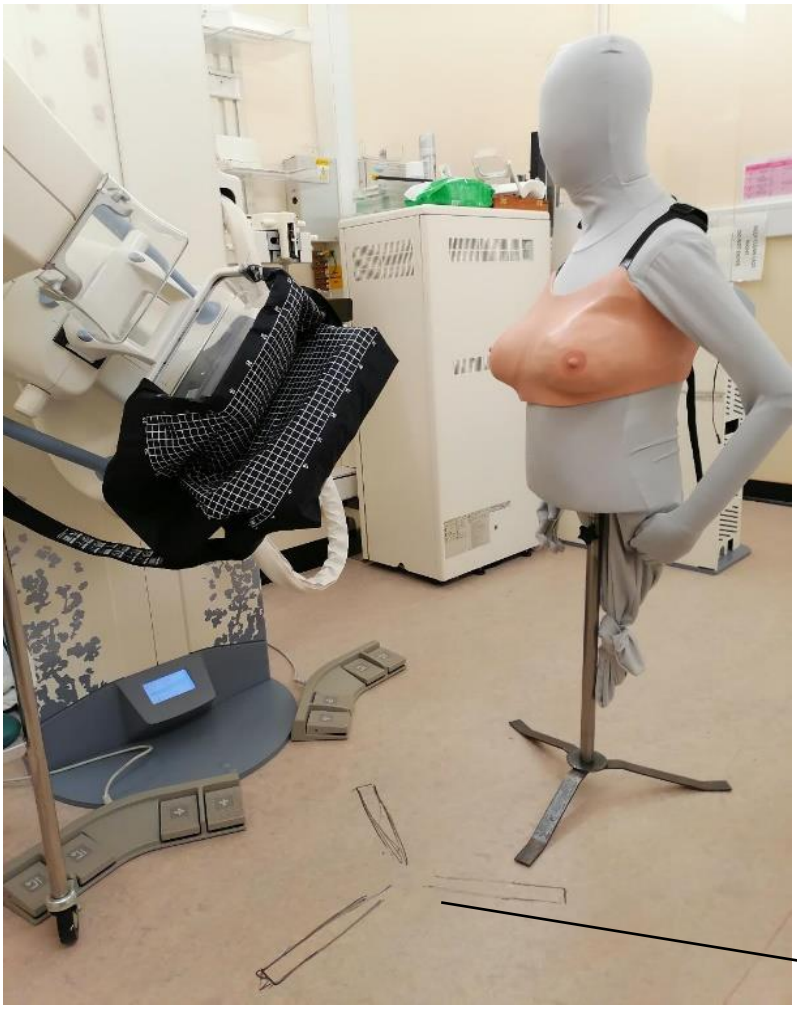

Figure 4.4 Model phantom placed on the exact marked floor for each of compression13

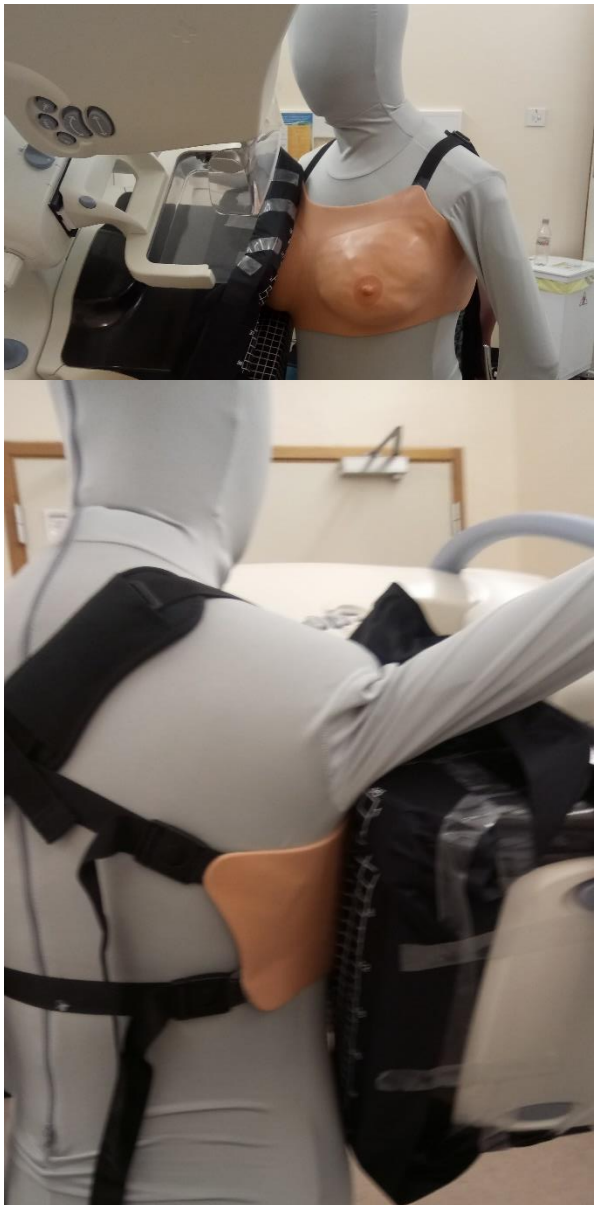

Figure 4.5 Model with breast phantom attachment positioned on the IR for compression.

Figure 4.7 demonstrates pressure mat reading at the same angle (45^0) but on different compression forces. The image on the left was recorded when the breast phantom was compressed at 5 daN. The force of 5 daN was not enough to create an acceptable breast phantom footprint on the mat. This was because there was not enough surface area contact to the paddle on top of the breast phantom and the IR at the bottom. In contrast with the pressure image on the right, compression force of 10 daN was adequate to create pressure footprint similar to mammographic image.

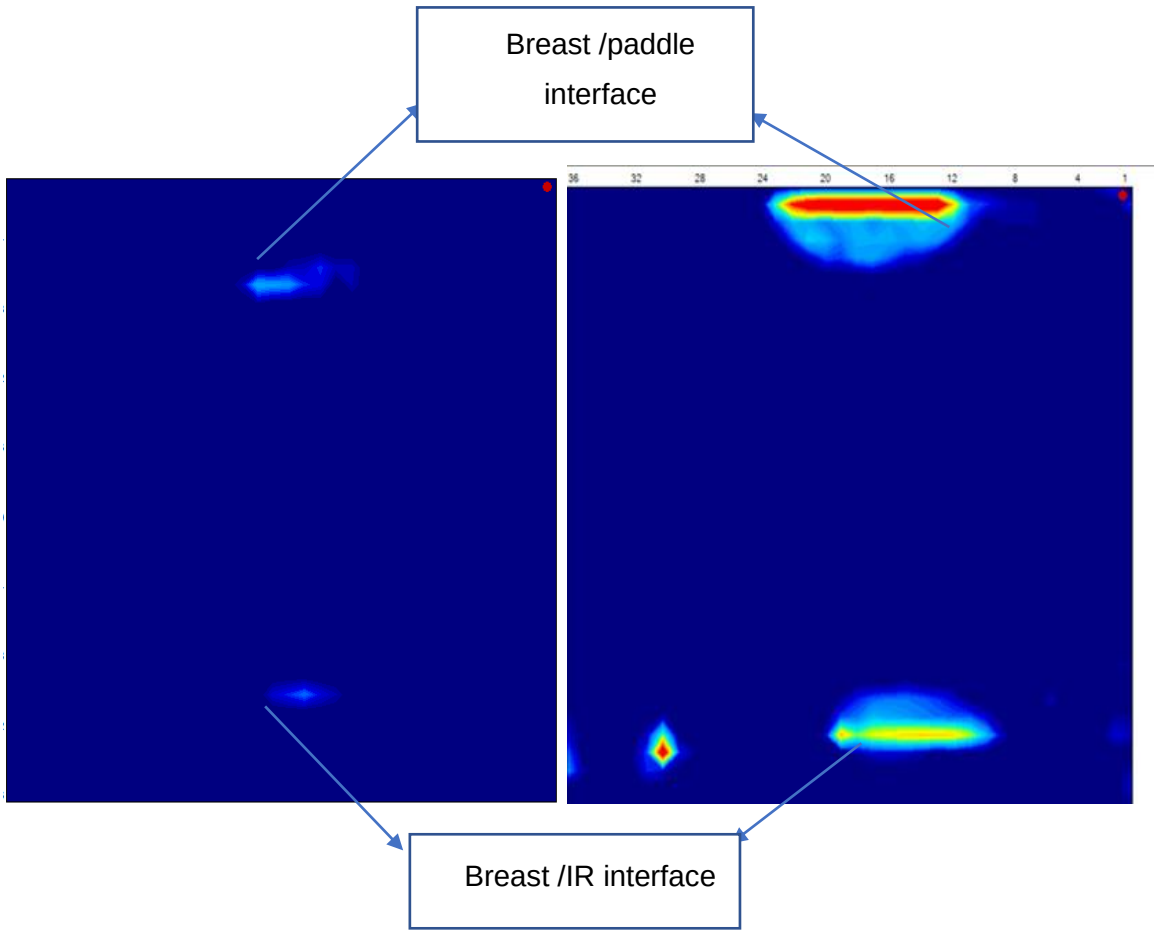

Figure 4.6 Pressure mat readings showing breast phantom pressure footprint at the same IR angle at 5 daN (on the left) and 10 daN (on the right).

Compressions were applied gradually and slowly until the required force of 10 daN was reached. The changes occurring while compression was applied was recorded on the pressure mat and the final 10 frames (readings were acquired at a frame rate 1 per second) with the maximum force 10 daN were used for statistical analysis. For repeated measures, 6 series of compressions (3 on each breast phantom) were made at 7 different IR angles. Six sets of data were generated from these. There usually was a drop in compression values displayed on the mammography unit for several seconds after compression was initially applied therefore, the last 10 frames (last 10 seconds of the acquisition time) were used as pressure was stabilised at the later stages. This phenomenon is confirmed by Hauge et al. (2012); Ma et al. (2015). Hauge et al. (2012) demonstrated drop in compression values which suggests that there could be compression paddle movement. Another study by Ma et al. (2016) measured paddle motion during the

clamping phase of a breast phantom for a range of machine/paddle combinations. They concluded that, all machine/paddle combinations exhibited motion and tilting and highest levels of motion was demonstrated during the first 10 seconds of the clamping phase.

4.5 Chapter Summary

This chapter addressed the validation for the method of the anthropomorphic phantom study. It explained why it was necessary to conduct a phantom study before moving on to human study.

The methodology for the phantom study was explained which involved securing an Xsensor pressure mat to cover the surfaces of the IR and compression plate and taking the sternal angle of the phantom model with a digital inclinometer. The phantom was positioned for MLO position and 6 series of compressions (3 on each breast phantom) were made at 7 different IR angles. The IR angles ranged from 40^0 to 70^0 in 5^0 increments.

The next chapter will discuss the analysis of data from the phantom study as well as presenting the results.

Chapter Five - Results Anthropomorphic Phantom Study

5.1 Data Cleansing

The numerical data was imported into an excel spreadsheet which was cleansed prior to data analysis. This involved deleting data points which were created by contact pressure which was not attributable to the breast phantom (artefacts). Artefacts mostly occurred at the breast phantom/IR interface. Notes made during compression identified the orientation and position of contact pressure measurement. Therefore, any other contact pressure points far and isolated from the main image were considered artefact and were subsequently deleted.

To prevent relevant data points from being deleted, a method was established to help identify artefacts from actual data points. Notes taken at the time of acquisition of contact pressure measurements were compared with data points on Excel worksheet and the following were identified:

1. All data points coverage from paddle/breast phantom interface consists of data within Excel cells K21:K31 and Y21:Y31 (165 Excel cells)
2. All data points coverage from IR/breast phantom interface consists of data within Excel cells K43:K51 and Y43:Y51(135 Excel cells)
3. Any other data point outside these cells were identified as artefacts and were deleted.

Figure 5.1 demonstrates data points from paddle/breast phantom interface, IR/breast phantom interface and other datapoints outside these interfaces identified as artefacts. The artefacts demonstrated are outside the range of data points for contact pressure measurement and were therefore deleted accordingly. The limitation to this data cleansing process is that cells to be included in data analysis is uniquely tailored for this phantom. This implies that, for the human study, as there was difference in the breast sizes and body habitus, the cells for inclusion and exclusion were drawn for each individual.

The pressure mapping system only records contact pressure therefore some parts of the phantom breast i.e., nipple area which was not in contact with the mat

did not record any pressure readings. However, ‘drop off’ data points that were within prescribed coordinates were included in data analysis.

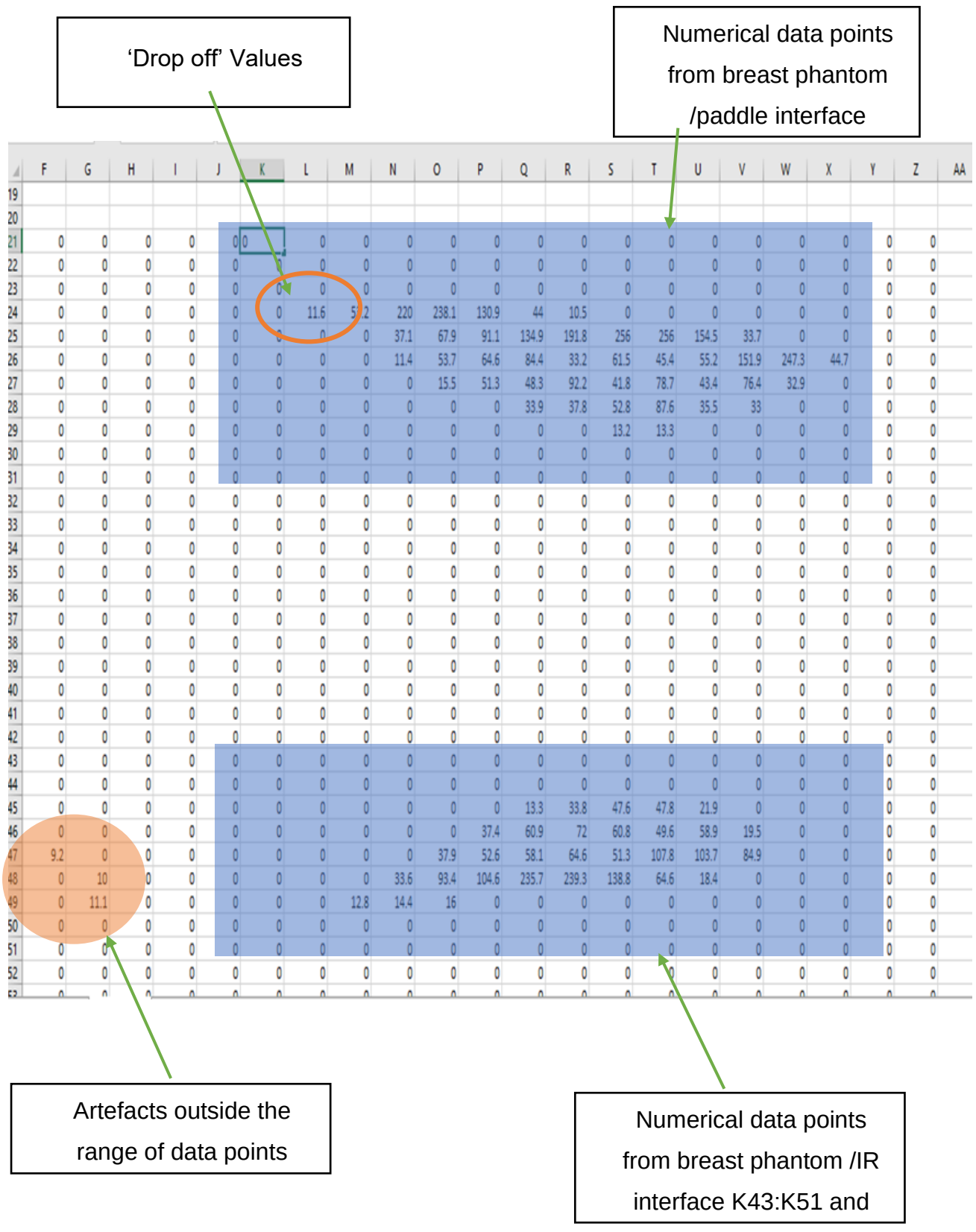
‘Drop off’ Values
Numerical data points from breast phantom /paddle interface
Artefacts outside the range of data points
Numerical data points from breast phantom /IR interface K43:K51 and

Figure 5.1 Data cleansing on Microsoft Excel spreadsheet

5.2 Data Analysis

Data from the phantom study was interpreted in two ways, visual description and mathematical analysis. Visual description entailed a description of the differences in visual appearance of contact pressure measurement. Notes made at the time of image acquisition with regards to contact pressure changes while compression was applied formed part of the visual description. Data points which generate contact pressure measurements and transferred onto a spreadsheet for mathematical analysis.

The model used for breast phantom had a sternal angle of 60^0 from the reading of inclinometer so that was referred to as the 'Experimental angle' for the phantom model; the IR positioned at 60^0 being parallel to the sternum of the phantom model. Contact pressure readings from this angle was used as a point of reference and compared with various angles throughout the study. Contact pressure readings recorded on Xsensor monitor (**Figure 5.2)** were exported as numeral data onto Excel spreadsheet for analysis (**Figure 5.3)**.

Contact pressure readings from the compressed phantom were recorded from the two sides of the breast phantom in contact with the pressure mat. On one side pressure applied from the IR (breast phantom/IR interface) and the other is that applied by the compression paddle (breast phantom/paddle interface). To achieve a uniform balance of pressure to the breast phantom, the amount of contact pressure applied by the paddle should be equal to that applied by the IR.

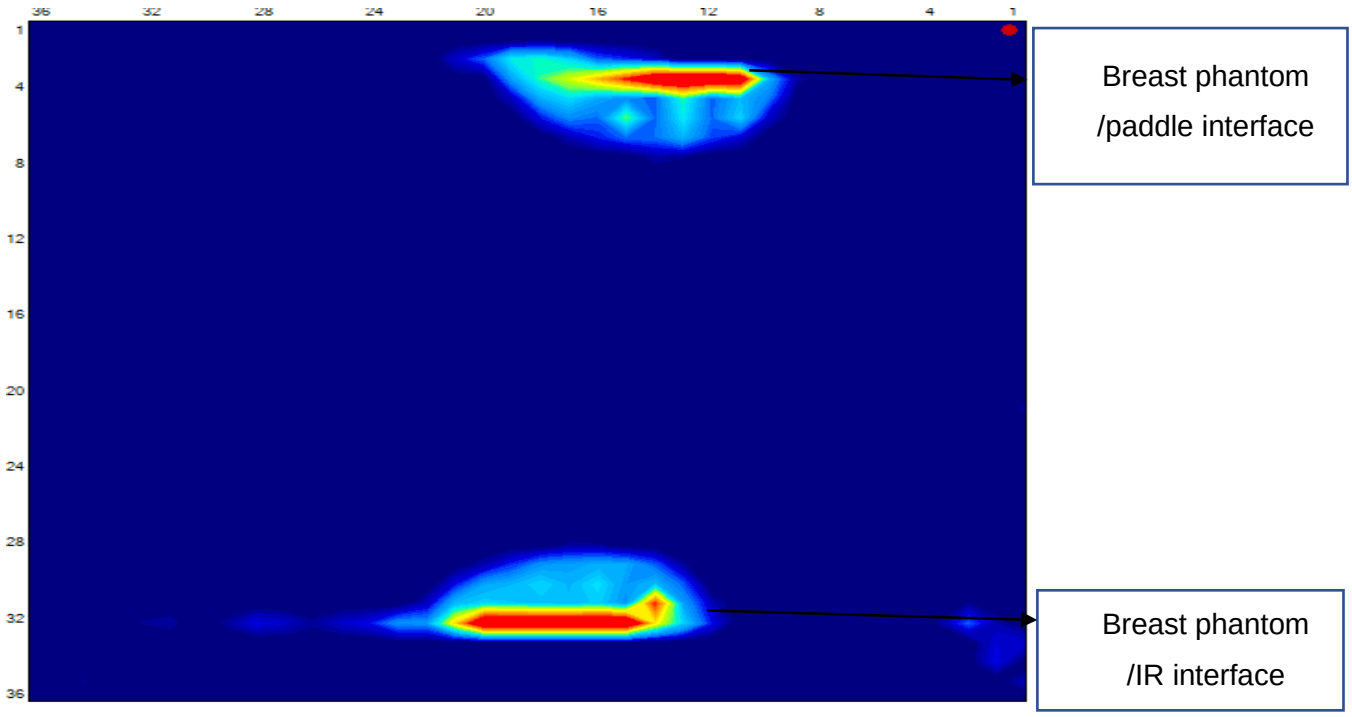

Figure 5.2 Contact pressure image representing breast/paddle interface and breast IR interface recorded on Xsensor monitor.

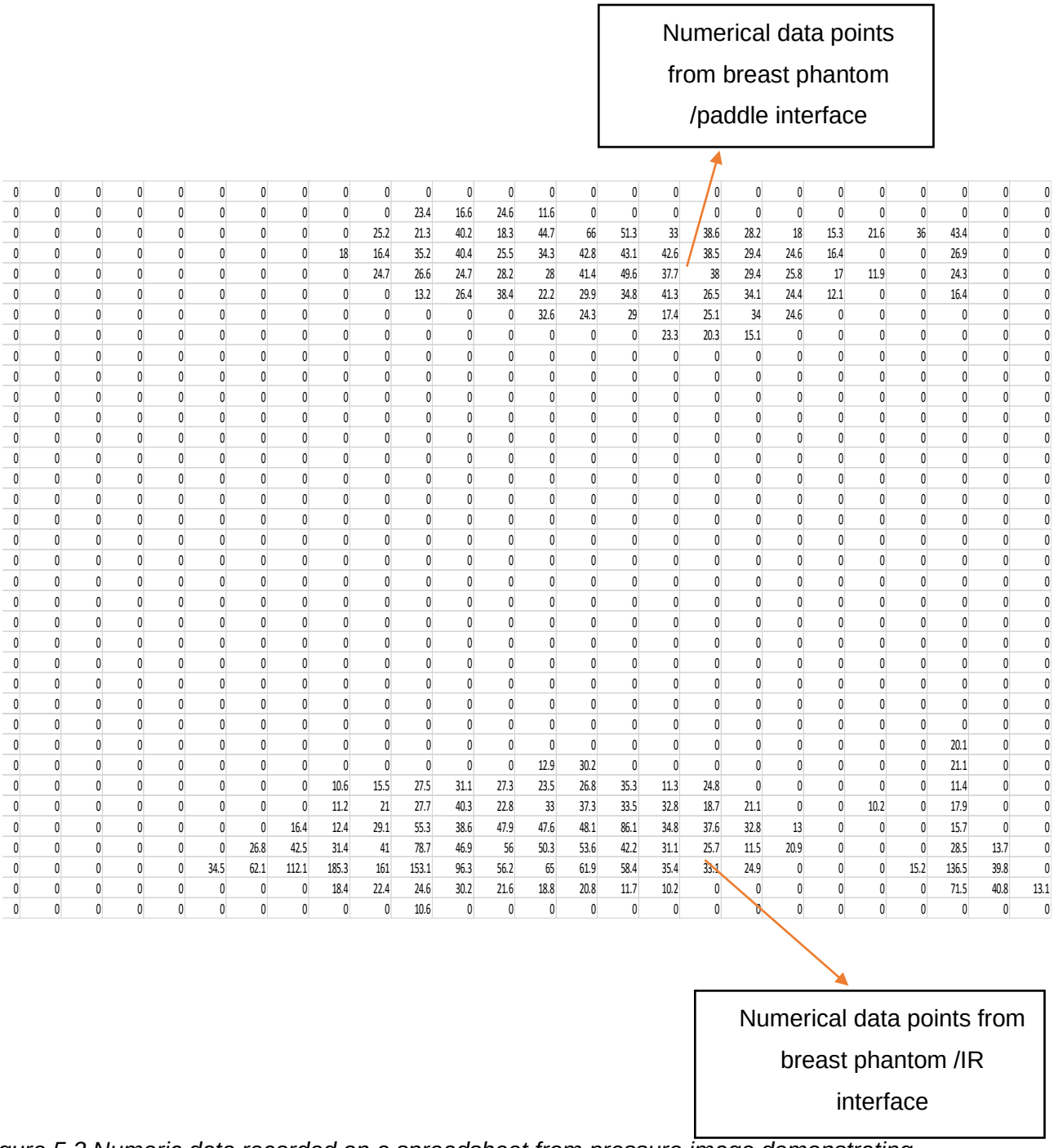

Figure 5.3 Numeric data recorded on a spreadsheet from pressure image demonstrating contact pressure from phantom paddle/interface and phantom/IR interface.

5.3 Visual Description

Data from the pressure mapping system is represented as a 2D or 3D image on a colour scale. **Figures 5.4 and 5.5** demonstrate breast phantom images represented in the form of pressure measurement (red indicating high pressure and blue indicating low pressure). It is to note that contact pressure measurement recorded did not generally include the axilla area of the phantom as it would be on a standard MLO mammographic projection. This was due to the fact that the phantom model has restricted movement in the upper limb and the thoracic region. During mammography, clients generally lean into the unit with the arm over the IR so as to include the axilla area in the MLO image. This is possible because humans have a wide range flexibility in the upper body, shoulders and arms and are therefore able to easily adapt to that positioning. In clients with limited upper arm and shoulder mobility, the MLO would usually not show most of the axilla area as they would be unable to lift the arm and lean into the unit and required. The MLO images produced in this instance were similar to that from the phantom.

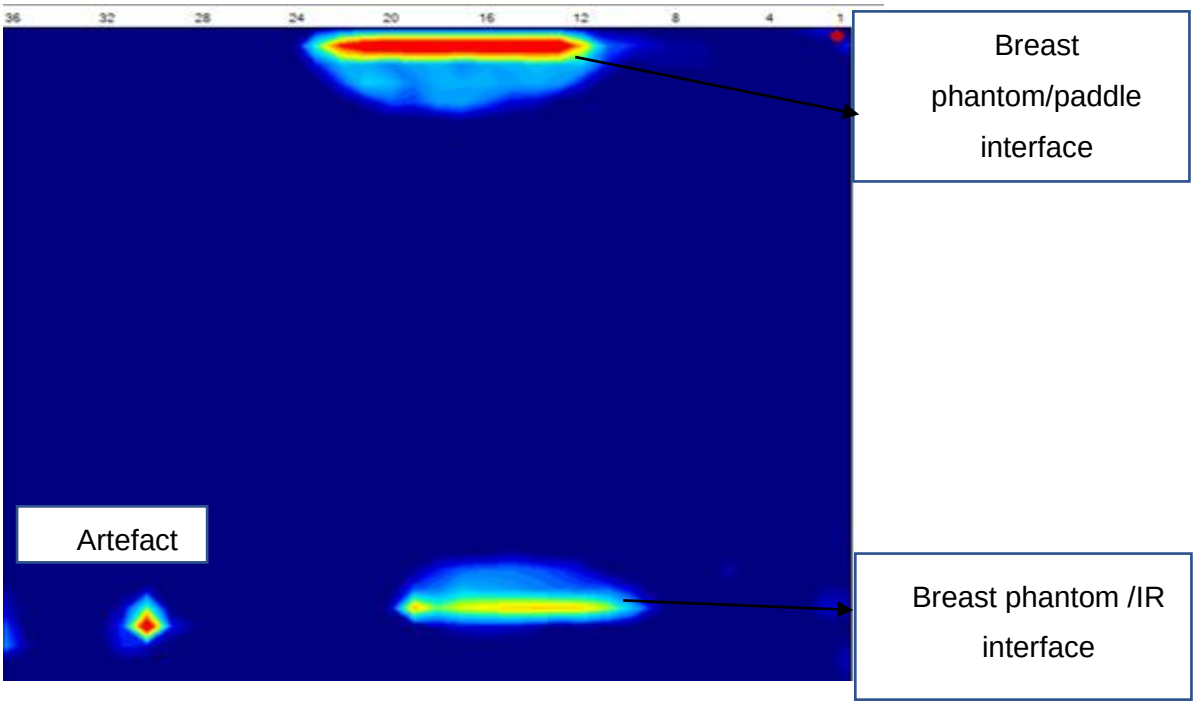

Figure 5.4 Breast phantom contact pressure footprint in 2D image of MLO projection.

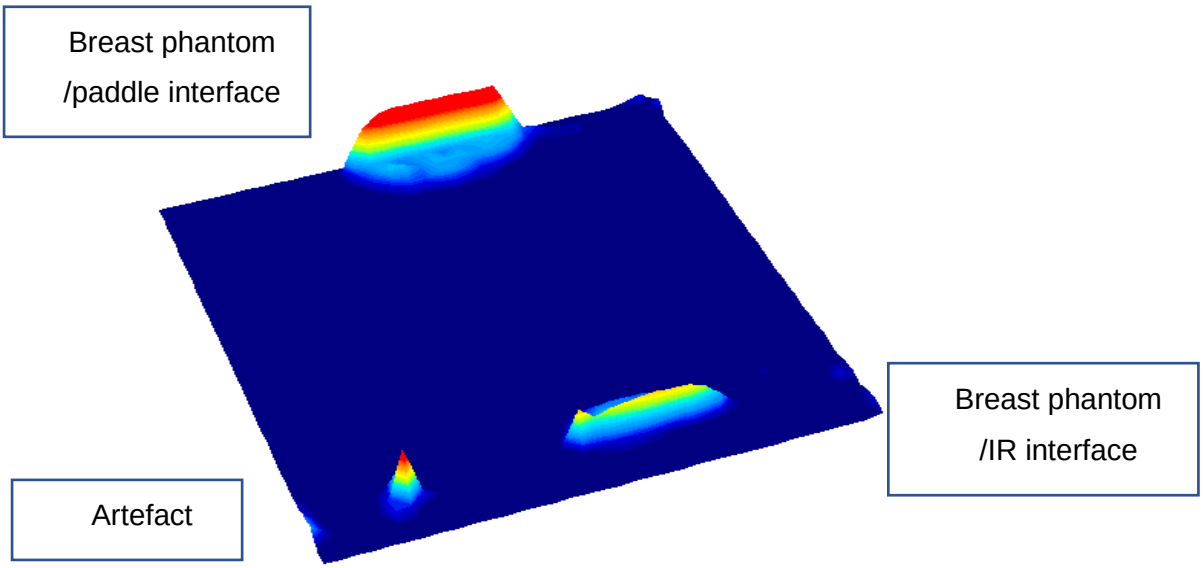

Figure 5.5 Breast phantom contact pressure footprint in 3D image of MLO projection

The visual description undertaken was based on 3 components: contact pressure, contact area footprint and artefact.

5.3.1 Contact Pressure and Contact Area Footprint

Contact pressure measurements were assessed and a description of the visual appearance of each image made. It is acknowledged that analysis such as this could be subjective, however it gives an insight on the general distribution of contact pressure from breast/IR interface and breast/paddle interface.

Figure 5.6 shows contact pressure image recorded on Xsensor pressure monitor on phantom breast compression. There is higher pressure (in red) on the breast phantom/paddle interface compared to breast phantom/IR interface. It is to note that, contact pressure measurements recorded do not have the same outlined MLO image of human breast (**Figure 5.7**). It was mentioned earlier that the most axilla area and the posterior part of the phantom could not be included during compression. This is a limitation of the study as there is a noticeable difference of contact pressure measurement between the phantom (**Figure 5.6**) and human breast (**Figure 5.7**). The most noticeable difference between these two pressure

measurements is contact area footprint. The human breast has relatively more contact area surface and there was greater contact pressure on the breast/IR interface compared with breast/paddle interface, the reverse is true for the pressure image on the phantom.

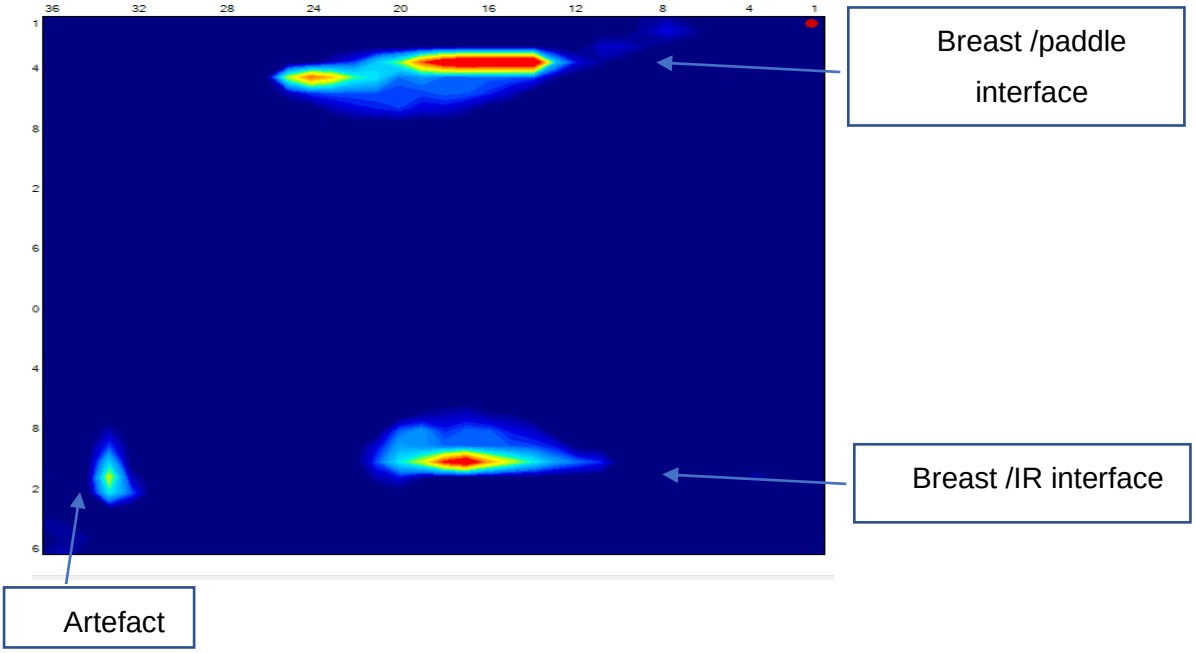

Figure 5.6 Breast phantom contact pressure image recorded on Xsensor pressure monitor in 2D.

Visual observation demonstrated that contact area footprint of the images varied at various angles and there was a noticeable asymmetric pattern between breast phantom/IR interface and breast phantom/paddle interface. Breast phantom/paddle interface always recorded greater area footprint compared to breast phantom/IR interface (**Figure 5.6**). For steeper IR angles 60^0 and over, images demonstrated some axilla area footprint (**Figure 5.8**). No such footprint was observed on images recorded for IR angles 55^0 and below. This could be due to that fact that at steeper angles, the IR was more parallel to the sternal angle of the phantom model therefore could demonstrate axilla area footprint.

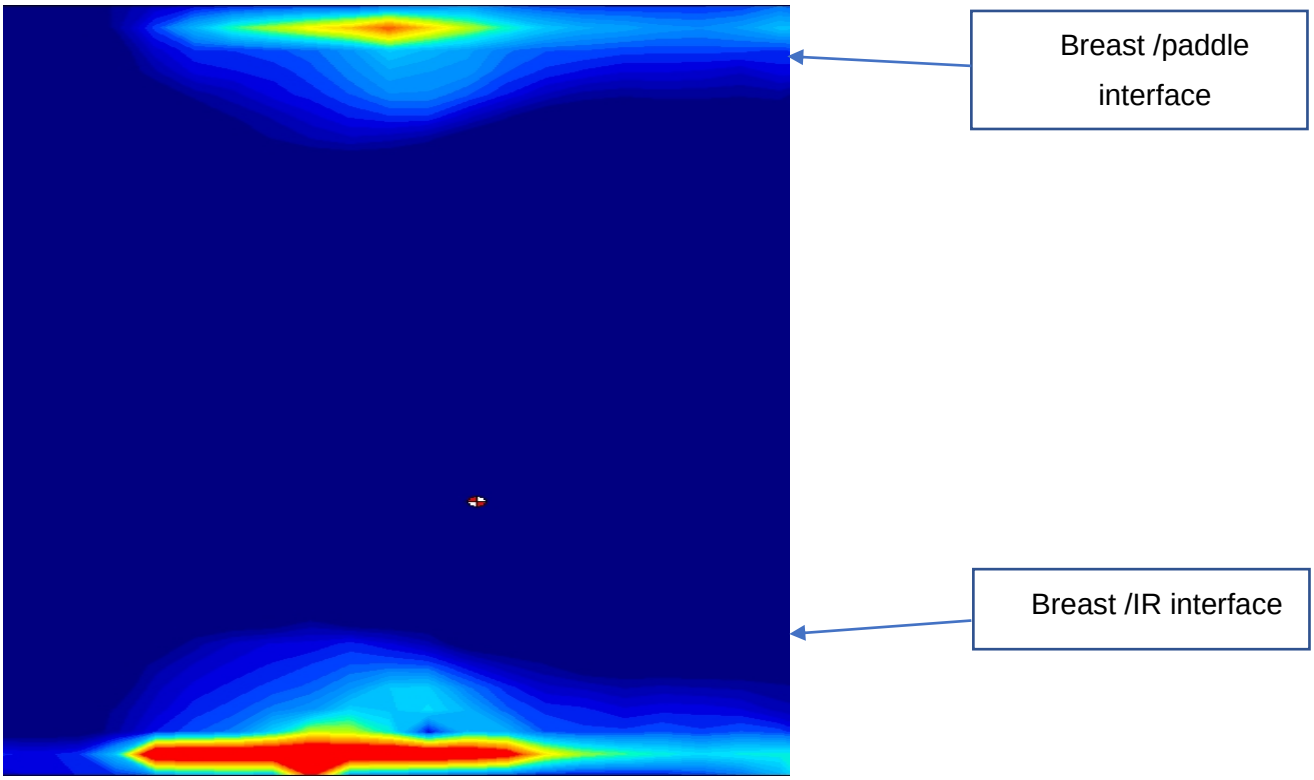

Figure 5.7 Human breast contact pressure footprint in 2D image of MLO projection (Smith, 2013).

It is worth noting that even though these images are MLO compressions, it does not show the back of the breast phantom to include some thoracic and axilla areas. The phantom model was not designed to provide those details. In addition, it is not flexible enough to be pulled over enough onto the IR as human would have done during positioning.

The limitation of using this phantom is that there was inadequate pressure measurement of the axilla region registered on mat. The reason for this was that, there was restricted movement of the torso for the axilla area to be fully positioned on the IR. Even though the phantom model had upper limbs required to aid in the positioning for MLO, the inability to manoeuvre the torso into desired position meant most part of the axilla was missed.

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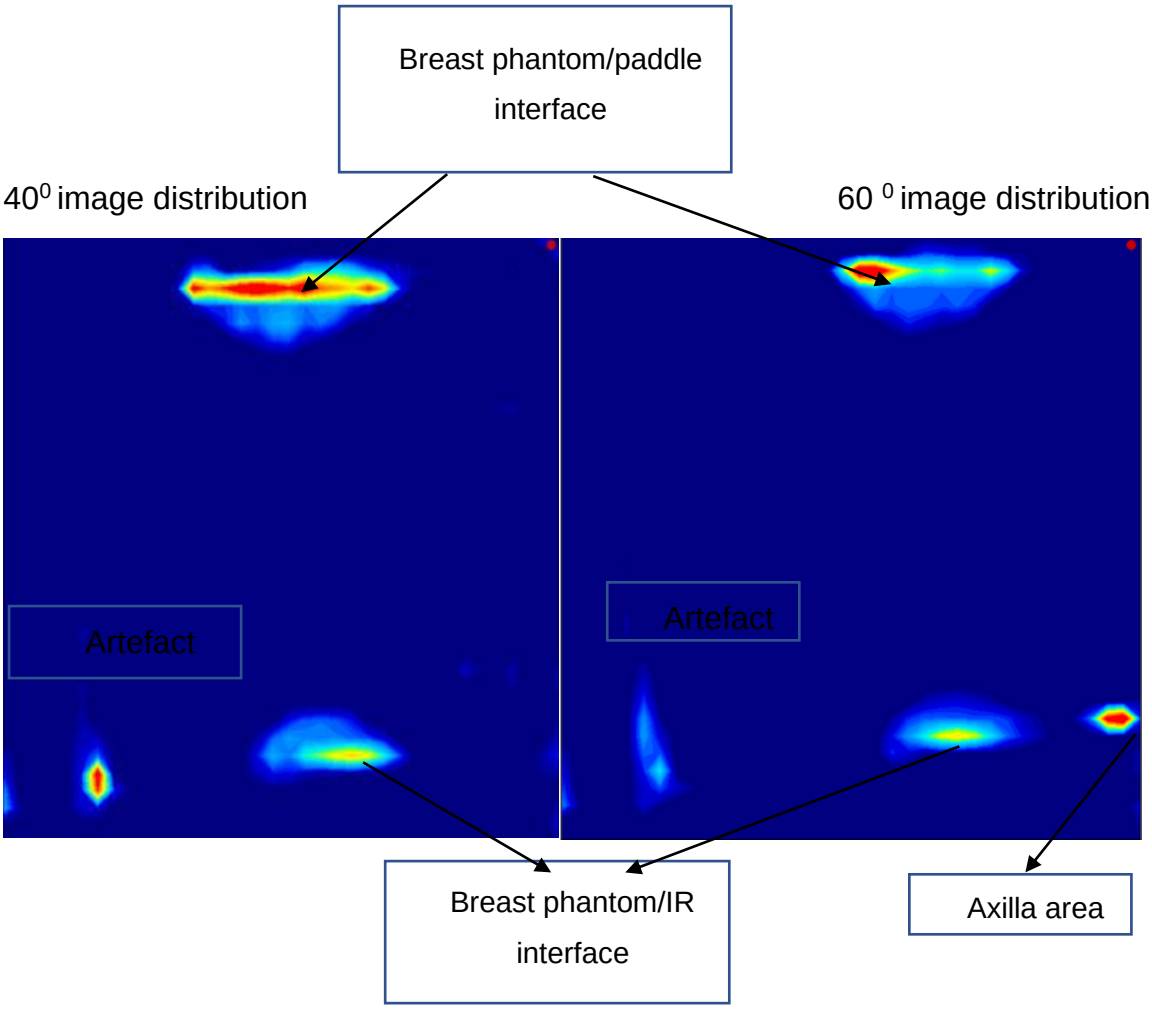

Figure 5.8 Contact pressure image balance from breast phantom/paddle interface and breast phantom/IR interface at angles 50^0 and 60^0

5.3.2 Artefacts

Artefacts were present on all images and the patterns were similar throughout the various angles, that is artefact where present on the same data points where there were creases on the pressure mat. Artefacts that did not relate to breast phantom footprints (i.e., creases from the pressure mat) were deleted (changed to zero) and were not included in analysis. There was a better contact pressure readings recorded at the breast phantom/IR interface near the axilla at the steepest angles of the IR compared to less steep angles. These readings were identified at IR angles 60, 65 and 70 degrees and it could be that these angles are closest to

being parallel to the sternum of the phantom model. From the observation of the researcher during compression, at these angles the phantom model fitted better on the top corner of the IR with more of the axilla and thoracic areas on the IR (**Figure 5.9**). In practice MLO images should demonstrate as far as possible the back of the breast phantom and the axilla area. Nevertheless, as the phantom was not flexible enough, lateral corner of the IR could not be pushed as deep as possible in the axilla as human would have done therefore, the axilla area was patchy and far disjointed from the main contact pressure. This is actually a limitation of the study as mobility for the model phantom is restricted. Details of the methods used to delete artefacts that were not related to the area of interest has been discussed earlier. Data cleansing of artefact has been explained earlier.

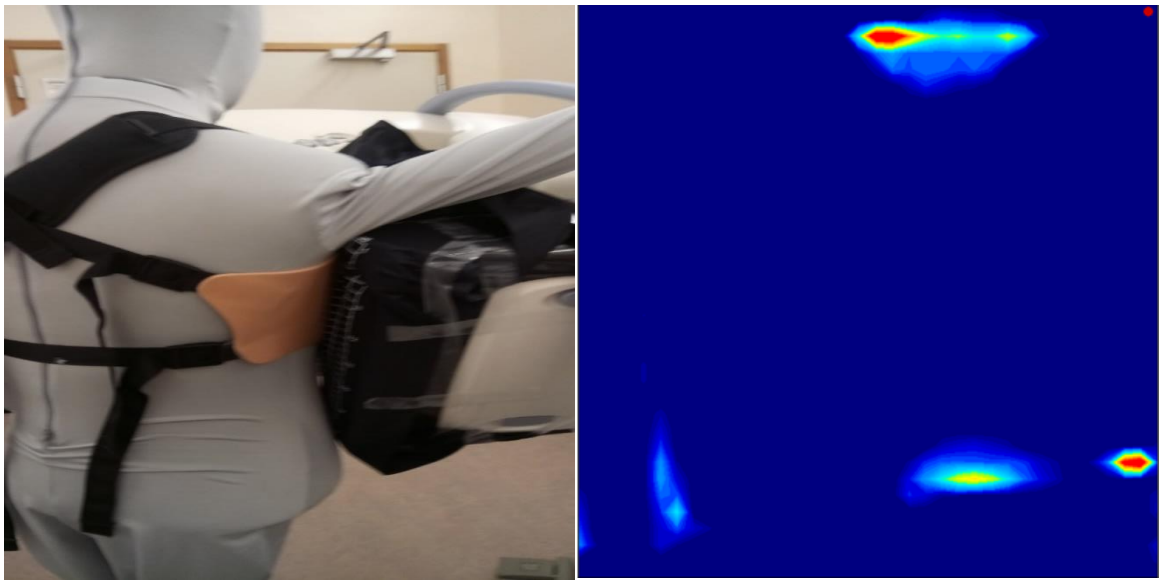

Figure 5.9 Phantom model positioned at IR angle 60^0 with the resultant contact pressure image.

5.4 Mathematical Analysis

Contact pressure data in numeric format were recorded on Xsensor pressure mat and exported to a spread sheet. This provided the basis for the mathematical analysis. This involved calculating the averages of frames recorded on contact pressure and contact surface area.

Calculation for balance of contact pressure and contact area were derived from the work of Hogg, Szczepura, et al. (2013); Smith (2013); Smith, Szczepura, et al. (2015) as discussed in chapter 3 **section 3.6.1.**

Instead of calculating pressure together with area (pressure per unit area) as it was done for UI in Smith's work (Smith, Szczepura, et al., 2015), these two parameters (pressure and area) were examined separately. Pressure and area were examined separately because it will give a clear indication of the actual pressure or area balance between IR and paddle interfaces without the interference of any other parameter. It is necessary to investigate these parameters on their own as they are independent of each other. A change in pressure does not always translate into change in area on compression of the breast. There could be a good balance of pressure between IR and the paddle but it does not necessary imply area balance between IR and paddle will be good as well, and vice versa. Pressure and area are independent from one another. On breast compression, increase in pressure does not always results in increase of contact area or decrease in breast thickness. Poulos and McLean (2004) adds that compression force can be applied with no resulting reduction in breast thickness.

To do this, ***Equation 1*** that is Uniformity Index = (A-B)/ (A+B) discussed in **section 3.6.1** was adapted to calculate Pressure Uniformity (PU) ***Equation 2*** and Area Uniformity (AU) ***Equation 3***.

PU is the average pressure applied by the paddle compared with the average pressure applied by the IR.

PU is calculated as follows:

Equation 2. P. U= (A-B)/ (A+B)

Where:

- A = average pressure applied by the paddle (mmHg)
- B = average pressure applied by the IR (mmHg)
- The PU value has the following implications. If PU = 0, there is equal pressure from the IR and the paddle (equal distribution). On the other hand,

if 0<PU>1, there is greater pressure from the paddle on the top of the implant, with 1= all pressure is applied by the paddle. However, if -1<PU>0, there is greater pressure from the IR on the underside of the implant, with -1= all pressure is applied by the IR.

Implant contact surface area is recorded from the footprint of the implant in contact with the IR on one side and the paddle on the other side. There is a well-balanced footprint when surface contact area of the implant from the IR side is equal to that from the paddle side. Area uniformity (AU) is the average surface area from contact with the paddle compared with the average surface area from contact with the IR.

AU is calculated as follows:

Equation 3. AU= (C-D) / (C+D)

Where:

- C = average area detected by the paddle (cm^2)
- D = average area detected by the IR (cm^2)
- The AU value has the following implications. If AU. = 0, there is equal surface area coverage from the IR and the paddle (equal distribution). On the other hand, if 0<AU.>1, there is greater surface area from the paddle on the top of the implant, with 1= all surface area is applied by the paddle. However, if -1<AU.>0, there is greater area footprint from the IR on the underside of the implant, with -1= all area footprint is applied by the IR.

For each compression, paddle and IR contact area footprints and contact pressure were recorded. For each breast phantom, 3 rounds of compressions (six series of data) applied resulted into 42 compressions over 7 IR angles (40^0 to 70^0 in the multiples of 5). A total of 10 frames (seconds) were recorded for each compression, therefore 420 periods of contact pressure data were collected and analysed. The average of these frames was calculated for each compression to represent the contact pressure or contact area footprint for each IR angle. The

average of the averages of all the 6 series of compressions (3 on each phantom breast phantom) were then calculated the represent the overall average contact pressure/contact area footprint for individual IR angle.

The balance of contact pressure between breast phantom/paddle and breast phantom/IR interfaces were different on all angles. The contact pressure registered on the breast/paddle interface was consistently higher than breast/IR on all angles as demonstrated in **Table 5.1**. This is represented graphically in **Figure 5.8**.

Table 5.1 The average of all contact pressure averages from all six compressions on various IR angles.

Breast phantom/paddle and breast phantom/IR interfaces pressure comparison							
IR angle	40^0	45^0	50^0	55^0	60^0	65^0	70^0
Average breast phantom/paddle pressure/mmHg	5.81	5.39	5.74	5.02	5.25	4.7	3.88
Average breast phantom/IR Pressure/mmHg	4.68	3.43	4.47	4.22	4.83	3.52	2.9

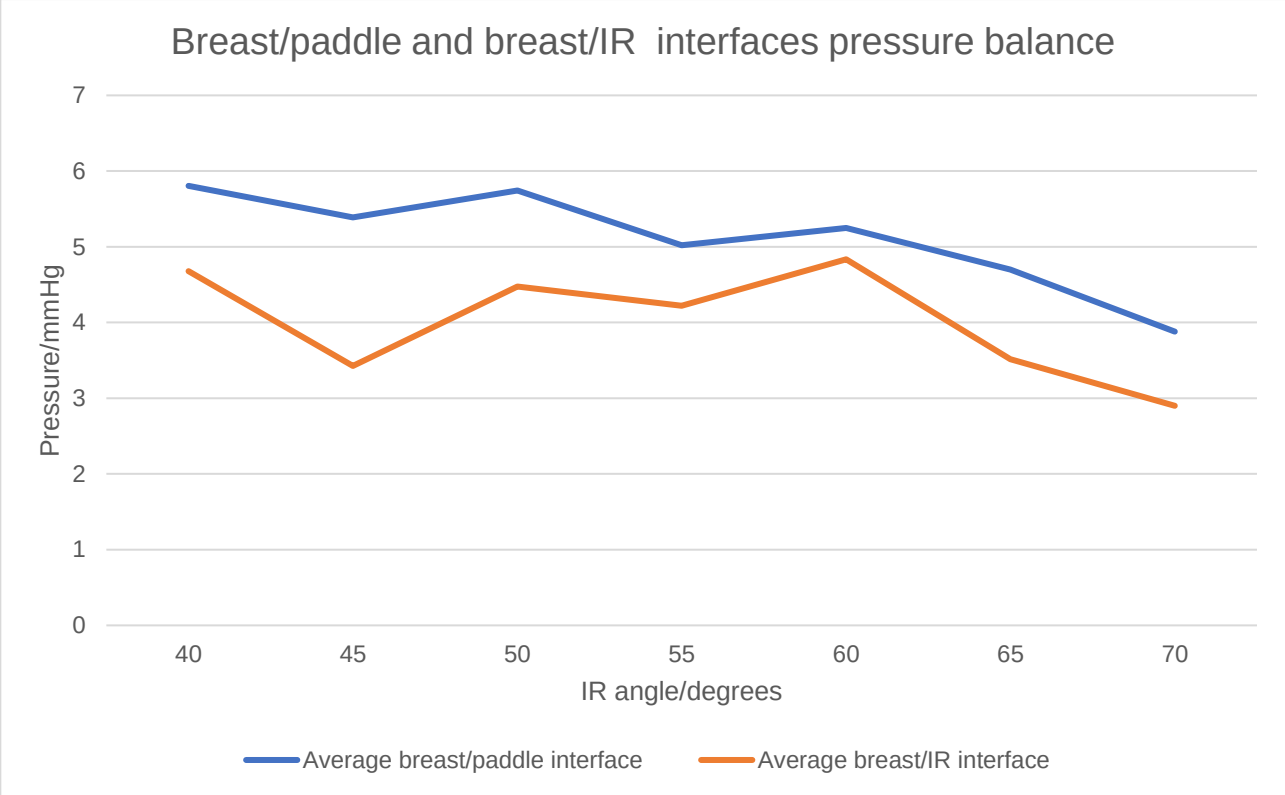

Figure 5.10 Comparison of contact pressure applied (mmHg) from breast phantom/IR interface and breast phantom/paddle interface.

Figure 5.10 above shows the relationship between contact pressure of the breast phantom on both the paddle and the IR interfaces. To have a perfect balance of pressure between these two interfaces, the pressure values must be the same. The closer the values of pressure from IR and paddle interfaces are, the better the balance of pressure. In a situation where there the pressure from breast phantom/IR interface is equal to that applied from breast phantom/paddle interface (perfect distribution), graphically, the two interfaces will merge and be represented by a single label.

For **Figure 5.10**, the closer the labels are with each other, the greater the balance of pressure between the two interfaces. The wider the gap between the labels, the less balance the pressure applied by the IR and the paddle. IR angle at 45^0 presented the least balance of pressure from both interfaces while IR angle at 60^0 provided a greater balance of pressure out of all the angles examined. Contact pressure balance difference between breast phantom/paddle and breast phantom/IR interfaces recorded at IR angle 45^0 was 1.96 mmHg and that of angle

60^0 was 0.42 mmHg. Lower difference in pressure value in this case represents better pressure balance between the two interfaces.

The pressure mat has a pressure limit of 256 mmHg and does not read any contact pressure beyond that. The upper limit pressure 265 mmHg was achieved on breast phantom/paddle interface from the pressure applied by the IR all the angles **Table 5.2.**

The maximum pressure applied to the breast phantom/IR interface however was much less and varied. The limit pressure (256 mmHg) was reached only at angle 60^0 and the lowest was 123.86 mmHg on angle 45^0. Comparing maximum pressure on both interfaces at angle 45^0, there was twice as much pressure applied on the breast phantom/paddle interface compared to breast phantom/IR interface.

The minimum contact pressure applied to the breast phantom/paddle interface ranges from 1.01 mmHg to 7.58 mmHg while that of breast phantom/IR interface was from 1 mmHg to 6.96 mmHg. In contrast with maximum contact pressure, on 3 of the angles (45^0,55^0, 70^0) there were more contact pressure applied to the breast phantom/IR interface compared to breast phantom/paddle interface. This could be due to the fact that there was less surface area contact on the breast phantom/IR interface therefore more pressure was applied on the smaller surface. It could be argued that there should be more contact surface area because of the inclusion of the axilla area however, this is not the case as the pressure mat will only read and record contact surfaces. Unlike mammography where part of the breast such as the nipple are still visualised on images although they are not in contact with the paddle or IR, pressure reading represents only areas in contact with the mat.

Table 5.2 The average of all the contact pressure averages readings(mmHg) on breast/IR interface and breast/paddle interface on all IR angles.

IR angle	40^0	45^0	50^0	55^0	60^0	65^0	70^0
Average Pressure breast phantom/paddle mmHg	5.80	5.39	5.74	5.02	5.25	4.7	3.88
Average Pressure breast	4.68	3.42	4.47	4.22	4.83	3.51	2.9

phantom/IR mmHg							
Maximum Pressure breast phantom/paddle mmHg	256	256	256	256	256	256	256
Maximum Pressure breast phantom/IR mmHg	174.9	123.8	204.3	214.3	256	194.7	172.68
Minimum Pressure breast phantom/paddle mmHg	7.58	1.06	4.78	1.02	2.73	1.01	2.13
Minimum Pressure breast phantom/IR mmHg	1	2.36	1	5.66	1	1	6.96

Table 5.3 Contact area footprint at various angles when compression force of 10 daN was applied on each breast phantom.

IR angle	**40^0**	**45^0**	**50^0**	**55^0**	**60^0**	**65^0**	**70^0**
Area breast phantom/paddle interface/cm^2	15.47	14.45	16.71	15.26	13.86	15.26	11.07
Area breast phantom/IR interface/cm^2	12.30	11.07	12.14	11.28	12.30	12.08	9.45

From **Table 5.3**, the contact surface area on phantom breast/paddle interface was much larger compared to the breast phantom/IR interface on all compressions. This is opposite to the average pressure where there was more contact pressure applied to the breast phantom/IR interface compared to breast phantom/paddle interface. It could be that contact pressure and area are inversely related. The differences in contact area footprint from breast phantom/ paddle interface and breast phantom/IR interface varied at each angle. The average of all averages of contact area footprint is recorded for all compressions (**Table 5.3**). Ten frames of data points on contact area footprint were recorded from each compression. A frame was recorded per second therefore 10 frames were recorded over 10 seconds. This was enough duration for pressure measurement to recorded and extending it beyond 10 frames would not have added any new information. In addition, application of compression during mammography usually is within 10 second during which the image is taken upon exposure.

The average of these frames was calculated for each compression. Six set of compressions (3 on each breast) were made. The average of the averages of all these 6 compressions were then calculated. Calculating averages provided a better representation of data as it covers the whole 10 seconds of compressions when the frames were recorded.

Figure 5.7 provides a 2D of breast phantom contact area as it appears on Xsensor pressure monitor at 2 angles (40^0 and 60^0). The breast phantom/paddle interface has a noticeably larger coverage to the breast phantom/IR interface. The greatest balance footprint was recorded at 50^0 with the breast phantom/paddle interface and breast phantom/IR interface contact area footprints of 16.71 cm^2 and 12.14 cm^2 respectively. The most symmetric of all was achieved at IR angle 60^0 with the difference in contact area footprint between the breast phantom/paddle interface and the breast/IR interface being 1.56 cm^2.

The average pressure on each compression on all 6 series of compressions recorded on the 7 angles were calculated. In total there were 42 compressions (Table 5.4). The mean pressure of 18.20 mmHg on breast phantom/paddle was higher than that of breast phantom IR interfaces of 16.79 mmHg. This implies there was more pressure on the breast phantom/paddle interface than the breast phantom/IR interface. The minimum and maximum contact pressure values at the breast phantom/paddle interface were 2.33 mmHg and 7.59 mmHg respectively while that from the breast phantom/IR interface were 1.22 mmHg and 7.77 mmHg. In addition, contact pressure values on breast phantom/paddle interface vary much less compared with the values from the breast phantom/IR interface (Figure 5.11).

Table 5.4 Contact pressure on all compressions from breast phantom/paddle interface and breast phantom/IR interface.

	Breast phantom/paddle interface pressure	Breast phantom/IR interface
Compressions	**42**	**42**
Maximum pressure	**7.59/mmHg**	**7.77/mmHg**
Minimum pressure	**2.33/mmHg**	**1.22/mmHg**
Average pressure	**18.20/mmHg**	**16.79/mmHg**
SD	**13.73**	**13.95**
Variance	**188.59**	**194.70**
Standard error	**2.11**	**2.15**

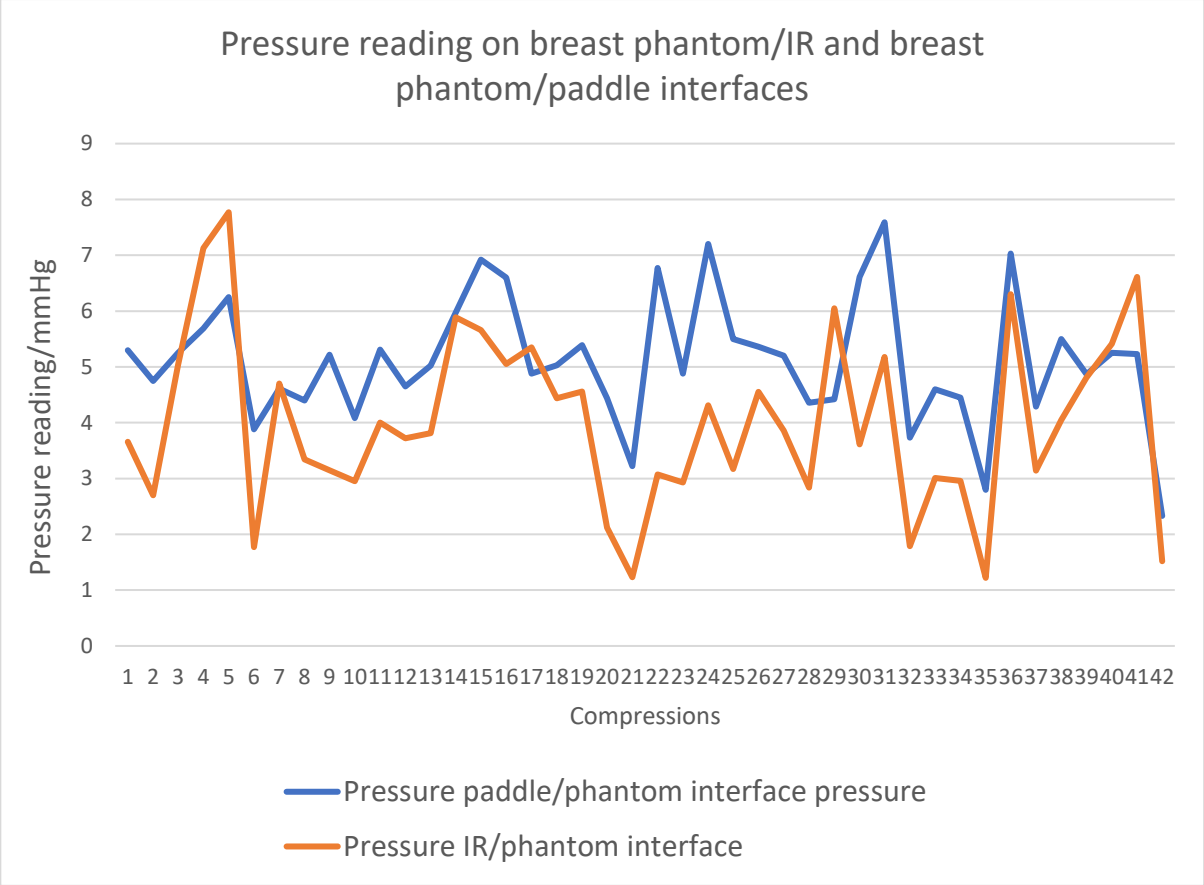

Figure 5.11 Contact pressure on all compressions from breast phantom/paddle interface and breast phantom/IR interface.

Similarly, the average contact area footprint on breast phantom/paddle interface for all compressions varies less than that of breast phantom/IR interface (**Figure 5.12**) (**Table 5.5**). This is likely due to that fact that not all the axilla area is in contact with the pressure mat due to the difference in density gf the pectoral muscle and breast tissue. The average area for all 42 compressions recorded on the breast/paddle (15.39 cm^2) inface was higher than that of the breast phantom/IR interface (13.13 cm^2). The greatest variation was the minimum area on both interfaces. Breast phantom/paddle interface had a minimum are of 6.46 cm^2 and breast phantom/IR recorded the minimum of1.77 cm^2. However, both interfaces recorded almost the same standard deviated of 7.96 and 7.75.

Table 5.5 Contact area on all compressions from breast/paddle interface and breast/IR interface.

	Area breast phantom/paddle interface	Area breast phantom/IR interface
Compressions	**42**	**42**
Maximum area	**21.29/cm^2**	**18.7/cm^2**
Minimum area	**6.46/cm^2**	**1.77 /cm^2**
Average area	**15.39/cm^2**	**13.13/cm^2**
SD	**7.96**	**7.95**
Variance	**63.42**	**63.27**
Standard error	**1.23**	**1.23**

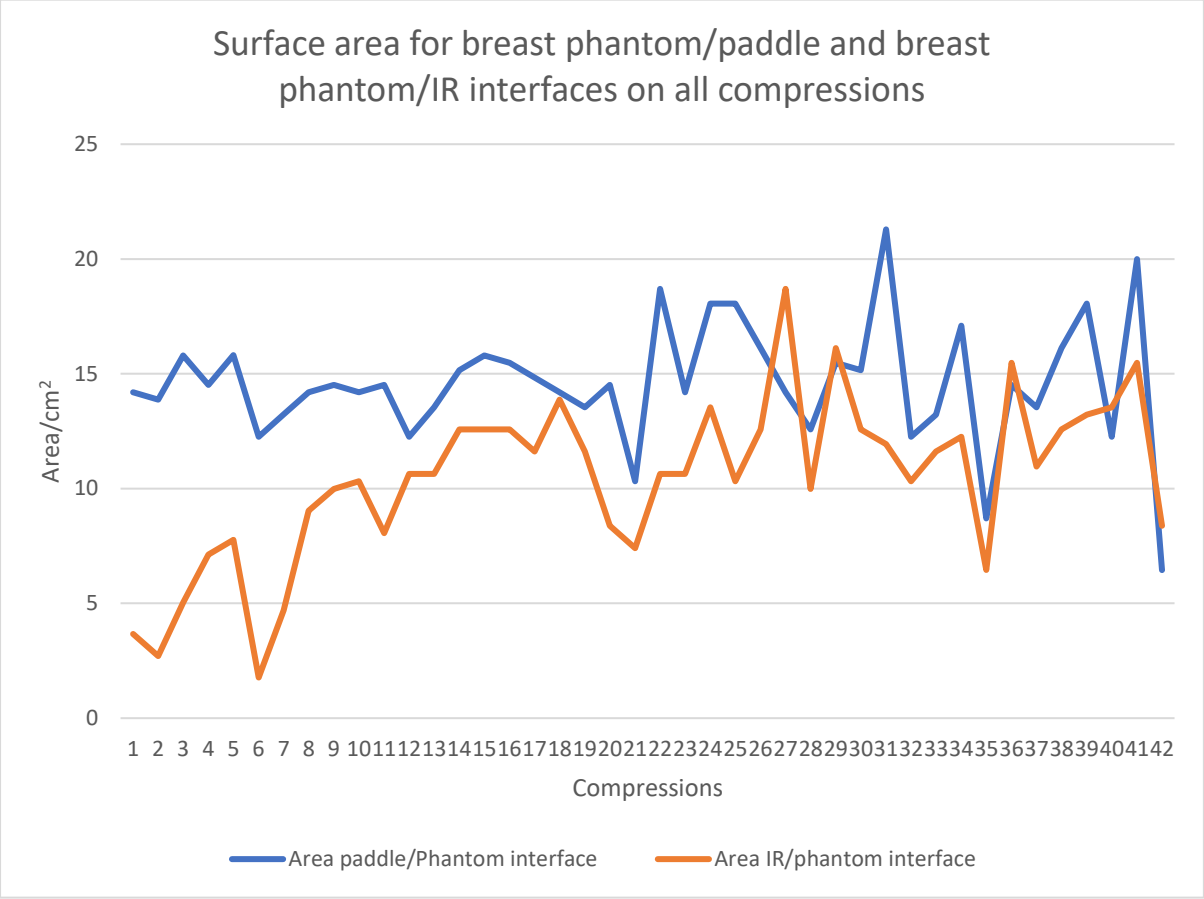

Figure 5.12 Contact area footprint on all compressions from breast phantom/paddle interface and breast phantom/IR interface.

The average contact pressure applied by the IR, average contact pressure applied by the paddle, average contact area footprint applied by the IR and average contact area footprint applied by the paddle were calculated. From these averages, PU and AU were analysed as follows: As mentioned earlier, all drop off data points were included in data analysis.

PU= (A-B) / (A+B)

AU= (C-D) / (C+D)

The SD of pressure and contact surface area were calculated.

Table 5.6 The average contact pressure (mmHg) and contact area footprint (cm^2) reading for all 6 compressions in numerical value.

IR angle	40^0	45^0	50^0	55^0	60^0	65^0	70^0
Ave Pressure breast phantom/paddle interface /mmHg	5.80	5.39	5.75	5.02	5.25	4.7	3.88
Area breast phantom/paddle interface/cm^2	15.47	14.45	16.72	15.26	13.86	15.26	11.07
Pressure/Area breast phantom/paddle interface	0.37	0.36	0.34	0.32	0.37	0.30	0.34
Average Pressure breast phantom/IR interface/mmHg	4.68	3.42	4.47	4.22	4.84	3.51	2.9
Area breast phantom/IR interface/cm^2	12.30	11.07	12.14	11.28	12.30	12.08	9.45
Pressure/Area breast phantom/IR interface	0.37	0.3	0.36	0.37	0.38	0.28	0.27
Area Check	27.78	25.53	28.86	26.55	26.17	27.35	20.53
Pressure Uniformity	0.11	0.215	0.115	0.115	0.06	0.17	0.21
Area Uniformity	0.12	0.13	0.15	0.14	0.05	0.12	0.07

Table 5.6 provides a summary of data collected. Attention was paid particularly to the difference in contact pressure and contact area footprint balance. Individual contact pressure applied on breast phantom/paddle interface and breast phantom/IR interface were analysed. Compression on each angle showed a pattern of more contact pressure on breast phantom/paddle interface compared to breast phantom/IR interface **Figure 5.13**.

In theory, Mercer, Hill, et al. (2015, p. 32) has stated that “an even and equal balance of contact pressure from both paddle and the IR of the breast phantom could reduce the discomfort experienced during compression”. For this reason, the IR angle that produce similar contact pressure pattern from both sides will have an even distribution of contact pressure through the breast phantom. Contact pressure readings on all the angles had a varying degree of balance from the two interfaces. The widest contact pressure difference occurred at IR angle 45^0, with the difference between the breast phantom/paddle interface (5.39 mmHg) and the breast phantom/IR interface (3.52 mmHg) contact pressure at 1.96 mmHg. It is the angle that recorded the least balance of pressure compared to all the IR angles investigated. Error bars represent the standard error of contact pressure data set. The errors are uniform on both the IR and paddle interfaces on all the angles.

The most even contact pressure balance occurred at 55^0 and 60^0. At IR angle 60^0, the difference in compression was only 0.42 mmHg, making this angle the suitable angle for an even contact pressure distribution.

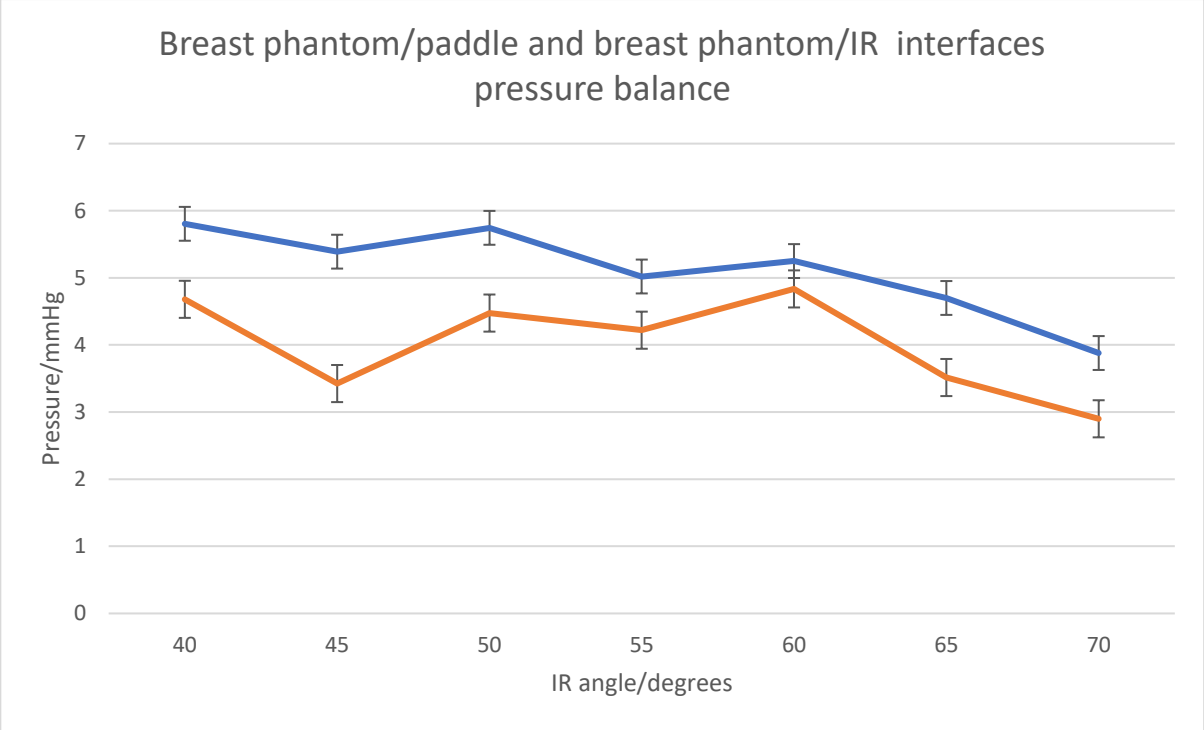

Figure 5.13 Comparison of contact pressure applied from breast phantom/paddle interface and breast phantom/IR interface.

In mammography, the contact area of breast on the compression paddle and IR is important as that will determine the amount of breast tissue to be imaged. MLO view is the only view that demonstrates all the breast tissue therefore, contact area balance between the IR and paddle plays a vital role. It is expected that, contact surface area on breast/paddle interface and the breast/IR interface should be equal and balanced. This will allow even distribution of force on either side of the breast which could result into a more comfortable procedure.

Compressions on the breast phantom generally achieved more contact surface area on breast phantom/paddle interface compared to the breast phantom/IR interface on all the angles. The difference was quite similar through the various angles and peaked at angle 50^0 as shown in (**Figure 5.15).** The graphical presentation on angle 50^0 demonstrates a much wider area footprint gap between breast phantom/IR and breast phantom/paddle, thus this angle produced the least balance of area footprint between these two interfaces. The most balanced contact area was archived at 60^0 where the breast/paddle interface

registered 13.86 cm^2 with the breast phantom/IR interface area at 12.3 cm^2. (**Figure 5.14**) presents the two interfaces as the closest together at IR angle 60^0.

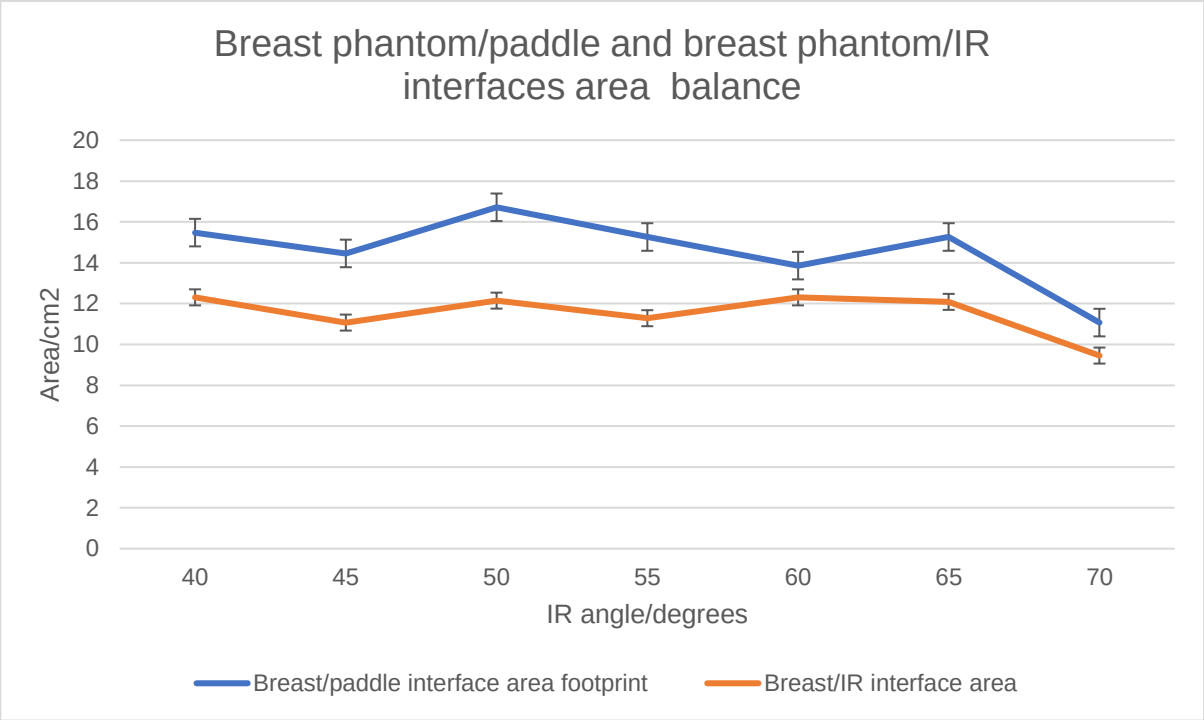

Figure 5.14 Comparison of contact surface area balance from the paddle and IR to the breast phantom.

The difference in contact surface area between the two interfaces is 1.56 cm^2, meanwhile contact area at angle 70^0 was equally balanced with the difference between the breast phantom/paddle interface and breast phantom/IR interface 1.62 cm^2. It is ideal to say that for this phantom model the best IR angle to use for an even contact area footprint balance is 60^0. The sternal angle of the phantom model was 60^0 and it was at this angle that larger contact area footprint was achieved on compression.

Where PU and AU are concerned, the closer the value is to zero, the better the balance of contact pressure/area footprint from the paddle and IR. On individual compressions, contact pressure and contact area footprint uniformity were always above zero indication there was more contact pressure applied by the

paddle to the top of the breast phantom and more surface contact area was registered at well (**Table 5.7**).

Table 5.7 Mathematical analysis of breast compression with resultant PU and AU.

IR angle	40^0	45^0	50^0	55^0	60^0	65^0	70^0
Pressure Uniformity	0.11	0.21	0.11	0.11	0.06	0.17	0.21
Area Uniformity	0.12	0.13	0.15	0.14	0.05	0.12	0.07

The relationship between these two uniformities is demonstrated on **Figure 5.15.** An equal balance of pressure and area footprint from the IR and paddle should result in a PU and AU of zero. The closer the PU and AU are to zero, the better the balance of pressure and area footprint on that IR angle (**Figure 5.15**). The further away the values are from zero, the less balanced the distribution of pressure and area footprint. The most obvious observation on the chat is that both pressure and area uniformities appear to converge at 60^0 which is the sternal angle of the model used for the experiment. It implies that when the IR angle is 60^0, it is positioned parallel to the sternum of the model.

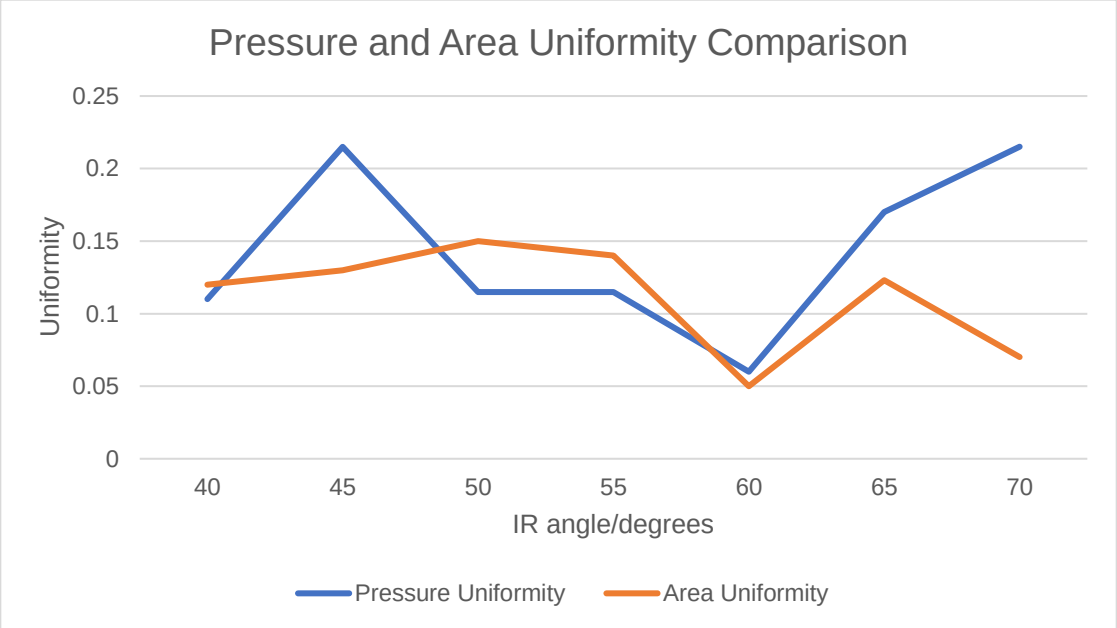

Figure 5.15 Combined contact pressure and contact area footprint uniformity for compressions.

Table 5.8 Statistical analysis of contact pressure from breast phantom/paddle interface and breast phantom/IR interface.

IR angle	40^0	45^0	50^0	55^0	60^0	65^0	70^0
Average Pressure breast phantom/paddle interface /mmHg	5.80	5.39	5.74	5.02	5.25	4.7	3.88
Average Pressure breast phantom/IR interface /mmHg	4.68	3.42	4.47	4.22	4.83	3.51	2.9
Average pressure (IR and paddle interfaces)	5.24	4.40	5.11	4.62	5.04	4.10	3.39
SD	0.79	1.38	0.89	0.56	0.29	0.83	0.69

Table 5.8 provides information on standard deviation (SD) calculated from the breast phantom/paddle interface and breast phantom/IR interface contact pressure applied to the breast on all angles. A small SD in this case will indicate an even contact pressure distribution from the breast phantom/paddle interface and breast phantom/IR interface. The largest SD recorded was at angle 50^0 with a mean of 5.1 and this means it has the lest even contact pressure distribution compared to all other angles. The SD at angle 60^0 with the mean of 5.04 at 0.29 is the lowest and presented the most even contact pressure distribution from the breast phantom/paddle interface and breast phantom/IR interface.

Table 5.9 Statistical analysis of surface contact area footprints on the breast phantom/paddle interface and breast phantom/IR interface.

	Breast phantom/paddle and breast phantom/IR interfaces area coverage comparison						
IR angle	**40^0**	**45^0**	**50^0**	**55^0**	**60^0**	**65^0**	**70^0**
Area breast phantom/paddle interface /cm^2	15.4	14.45	16.71	15.26	13.86	15.26	11.07
Area breast phantom/IR interface/cm^2	12.30	11.07	12.14	11.28	12.30	12.08	9.45
Mean (area)	13.89	12.76	14.43	13.27	13.08	13.67	10.26
SD	2.24	2.39	3.23	2.81	1.09	2.24	1.14

Comparison of contact surface area is demonstrated on **Table 5.9**. The SD values for contact surface area are similar to that of contact pressure distribution discussed earlier (**Table 5.8**). Angle 60 provided the least SD value and therefore the contact area of the IR is much similar to the paddle compared to all other angles.

In summary, the sternal angle of the phantom model measure with digital inclinometer was 60^0. The PU and AU calculated for this experiment indicates that, at IR angle 60^0 there was a greater balance of pressure and area footprint from the IR and paddle compared to all the other angles investigated. With the IR angled at 60^0, it was parallel to the sternal angle of the phantom model and it was at this angle that the greatest balance of pressure and area footprint was recorded.

5.5 Chapter Summary

This chapter presented data analysis and the results of the phantom study. Visual description of data involved Compression reading on the Xsensor pressure mapping system were transferred into numeral on Microsoft excel and then cleansed from artefact for analysis. Visual analysis involved the visual description of pressure and area images.

The data transferred into excel was mathematically analysed to calculate for average pressure and area of all compression. The PU and AU for compressions done on the various angles were also calculated.

This study demonstrated that with the IR angled at 60^0, it was parallel to the sternal angle of the phantom model and it was at this angle that the greatest balance of pressure and area footprint was recorded.

Chapter Six - Discussion and Conclusion

6.1 Chapter Overview

This chapter will summarise the results of the phantom study and relate it to available literature on mammographic positioning. Conducting a phantom study to develop a method, using the sternal angle, to allow selection of the correct IR angle was necessary to validate the method for human study.

6.2 Discussion

Mammographic positioning plays an important role in the quality of images produced. It is the single most important factor in optimising mammographic image quality as without all the breast tissue included on a mammogram all other aspects of the image quality are not relevant. MLO is the only projection that must show most if not all, of the breast tissue, in a single view (Anja et al., 2019; Dronkers et al., 2001; Ikeda & Miyake, 2016a; Popli et al., 2014) therefore, pressure and area balance between the IR and paddle plays a vital role. Positioning for the MLO projection requires the IR to be at an angle, however the selection of IR angle depends solely on the practitioner.

In practice, the practitioner is guided by the body habitus of the client (Anja et al., 2019), as a result, IR angle varies from client to client. Selection of IR angle that is personalised to the client according to Mercer, Hill, et al. (2015), it enables effective compression force balance between the IR and compression paddle with maximum breast footprint. To achieve effective compression balance, they recommend positioning the IR parallel to the sternal angle of the client. The selection of incorrect angle could lead to uneven compression force balance which could increase the levels of pain for the clients due to higher pressure points.

This study investigated contact pressure balance and contact area distribution between the breast phantom/IR and breast phantom/paddle interfaces for compressions at various IR angles ranging from 40^0 to 70^0 in 5^0 increments. On each of the angles, compression force of 10 daN was applied to a 685g silicone gel breast phantom and the final 10 frames (seconds) of pressure readings were recorded on Xsensor pressure mat.

The results of the experiment indicated that contact pressure from the breast phantom/paddle interface was consistently greater than that on breast phantom/IR interface on compressions at all IR angles. Contact pressure balance between breast phantom/paddle and breast phantom/IR interfaces varied on all seven IR angles examined. There was greater balance of contact pressure on steeper IR angles (60^0 and above) compared to less steep angles (55^0 and below). Compression at IR angle 45^0 presented the least balance of pressure from both interfaces while IR angle at 60^0 provided a greater balance of contact pressure. IR angle of 45^0, often recommended for use in mammography provided the worst balance of pressure.

Contact pressure balance difference between breast phantom/paddle and breast phantom/IR interfaces recorded at IR angle 45^0 was 1.96 mmHg and that of angle 60^0 was 0.42 mmHg. For balanced distribution of pressure, contact pressure applied from both interfaces should be equal. Lower difference in pressure value between the two interfaces represents better pressure balance and verse versa. In this case, IR angle 60^0 recorded the most balanced contact pressure distribution and 60^0 is also the sternal angle of the phantom model. It is at this angle that the IR is parallel to the angle of the sternum of the phantom model. This confirms the statement by Mercer, Hill, et al. (2015, p. 179) “The aim of the MLO is to get the sternal angle and the IR parallel to each other to enable effective compression force balance between the IR and the paddle”.

Different contact area footprint balance values between breast phantom/paddle interface and breast phantom/IR interface were recorded on all IR angles. The contact area footprint registered on breast phantom/paddle interface was greater than that of breast phantom/IR interface on all compressions. The greatest imbalance between these two interfaces was recorded at IR angle 50^0 with a difference of 4.57 cm^2 between breast/paddle and breast phantom phantom/IR interfaces. On the other hand, the most balanced contact area footprint was recorded at angle 60^0 with a difference 1.56 cm^2 between the two interfaces. The lesser the area value difference between the two interfaces, the more balanced the area footprint is. It is expected that, contact surface area on

breast phantom/paddle interface and the breast phantom/IR interface should be equal and balanced. This will allow even distribution of force on either side of the breast which could result into a more comfortable mammographic procedure.

PU and AU were calculated for each angle. The closer the PU of an angle is to zero the better the balance of contact pressure between the IR and the paddle. When PU is zero it indicates equal contact pressure from the IR and the paddle (equal distribution). There is equal contact area footprint on both the IR and paddle when the AU is zero.

There were varying PU values for the IR angles investigated (40^0 to 70^0) during compressions of the breast phantom. PU values ranged from the highest of 0.20 recorded on IR angle 70^0 and 45^0 to the lowest of 0.06 on IR angle 60^0. Three angles (40^0, 50^0 and 55^0) recorded the same PU value of 0.11 and IR angle presented the second highest PU value of 0.21.

There is equal pressure from the IR and the paddle (equal distribution) when the PU value is zero. When PU is more than zero, it indicates greater pressure from the paddle, however when the value is less than zero, then greater pressure is applied from the IR. PU on all the various angles investigated were less than zero indicating there was more contact pressure applied to the breast phantom by the paddle compared to the IR. Angles 45^0 and 70^0 recorded the least balance of contact pressure between the IR and the paddle, with both recording a PU of 0.21, while the most balanced contact pressure distribution was recorded at 60^0 with PU of 0.06. The difference between these two PU values is 0.15.

The sternal angle of the phantom model measured by the inclinometer was 60^0. This was the same IR angle which produced the greatest balance of contact pressure between the IR and the paddle. To get a perfect balance of pressure from the IR and paddle, PU must be equal to zero. For this study, the closest PU value to zero (0.06) was recorded at IR angle 60^0 and the sternal angle of the phantom model measured with an inclinometer was 60^0. At this angle, the IR is

parallel to the sternal angle of the phantom angle and it also resulted in the greatest pressure distribution between IR and paddle.

The greatest imbalance of contact area footprint between paddle and IR was registered at angle 50^0 with the value AU value of 0.15 and the greatest area balance was registered at angle 60^0 with AU value of 0.05. With regards to breast phantom area footprint, IR at 60^0 (Sternal angle for phantom model) produced greater footprint balance with AU of 0.05 compared to the other angles.

The sternal angle of the phantom model was 60^0 and it was when the IR was angled parallel (60^0) to the sternal angle that a greater pressure and area balance was achieved.

6.3 Study Limitations

The phantom utilised provided the main limitation of this study. The contact pressure measurements produced did not demonstrate the footprint of a usual MLO breast image; the back of the breast phantom (thorax region) and the axilla area were not demonstrated. This was due to the chest and the axilla regions usually demonstrated on MLO views were not included during compressions. The lateral corner of the IR could not be pushed as deep as possible in the axilla of the phantom model for compression. It was because chest area was not designed to suit that purpose and there was restricted movement of the upper limb to allow compression of the axilla region.

As such only the contact pressure and contact area footprint were recorded by the pressure mat. Other areas of the breast phantom that were not in contact with the mat during compressions were not included in analysis. Areas like the anterior part of the breast phantom and the nipple usually did not have direct contact with the paddle nor the IR so no pressure readings of these areas where recorded.

The second limitation of the study was the fact that the Xsensor pressure mapping system has the maximum limit of pressure that is detectable (256 mmHg). Contact pressure readings beyond this value is under-recorded, the main issue is that there is no means to detect by how much the mat is under-recording pressure values. This could mean vital information may be potentially missed as a result of the inability of the mat to record pressure values greater than 256 mmHg.

6.4 Areas for Improvement Prior to Human Study

One of the reasons of conducting the phantom study was to test the reliability and validity of the method so the necessary changes and adjustments are made prior to the human study. Several areas were noted for improvements:

- Artefacts were recorded during phantom breast compression which were not of value to the area of interest. Some of these artefacts resulted from creases with the pressure mat. To minimise the number of artefacts caused by the creases in future study, more effort was made to straighten and evenly spread out the mat before securing it on the IR and paddle.
- The pressure mat recorded a lot of noise when the monitor was plunged into power supply during data acquisition. The noise created as a result of this renders pressure measurement unusable for purpose. This was not anticipated before the start of the study. To rectify this problem in the human study, the monitor was fully charged before being used for data collection.
- It is anticipated that when the human study is conducted, there could be greater breast footprint for steeper angles because it will include most of the thoracic and axilla area. This is because unlike the phantom model which had restricted upper limb movement, the human could be positioned rightly on the IR to include compression of the axilla area.

6.5 Chapter Summary

This chapter has presented the discussion on the result of the phantom study. From the results, it was concluded that when the IR angle is parallel or close to the angle of the sternum, there is an even distribution of contact pressure from the breast phantom/paddle interface and breast phantom/IR interface and an improved breast phantom contact area footprint. Limitations of the study were outlined and areas for improvement for conducting human study were recommended.

Chapter Seven - Human Study (Phase Two)

7.1 Chapter Overview

This chapter will describe and justify the method used in phase two of the study. Ethical considerations will also be highlighted. In phase two, Xsensor pressure mapping system was used to compare pressure and area balance for MLO position for reference angle of 45^0, and an angle based on the measurement of the angle of the sternum of the human participant. This part of the study was undertaken on 16 participants using the same mammography unit as phase one of the study.

7.2 Ethical Considerations

Ethics is one of the vital components of health and medical care in general, and in the public healthcare sector in particular (Kooli, 2021). Research ethics govern the standards of conduct for scientific researchers and it warrants researchers adhere to ethical principles in order to protect the dignity, rights and welfare of research participants (WHO, 2011). It also ensures researchers adhere to the ethical norms of research such as being honest, not falsifying or misinterpreting research data and avoiding /minimising error during the research process.

Ethical approval was granted by both the University of Salford (**Appendix III**) and Health Research Authority (HRA) (**Appendix VI**) before data collection commenced. The management of Tameside and Glossop Integrated Care NHS Foundation Trust gave the permission for the research work to be carried out at the breast unit of the radiology department (**Appendix** I**V**). The Research and Development Department of the hospital provided confirmation of capacity and capability for the study (**Appendix V**).

7.2.1 Recruitment Strategy

The approved recruitment strategy used for phase two of the study was that emails were sent out within the Hospital Trust (**Appendix IX**). Interested volunteers were asked to contact the researcher for further information on the study. Volunteers who expressed interest in participating in the study were sent participants'

information sheet (**Appendix X**) via email, which contained the study information. The participants' information sheet was written clearly so that it would be understood by non-medical or non-healthcare people. Volunteers who agree to participate in the study were required to sign a consent form to confirm (**Appendix XI**). Records of these were kept in a locked cabinet, within the Hospital Trust and could only be accessed by the researcher and members of the research team within the Trust.

7.2.2 Right to Withdraw

With regards to the consent form, it was indicated that participants had the right to withdraw from the study, without giving any reason for doing so at any time. It was to protect the autonomy of participants. The right to withdraw is a central principle of research ethics and helps to frame the relationship between researcher and participant (Melham et al., 2014). From an ethical point of view, it was important participants knew they can withdraw from taking part in the research if they have a change of mind. In this case the participant would have their data already collected deleted from the study records. During the procedure, if the researcher detected any current signs or symptoms (e.g., breast lumps, inverted nipple dimpling) the participant will be withdrawn immediately from the study and will be advised to see their GP as soon as possible.

7.2.3 Risk Assessments

For this research all covid risk assessment requirements as discussed **section 7.6** was adhered to prior to data collection (**Appendix VII and VIII**). The University of Salford risk assessment form was submitted and approved by the Ethics Committee prior to any data being collected. Also, Tameside mammography unit (setting for the research) local rules for radiation safety compliance form was read, completed and returned to the radiation protection supervisor in the Trust. Although there was no ionising radiation used in this research work it was a departmental requirement for all individuals using the equipment. Daily QA is required to be under taken each day before the equipment is used for any purpose and this involves radiation hence the significance of knowing the local rules for the department. It was also important to have knowledge of the department's radiation

local rules to be aware of the radiological hazards which may be present and the detailed working arrangements for the department. In addition, it is important to know the names and contact details of responsible people such as radiation protection supervisor (RPS) in case there are any concerns.

7.2.4 Data Protection

The privacy of participants was protected at all times. The research adhered to the data protection guidelines provided by General Data Protection Regulation (GDPR). GDPR (2018) states that “personal data shall be processed lawfully, fairly and in a transparent manner in relation to the data subject”. It also encourages data to be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised processing. Participants’ information was kept in a secured location, and locked, and could only be accessed by the researcher and members of the research team. Privacy protection of participants were clearly stated in the participant information sheet prior to data collection and agreed on during the consent process. Data collected was anonymised so volunteers would not be identified. Volunteers were allocated numbers by the researcher, and this coded identifier was used for the research records. None of the volunteers used were identified in any conference and seminar presentations. They would also not be identified in subsequent journal publications or conference papers.

7.3 Phase 2: Method

The method for phase two of this research involved population and sampling for participants to take part in the study. Inclusion and exclusion criteria were set out for sampling the required participants for the study

7.3.1 Population and Sampling

The study population were healthy, female volunteers. They were members of staff of Tameside and Glossop NHS Hospital.

This was a feasibility study with a sample size of 16 participants. Participants were recruited via email **(Appendix IX).** The Trust Intranet/ Corporate Communications was used to seek participants by way of a trust wide email directed at all female employees of Tameside and Glossop Integrated Care NHS Foundation Trust.

As this was a feasibility study, it was not appropriate to perform a sample size calculation for such work. This is commonplace in feasibility studies however, there should be some justification and Billingham et al. (2013) confirms that calculating sample size is not necessary for feasibility studies. A sample size was based on similar work by Smith (2013); Smith, Szczepura, et al. (2015) where they investigated similar area and pressure balance in the CC view. This project had a sample size of sixteen healthy, female volunteers. The outcomes from this very similar study were able to demonstrate statistical differences, and therefore the same sample size was used in this study.

An information sheet **(Appendix X)** was linked to the invitation e-mail and potential participants were invited to make contact for further information and an informal and confidential explanation. The information sheet detailed exclusion criteria and inform women that the research would take place at a given time at the breast unit of Tameside and Glossop NHS Hospital.

7.3.2 Inclusion Criteria

Women between the ages of 40-75 and with all breast sizes were included. The NHSBSP currently offer screening mammograms to women between the ages of 50-70 and it was extended to 47 and 73 years old on the AgeX trial (NHSBSP AgeX Trial, 2020). The starting age for qualifying participants was put at 40 years because mammography is offered to symptomatic women from age 40 and the cut off age of 75 years was chosen to include all women eligible for the national breast cancer screening programme.

Additionally, screening is offered to higher risk women at a younger age before they are enrolled into the population screening programme This group include

women with significant family history of breast cancer and previous supradiaphragmatic radiotherapy e.g. treatment for Hodgkin's disease, (NHSBSP, 2013). Annual Mammographic surveillance starts from the age of 40 for these women (NICE, 2013) and no asymptomatic woman was offered surveillance mammogram before they turn 40. This is justified as younger women usually have denser breasts and the diagnostic quality of images are impaired by this. Dense breast tissue is a common finding that decreases the sensitivity of mammography in detecting cancer. The detection of lesions in the glandular part of a dense breast is very difficult and also the superimposition of different layers of the normal tissue can mimic an architectural distortion of lesion (Mokhtar & Mahmoud, 2014). According to Horny (2018), this could lead to an increase in false–positive findings, unnecessary breast biopsies, anxiety, and increased costs (Slanetz et al., 2015; Yeh et al., 2015). Again, a denser breast is likely to resist compression during mammogram and could result into a fair amount of pain and discomfort hence the reason to recruit participant from the age of 40. The cut off age of 75 is appropriate as the majority of women working at these institutions are below that age and AgeX screening stops at age 73.

7.3.3 Exclusion Criteria

Firstly, males were excluded because more than 98% of mammographic examinations are undertaken on females. The low incidence of breast cancer in males does not warrant screening mammography Popli et al. (2009) therefore, only symptomatic mammography is offered to males. Secondly, women with history of previous breast surgery were excluded as these women are more likely to have existing painful breast. Thirdly, women with breast augmentation such as implants and injectable fillers were excluded to prevent any adverse effect such as rupture of implant rupture.

The next group of women excluded in the study were those with breast implants, loop recorder or pacemaker in situ. Application of compression is usually limited on these devices and this might interfere with the results of the study. For women with breast implants, limited compression is applied during mammogram anyway so the results from these women if included in the study might not be a true

representation of pressure. Again, repeated compression might cause an adverse effect such as implant rupture.

Those women undergoing treatment for breast cancer were also excluded. These women are most likely having existing pain in the breast from treatment and might not be psychologically ready to take part in a study. Finally, women who do not have the ability to consent due to learning disability or other conditions were excluded.

7.4 Risk Assessment for Covid 19

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causing coronavirus disease 2019 (COVID-19) rapidly evolved from an epidemic outbreak in Wuhan, China (Zhu et al., 2020) into a worldwide pandemic (Lizancos Vidal et al., 2021; Terpos et al., 2020). A new infectious disease with high transmissibility (He et al., 2020; Wölfel et al., 2020; Zhan et al., 2021).

The World Health Organization (WHO) declared a global health emergency on January 30th, 2020, due to the spread of SARS-CoV-2 and its disease COVID-19 beyond the People's Republic of China (Lizancos Vidal et al., 2021). The unanticipated and rapid spread of Covid-19 around the world in early 2020 compelled governments to implement public health measures in an attempt to curb infection rates and excess mortalities (Briggs et al., 2021).

In healthcare facilities in the UK, several infection control measures were put into place to protect patients and health care workers from getting infected and subsequent spread of the virus These measures include social distancing, wearing of face mask, frequent handwashing and sanitisation of the hands.

Extra measures were taken to protect participants and the research team during data collection. Participants went through a covid assessment questions (**Appendix VII**) prior to the start of the procedure. If the participant answers yes to any of the questions, the procedure was delayed for the appropriate time to pass (period of isolation) usually 10 days after the first day of symptoms or depending

on situation (Public Health England, 2021c). This was the existing Government guidelines during the period of data collection.

To adhere to hospital guidelines with regards to social distancing, participants were to attend for the procedure on strict appointments times. Allocated appointments were schedule when there were no patients being attended to (after working hours and weekends) in the department. This was purposely done to ensure participants did not come into contact with any other individual other than the researcher during their time in the department. In addition to this, the researcher completed a covid checklist (**Appendix VIII**) before and after each data collection with each participant.

As per Government guidelines (Public Health England, 2021c) and Tameside hospital policy, it was compulsory for everyone to wear a face covering while on the hospital grounds unless exempted. Again, staff who were patient facing were to wear full personal protective equipment (PPE) which includes apron, hand gloves and visors where applicable. The research had full PPE on before contact with participants to prevent the spread of the virus. Participants were encouraged to sanitise their hand with hand gel upon entering and leaving the mammography department.

The mammography examination room was routinely wiped down before and after each participant. A suitable disinfectant wipe was used to clean all surfaces including mammography unit, control panel, participant chair, door handles and computer. As an extra precaution, the researcher took a lateral flow test to check for the absence of covid infection each day of data collection.

7.5 Chapter Summary

This chapter discussed the ethical procedure for human study. These include the recruitment strategy with sixteen participants, the right to withdraw from the study, privacy and confidentiality of data collected. As data was collected during the period of Covid pandemic, a risk assessment was produced and undertaken by the

participants and researcher. The method of the study including inclusion and exclusion criteria were discussed.

Chapter Eight - Methodology (Phase Two)

8.1 Chapter Overview

This chapter will detail the methodology used for the human research study which includes recruiting participants, study design, data collection and analysis and ethical issues. In this study, participants had their sternal angle measurement taken (experimental angle). There were two compressions on both breasts (four in total), one with the IR positioned at the angle of the sternum (experimental angle), the other at the reference angle of 45^0.

Participant's height, weight and bra size were measured and pressure and area readings from both experimental angles and the angle were recorded and analysed.

Participants then completed a pain score questionnaire after compressions to rate their pain experience on compression of the breast on both the experimental and reference angles.

8.2 Data Collection

Participants spent a maximum of an hour in the hospital on the day of participation. The procedure was explained and a signed consent (**Appendix XI**) was taken. After that, the weight and height of participants were taken and recorded on a data recording sheet (**Appendix XII**). The weight and height information were used to ascertain whether there was any relation between these parameters and the sternal angle.

Participants were asked to undress from the waist up leaving the bra on and to remove all jewellery round the neck and chest. This was to avoid any artefact from foreign items on the upper body from appearing on pressure measurement recorded.

Measurement for bra size for each participant was then taken with the bra still on. This was done by taking round measurement just below the breast and

underarm with a measuring tape. This measurement was the band size. The bust size measure was recorded by measurement loosely around the fullest part of the bust line. The cup size was calculated by subtracting the band measurement from the bust measurement. The number resulting from this was then compared on the bra measurement chat (**Table 8.1**) to get the cup size.

Table 8.1 Bra measurement Chart

(Klein, 2020)

BUST MEASUREMENT	BAND MEASUREMENT	BRA SIZE
83.5	69-71	32 A
86	69-71	32 B
89	69-71	32 C
91.5	69-71	32 D
94	69-71	32 DD
86	74-76	34 A
89	74-76	34 B
91.5	74-76	34 C
94	74-76	34 D
96.5	74-76	34 DD
89	79-81	36 A
91.5	79-81	36 B
94	79-81	36 C
96.5	79-81	36 D
99	79-81	36 DD
91.5	84-89	38 A
94	84-89	38 B
96.5	84-89	38 C
99	84-89	38 D
101.5	84-89	38 DD

The angle of the sternum was measured with the bra taken off by placing a digital inclinometer device on the sternum of each participant and sternal angle reading recorded. This was done by placing the inclinometer directly on the sternum of participants to take the angle. To maintain consistently and accuracy, measurements were taken with participants in a standing position and the upper edge of the inclinometer placed at the jugular notch to run down the length of the sternum. Inclinometer measurements were taken 3 times while participants were in the erect position and the average of these angle readings was used for setting the angle on the machine.

The Xsensor pressure mapping system was secured on the mammographic unit to cover the IR and compression plate, as per the phantom study, **(Figure 8.1)**. The pressure mat was used to read the contact pressure and contact area between the ‘breast and the compression paddle’ and the ‘breast and IR’.

During the phantom study (phase one) it was found that some of the artefacts on the pressure readings were the result of creases in the mat. In order to minimise the number of these artefacts more effort was made to straighten and evenly spread out the mat before securing it on the IR and paddle. Additionally, the pressure mat recorded a lot of noise when the monitor was plugged in to the mains power supply during data acquisition, the noise was of sufficient magnitude that the resulting data was unusable. For this study, the pressure mat and monitor were fully charged before being used for data acquisition to allow the battery to be used rather than a mains power supply.

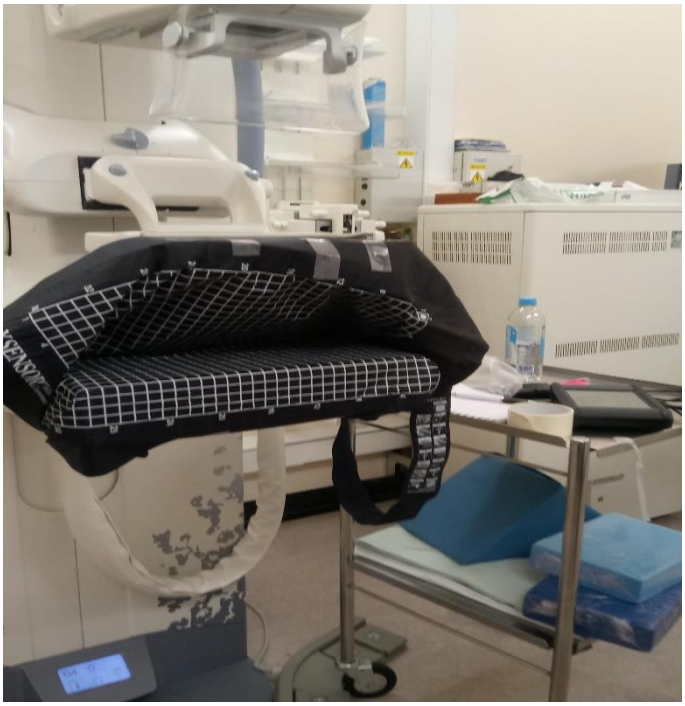

Figure 8.1 Xsensor pressure mat system wrapped around the IR and the paddle.

Depending on the size of the breast of participants, the appropriate compression paddle size was used (24x30 or 18x24). Each participant was

positioned for conventional MLO view and received four compressions, two on each breast (**Figure 8.2**).

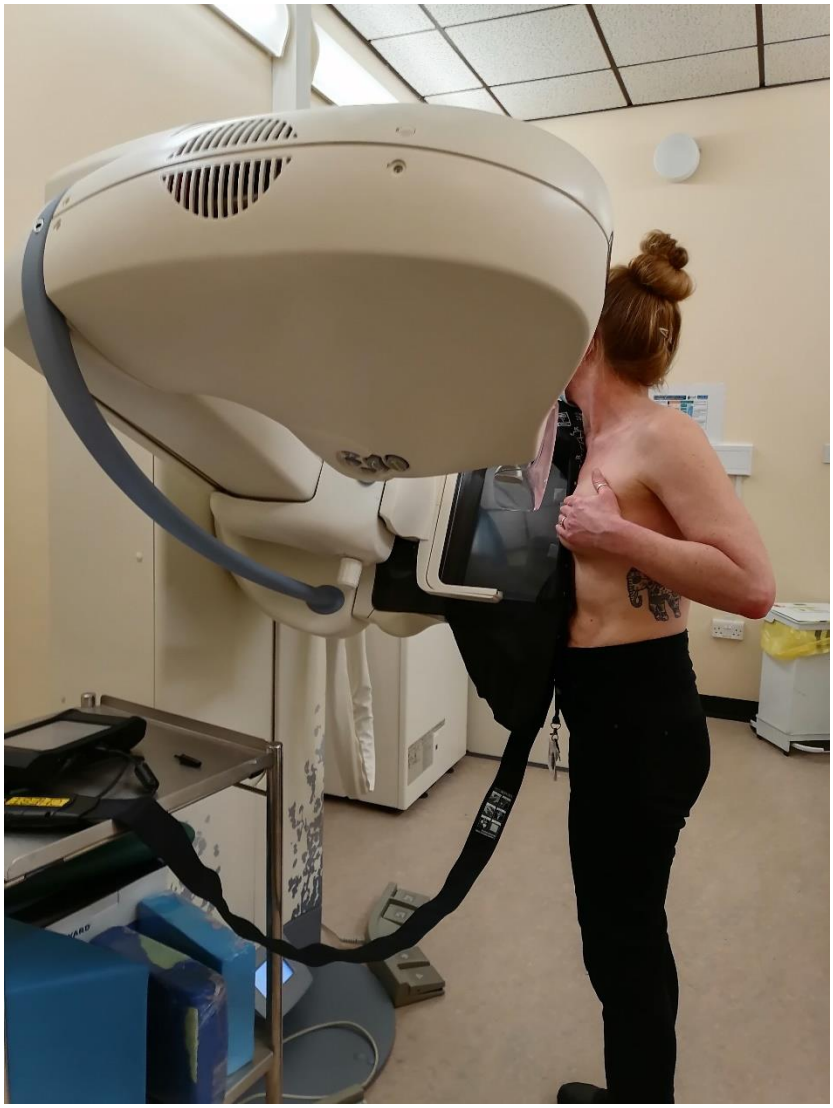

Figure 8.2 Participant positioned MLO compression on Xsensor pressure

From the 16 participants, 32 breasts were positioned in total, and from 2 sets of data (reference and experimental angle compressions) 64 data points were generated. The 32 breasts consist of right and left breasts of each participant. Data was analysed separately for the right and left breast which was 16 sets for each. The reason for separating right breast compression from the left breast for analysis was because breast asymmetry is common in human and could present varying surface contact area. According Simmons (2018), “during puberty, the left and right breast often develop at a slightly different pace. Breasts may appear

asymmetrical until they have finished growing, or they may remain different shapes and sizes throughout a person's life". Chesebro et al. (2016) adds that asymmetry of the breast in some women could be considered normal variant unless associated with a mass, microcalcifications, or architectural distortion.

Another reason for analysing compressions of the right and left breast separately was to eliminate any positioning bias. Even though the researcher positioned all participants, the technique for positioning each side of the breast may vary slightly depending on which arm is the dominant one for the researcher. This may be a subtle difference in positioning however, it could have an impact on the results if combined.

The first set of compressions was on a reference angle of 45^0 for MLO positioning. In practice, IR angle ranges from 40^0 to 55^0 depending on the body habitus, however IR angle of 45^0 is the most used by practitioners. Lee et al. (2003) advocated an angle of 45^0 as an average for most women. The second set of compressions was performed at the experimental angle derived from the inclinometer measurements on the sternum.

The applied compression force for each participant, was limited within the range of 9-13 daN . Hogg, Taylor, et al. (2013) recommended compression force within this range as the optimal range where the effect of a change in breast thickness was evident. It was noted after 13 daN the change in breast thickness with an increased compression force was not evident.

The applied compression force varied between participants, as each participant had different tolerance level to breast compression. However, to be able to compare pain experience, compression force was kept the same within the four compressions for each participant, this was important in order to assess the effects of the change of angle on the findings for the same participant.

Each pressure map reading required 15 seconds of compression. Contact pressure and area reading recorded for the last 10 seconds was used for analysis,

the initial 5 seconds allows the compression reading on the equipment to stabilise. There was a break of 1-2 minutes between compressions. This allows the researcher to change the angle of the IR as well as offer a short rest for the participant. Each participant was allocated 1 hour for the whole procedure.

Data collection was completed after compression reading were recorded and participants could then dress and leave. As started in the participants information sheet provided before consent was taken, participants were reminded it is unlikely that anything adverse will happen. However, if they had any concerns after the procedure, they are to contact the researcher or one of the research supervisors.

Contact pressure and surface area were calculated for both the breast/paddle interface and breast/IR interface. From the contact pressure, pressure uniformity between breast/IR interface and breast/paddle interface was calculated using the formula started in Chapter 5 **section 5.4**.

The statistical method used was a paired two tailed t-test to determine the critical value ($p \leq 0.05$). With the standard alpha level set at 0.05, when the p-value from the data is equal to or less than 0.05, then there is less than 5% chance that the data is random and a greater than 95% chance that the data is truly significant. Data can only be significant if p-value is very small (< 0.05) and the confidence value is greater than 95% (> 0.95).

The null hypothesis was tested to ascertain if there is any significant difference between pressure and area balance on positioning at the sternal angle and the reference angle of 45^0.

8.3 Pain Score Questionnaire

To assess pain experience on compression of the breast on the experiment and reference angles, an 11-point pain intensity numerical rating score (NRS) questionnaire (**Appendix XIII**) was completed after the two compressions on each

breast. This is a validated pain tool where 0-no pain and 10 =worst possible pain (Farrar et al., 2001; Williamson & Hoggart, 2005) and they will rate the degree of pain/discomfort for compression experienced for each compression. Williamson and Hoggart (2005) explored three commonly used pain rating scales, the Visual Analogue Scale, the Verbal Rating Scale and the Numerical Rating Scale to provide information needed to understand the main properties of these scales. They concluded that all three pain-rating scales are valid, reliable and appropriate for use in clinical practice, however NRS has good sensitivity and generates data that can be statistically analysed.

Chauny et al. (2016) investigated the challenges when using 11-point NRS (0-10). The conclusion was that NRS has good discriminant power and is less biased by specific baseline pain intensity values when used with slope of relative pain intensity difference (SlopePID). This pain score has been utilised effectively in a study by Nelson et al. (2020) in an observational study of mammography pain. Nelson et al. (2020) investigated patient's experience of pain relating to mammography and compared pain score between different groups of patients. The tool has been recently assessed in a study assessing pain in mammography and is a well-established tool for evaluating acute pain intensity (Chauny et al., 2016; Moshina et al., 2020).

Participants scored their pain experience after compression of each breast that is, compression at the reference angle and experimental angle. Halfway through compressions after the pressure and area reading has been recorded for one side of the breast, the questionnaire was completed for that side. Pressure readings were then taken for the contralateral breast after which another pain questionnaire is completed for that side. In total participants gave four pain rating, one for each compression.

Pain scores could be influenced by repeated compression by causing breast tenderness, but it could also skew it to less painful subsequent compression when participants have gone through the first compressions and are now more relaxed and comfortable and know what to expect from the procedure. To try and minimise

the impact of repeated measures (compression) on the pain experience, compressions were done on alternate angles for each breast, i.e., when the first compression on the left breast was taken on the experimental angle, the contralateral had the first compression taken on the reference angle and vice versa.

Pain experienced score was analysed using descriptive and mathematical statistical analysis. Descriptive analysis was used because it allows the description and summarisation of characteristics of responses such as the averages and standard deviation of variables. Descriptive statistics allows for data to be simply visualised and for more insight to be gained. The relationship between variables can also be assessed by using this procedure.

8.4 Chapter Summary

This chapter has discussed the methodology of phase two of this research which was the human study. It has outlined the process of data collection which includes weight, height bra and sternal angle measurements. Four breast compressions were applied on both the experimental and reference angles in the MLO positioning for each participant and pressure readings were read and recorded on Xsensor pressure mapping system.

Participants completed a pain score questionnaire to rate their pain experience on all four compressions.

Chapter Nine - Results (Phase Two)

9.1 Chapter Review

This chapter contains the analysis and results of phase two study. The hypotheses set out in chapter one **section 1.12** were tested in this chapter and results presented. The analysis of these results is presented using t-test for pressure and area uniformity and Mann-Whitney U-test for pain score. Descriptive and inferential statistics were used to present the results of the pain scale questionnaire completed by participants in this chapter. The correlation between the height and sternal angle, then height and BMI of participants were also tested using Pearson's correlation. Results from the various tests were discussed at the end of the chapter.

9.2 Data Cleansing

Pressure measurement recorded on the Xsensor pressure mapping system were exported as numeral data onto Microsoft Excel spreadsheet. A similar data cleansing format conducted during the phantom study in chapter five **section 5.1** was used.

Numerical data imported onto spread sheet was cleansed prior to data analysis. It involves deleting data points which were created by contact pressure which was not attributable to the breast phantom (artefacts). Artefacts mostly occurred at the breast/IR interface. Notes made during compression identified the orientation and position of contact pressure measurement. Therefore, any other contact pressure points far and isolated from the main image were considered artefact and were subsequently deleted.

9.3 Data Analysis

The 16 female participants for the study had an age range of 41 to 68 years with the mean age of 52.5 years and SD of 6.5. The minimum and maximum weight measured were 56.2kg and 127.3kg respectively with a mean weight and SD of 83.4kg and 22.9 (**Table 9.1**).

The body mass index (BMI) ranged from 20.2 to 44.1 with a mean of 30.1 and SD of 7.4. Bra sizes varied from 32C to 44DD. Sternal angle measurements ranged from 53^0 to 70^0 with an average of 61.9^0 for all participants. The height and weight of an individual does have an influence on the angle of the sternum. A tall slender woman is more likely to have a steeper sternal angle compared to a short and stout individual (Dronkers et al., 2001).

From the demographics of participants, it appears that most of participants (11) with higher BMI (overweight and obese) recorded lower sternal angle (**Table 9.1**). Participant 13 recorded the highest BMI of 42.9 kg/cm^2 and had a sternal angle 56^0 which was the second lowest angles recorded for all participants. The steepest sternal angle was 70^0 on participants 8 and 10 and they recorded the BMI of 22.3kg/cm^2 and 20.3 kg/cm^2 respectively. The BMI of 22.3 kg/cm^2 and 20.3 kg/cm^2 are the two lowest recorded and fall within healthy category on BMI chat. The correlation between sternal angle and height and that of sternal angle and BMI were calculated later on in **subsection 9.6.2**.

Table 9 1 Demographics of all participants

	Age/yr.	Sternal angle/^{0}	Weight/kg	Height/cm	BMI/ Kg/m^2	Bra size
1	55	67	76	160	29.7	38DD
2	51	65	65.8	167	23.6	36DD
3	56	60	62.4	167	22.4	36C
4	58	60	85.3	167	30.5	32C
5	41	53	123.2	167	44.1	40G
6	52	60	101.6	171	34.5	40FF
7	68	65	76.2	165	27.9	38B
8	48	70	57.2	160	22.3	34B
9	47	62	104.3	170	35.9	44DD
10	51	70	56.2	167	20.2	34AA
11	47	62	76.2	160	29.7	36E
12	47	58	104	165	38.2	42E
13	49	56	124.3	170	42.9	40F
14	52	60	65.3	158	26.2	36B
15	61	58	96.6	177	30.3	40F
16	57	64	59.4	162	22.6	36B
Average	**52.5**	**61.9**	**83.4**	**165.8**	**30.1**	
Max	**68**	**70**	**124.3**	**177**	**44.1**	
Min	**41**	**53**	**56.2**	**158**	**20.2**	
Std Dev	**6.5**	**4.8**	**22.9**	**4.9**	**7.4**	

After cleansing the numerical data on Excel, the averages of all compression on each participant were taken for the last 10 frames of pressure measurement recorded.

Pain experienced score was analysed using descriptive and mathematical statistical analysis. The inferential statistics used was Mann Whiney U-test. The Mann-Whitney U-test is used to compare differences between two independent groups on a single, ordinal variable with no specific distribution (McKnight & Najab, 2010). As this is a non-parametric test version of the parametric t-test, it is appropriate to use to compare pain score on compression from reference and experimental angles as the data has no specific distribution.

For each participant, 4 pressure measurements were recorded on compression, 2 on each side of the breast. Analysis was done differently for each side of the breast. **Figure 9.1** and **Figure 9.2** represent compression images of the breast and the same information translated into numerals on Excel.

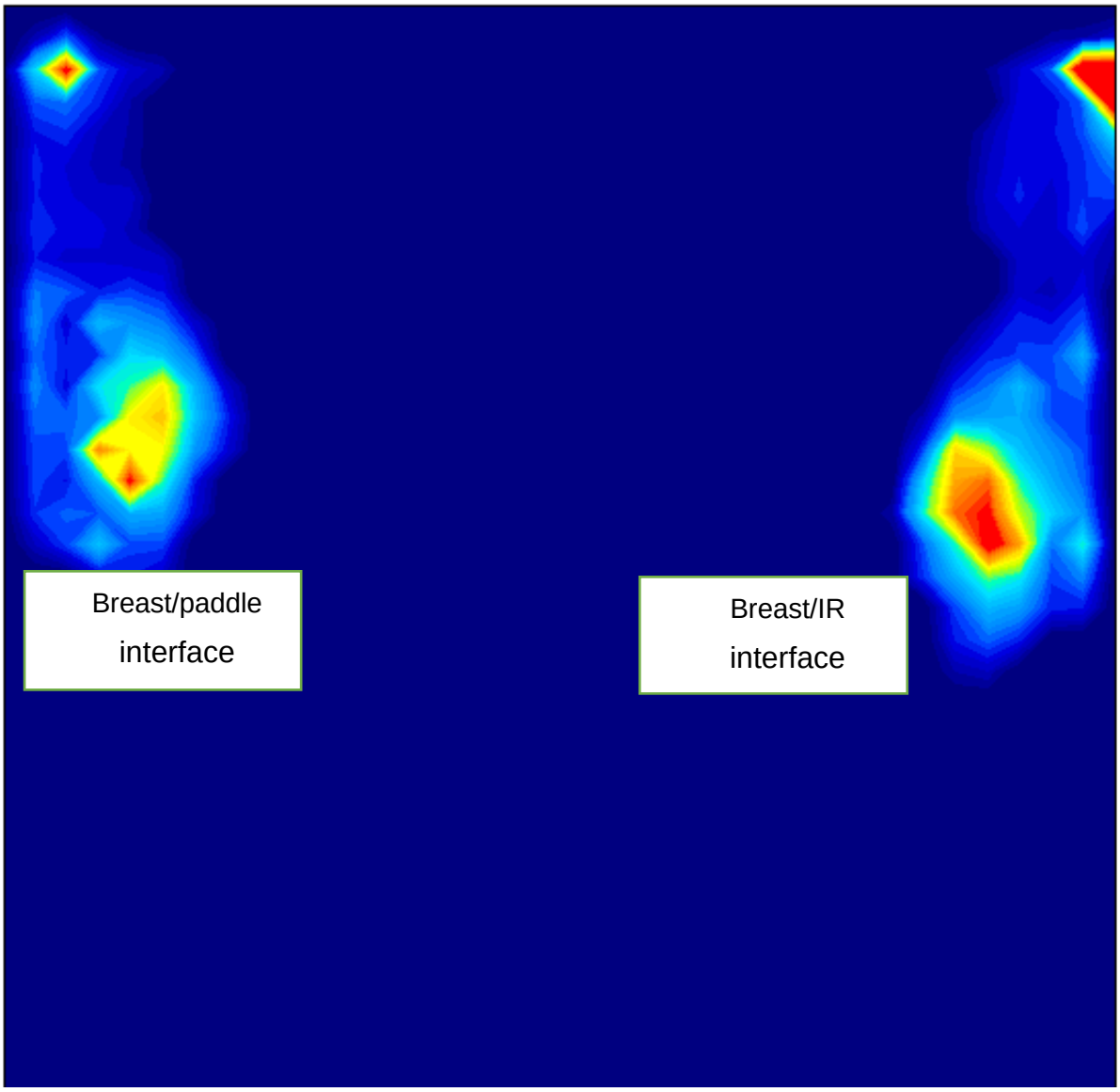

Figure 9 1 Pressure measurement demonstrating breast/IR and breast/paddle interfaces.

0	0	0	0	11.9	0	0	0	0	0	0	0	11	12.3	20.9	35	13.1	19	13	15	0	0	26.1
0	0	38.3	34.5	0	0	0	0	0	0	0	0	16.5	45.9	76.2	44.4	27.7	51.4	45	37.4	33.1	32.5	85.9
45.5	248.3	87.6	25.9	20.6	0	0	0	0	0	0	0	0	0	0	0	35.9	26.5	20.8	27.7	49.5	256	256
256	46.3	23.2	14.3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	18.2	40.6	256
157.5	33.2	30.9	12.3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12.4	16.2	30.9	256
80	30.8	12.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11.2	0	18.5	130.4
46	10.5	15.5	11.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	13.7	11.5	20.1	102.2
39.3	16.8	12.8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	16.2	26	125.9
40.6	19.8	0	11.6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12.5	23.2	28.8	104.6
31.7	18.4	18.8	0	12.4	0	0	0	0	0	0	0	0	0	0	0	14.8	12.6	0	12.1	13.6	30.3	142.5
29.5	21.6	17.1	18.8	0	0	0	0	0	0	0	0	0	0	0	0	0	11.2	0	0	22.8	30.2	204.1
24.6	15.6	16	21.1	22.4	0	0	0	0	0	0	0	0	0	0	0	14.6	10.8	0	15.8	24.8	32.2	238.4
27	22.2	20.3	24.7	10.9	13.5	0	0	0	0	0	0	0	0	0	0	15.7	19	0	22	23.2	36.4	256
26.6	16.1	22.6	35.1	34	17.1	10.4	0	0	0	0	0	0	0	0	0	23.2	24.3	25.4	26	25.9	35.4	256
16.9	22.6	35.5	30	25.7	21.6	15.9	0	0	0	0	0	0	0	0	0	37.5	39.9	28.3	24.5	27.3	50.6	256
15.2	23.6	28.3	44.2	36.7	53.7	21.7	0	0	0	0	0	0	0	0	32.1	22.7	61.7	38.6	32.1	34.1	47.4	256
26.1	29.9	43.1	40.8	65.1	193.5	31.7	0	0	0	0	0	0	0	0	29.6	61.8	69.1	44.7	37.8	35.3	48.4	256
24.8	30.5	38.7	45.2	39.9	28.5	32.7	0	0	0	0	0	0	0	19.8	41.7	45.2	62.8	36.9	48.5	44.4	124.5	256
29.9	32.7	44.7	33.9	31.8	52.1	38.8	0	0	0	0	0	0	0	12.8	138.2	72.8	54.6	71.5	50	39.1	52.9	256
28.3	36	39.8	32.3	48.7	39.7	20.6	0	0	0	0	0	0	0	12.9	55.8	67.4	69.5	49.7	38.4	32.7	56.1	256
22.9	19.4	25.9	48.9	53.8	23.2	14.7	0	0	0	0	0	0	0	14.7	48	35.9	74.1	51.6	44.3	34.2	42.6	256
0	11.8	16.2	17.3	14.9	18.7	0	0	0	0	0	0	0	0	0	26.4	40.2	76.2	69.8	40.4	32.4	28.7	256
0	0	0	0	19.6	0	0	0	0	0	0	0	0	0	0	44.4	22.2	48	42.8	33	23	19.9	85.8
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11.9	14.5	20.4	10.3	0	0	51.2
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Figure 9 2 Numerical representation of pressure on Microsoft Excel spreadsheet.

2D raw images produced from the Xsensor system were analysed for each data set.

A. **Pressure symmetry**: Demonstration of even compression applied from breast/IR and breast/paddle interfaces. It is assumed that balanced contact pressure from both interfaces will result in minimal discomfort/pain experienced during the procedure.

B. **Area footprint symmetry**: A pressure image with the same amount of breast tissue in contact with both the IR and paddle demonstrates even compression. It is again assumed that this will minimise discomfort/pain as the applied compression force is distributed over the largest possible area.

In summary, it is assumed that an image which is symmetrical in both contact area footprint and contact pressure, is likely to provide a more comfortable experience for the participants.

Contact pressure measurement was translated into numerical data and transferred onto a spreadsheet for mathematical analysis. The data from the Xsensor pressure mapping device was analysed using Microsoft Excel. The following were calculated:

a) Area of breast in contact with paddle and area of breast in contact with image receptor.
b) The maximum pressure applied to any part of the breast; minimum pressure applied to any part of the breast.
c) The average pressure applied from above the breast; average pressure applied from below the breast.
d) Pressure uniformity on both sides of the breast expressed on a scale between -1 and +1, where '0' represents perfect balance.
e) Area Uniformity on both sides of the breast expressed on a scale between -1 and +1, where '0' represents perfect balance.

A paired t-test was used to compare the following-

1. Area on breast/IR interface at 45^0 against area on breast/IR interface at experimental angle – a comparison of 86 datasets from both breast (4 on each breast).
2. Area on breast/paddle at 45^0 against area on breast/paddle interface at experimental angle – a comparison of 86 datasets.

3. Pressure from breast/paddle interface at angle 45^0 against pressure from breast/paddle interface at experimental angle – a comparison of 86 datasets
4. Pressure from breast/IR interface at angle 45^0 against pressure from breast/IR interface at Experimental angle – a comparison of 86 datasets.

From the set of data, PU, and AU from the IR to the breast and the paddle to the breast was compared. Calculations for these two has been discussed earlier in the report in chapter five **section 5.4**.

9.4 Hypothesis One

Null hypothesis H_0 one: There is no significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and it is positioned at a reference angle of 45^0 during MLO projection.

Alternative Hypothesis H_1 one: There is a significant difference between contact pressure distribution when the IR is positioned parallel to the sternal angle (experimental angle) and it is positioned at a reference angle of 45^0 during MLO projection.

To reject or not to reject the null hypothesis, a two tailed statistical t-test was used. The averages of the 10 frames of each pressure readings were taken for each participant and these were used for analysis.

For the benefit of this report the pressure readings recorded on the breast/paddle interface on the reference angle was referred to as ‘ref paddle’ while pressure recorded on breast/IR interface on the reference angle was referred to as ‘ref IR’. The same principle was applied to pressure reading recorded on breast/IR interface the experimental angle referred to as ‘exp IR’. Pressure reading on breast/paddle interface on the experimental angle was ‘exp paddle’.

9.4.1 Average Pressure

Compressions were analysed separately for left and right breast for the 16 participants as discussed in **section 8.2**. The largest pressure paddle difference between the experimental and reference angles on the left breast was 2.63 mmHg while that of the right breast was 4.96 mmHg (**Table 9.2**). The largest difference on IR interface on the left and right breast was 13.85 mmHg and 9.45 mmHg respectively.

The average pressure recorded on all compressions for all 16 participants on the left breast is presented in **Figure 9.3**. Participant 5 recorded the highest average pressure of 13.85 mmHg on IR interface on the experimental angle. The lowest average pressure was 2.14 mmHg on paddle interface for the experimental angle compression on participant 13.

The breast/IR interface recorded more pressure on both the experimental and reference angle than paddle interface for all compressions.

The mean breast/paddle interface pressure for reference angle recorded on for all participants on the left breast was 4.79 mmHg with a SD of 1.28 while that on experimental angle was 4.04 mmHg with SD 0.98. The result of the t-test ($p \leq 0.009$) shows that there was a statistically significant difference in the mean pressure between these two sets of readings. This is in contrast with mean breast/IR interface pressure for reference and experimental angles on the same breast. It recorded mean for reference angle breast/IR pressure of 6.98 mmHg with SD of 2.25 and mean for experimental angle breast/IR interface pressure of 5.39 mmHg with SD of 2.61. The resultant p-value was 0.699. For the same compression force, there is a significant difference to the mean pressure applied on breast/paddle interface on the two angles but no difference on the breast/IR interface. For right breast compression, p-value of 0.163 was the result of the t-test on mean pressure on reference and experimental angle for breast/paddle interface. Reference and experimental breast/IR interface had p-value of 0.297. For the right breast there was no significant difference of mean pressure on either

the IR or paddle interfaces for compressions on both experimental and reference angles.

Table 9 2 Average pressure balance from the paddle and IR calculated for both right and left breast

PRESSURE	LEFT						RIGHT					
#	Ref paddle	Exp paddle	Difference	Ref IR	Exp IR	Difference	Ref paddle	Exp paddle	Difference	Ref IR	Exp IR	Difference
1	6.97	4.34	2.63	12.19	9.28	2.91	3.11	3.56	-0.45	6.08	5.63	0.45
2	5.16	4.44	0.72	7.13	7.71	-0.58	4.37	6.78	-2.41	7.29	11.23	-3.94
3	5.87	5.47	0.4	8.91	7.27	1.64	5.07	5.85	-0.78	6.55	7.65	-1.1
4	6.9	5.13	1.77	10.17	7.14	3.03	3.22	6.17	-2.95	7.94	9.77	-1.83
5	5.87	3.27	2.6	7.27	13.85	-6.58	6.76	5.85	0.91	17.45	17.38	0.07
6	3.53	3.51	0.02	5.35	5.73	-0.38	4.18	3.57	0.61	5.19	6.05	-0.86
7	5.4	4.23	1.17	6.58	5.01	1.57	5.74	5.11	0.63	10	7.25	2.75
8	6.1	5.44	0.66	6.44	5.67	0.77	5.8	5	0.8	8.79	5.69	3.1
9	3.2	3.2	0	3.65	3.65	0	3.53	3.78	-0.25	3.9	5.58	-1.68
10	4.13	4.77	-0.64	4.94	5.17	-0.23	4.35	3.2	1.15	5.66	3.33	2.33
11	3.89	4.14	-0.25	7.75	6.63	1.12	2.74	2.8	-0.06	7.92	7	0.92
12	4.02	4.12	-0.1	9.18	10.57	-1.39	4.1	4.81	-0.71	7.47	6.4	1.07
13	4.18	2.14	2.04	5.84	6.26	-0.42	2.57	3.1	-0.53	8.68	9.78	-1.1
14	4.75	4.57	0.18	5.02	4.34	0.68	4.23	4.04	0.19	4.34	6.75	-2.41
15	3.66	2.73	0.93	6.81	4.55	2.26	3.63	4.31	-0.68	6.79	8.11	-1.32
16	2.98	2.89	0.09	4.53	5.39	-0.86	4	8.96	-4.96	8.47	17.92	-9.45
Average	**4.78**	**4.02**	**0.76**	**6.98**	**6.76**	**0.22**	**4.21**	**4.80**	**-0.59**	**7.65**	**8.47**	**-0.81**
Maximum	6.97	5.47	2.63	12.19	13.85	3.03	6.76	8.96	1.15	17.45	17.92	3.1
Minimum	2.98	2.14	-0.64	3.65	3.65	-6.58	2.57	2.8	-4.96	3.9	3.33	-9.45
Std Dev	1.28	0.98	1.01	2.25	2.61	2.25	1.15	1.62	1.61	3.10	4.06	3.01
Variance	1.64	0.96	1.03	5.07	6.85	5.07	1.33	2.65	2.61	9.62	16.52	9.06
Std Error	0.32	0.24	0.25	0.56	0.65	0.56	0.28	0.40	0.40	0.77	1.01	0.75
T-test		**0.009**			**0.699**			**0.163**			**0.297**	

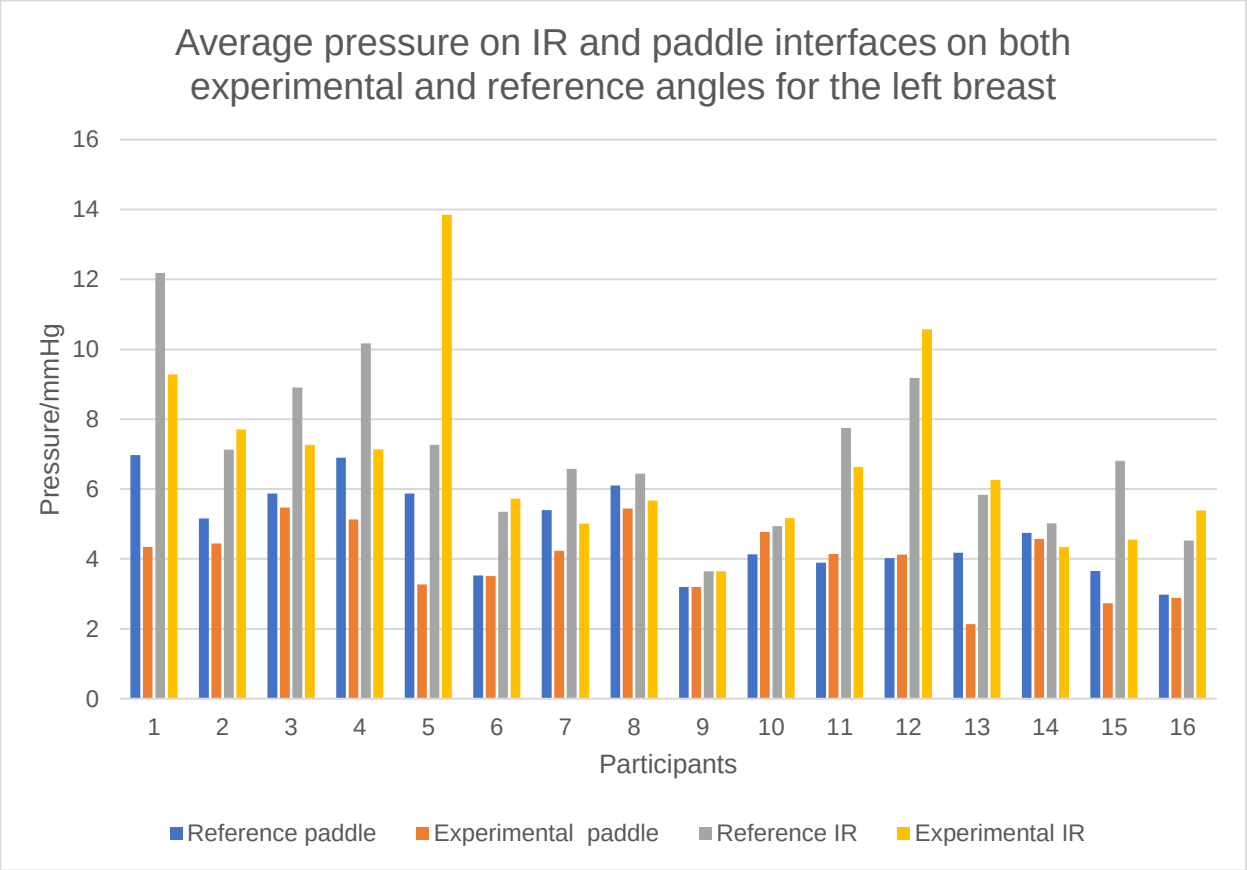

Figure 9 3 Average pressure on compression of the left breast

The right breast recorded reference paddle pressure of 4.21 mmHg with SD of 1.16 (**Figure 9.4**). For the experimental paddle pressure of the same breast, the mean was 4.81 mmHg with SD of 1.63. The resultant p-value for these was 0.1629 and this indicates a similar pressure applied to the breast from both the paddle and the IR.

The mean of 7.66 mmHg and 8.45 mmHg was recorded for ref IR and exp IR respectively. The right breast recorded its highest and lowest average pressure of 17.92 mmHg and 3.9 mmHg respectively with p-value of 0.2974.

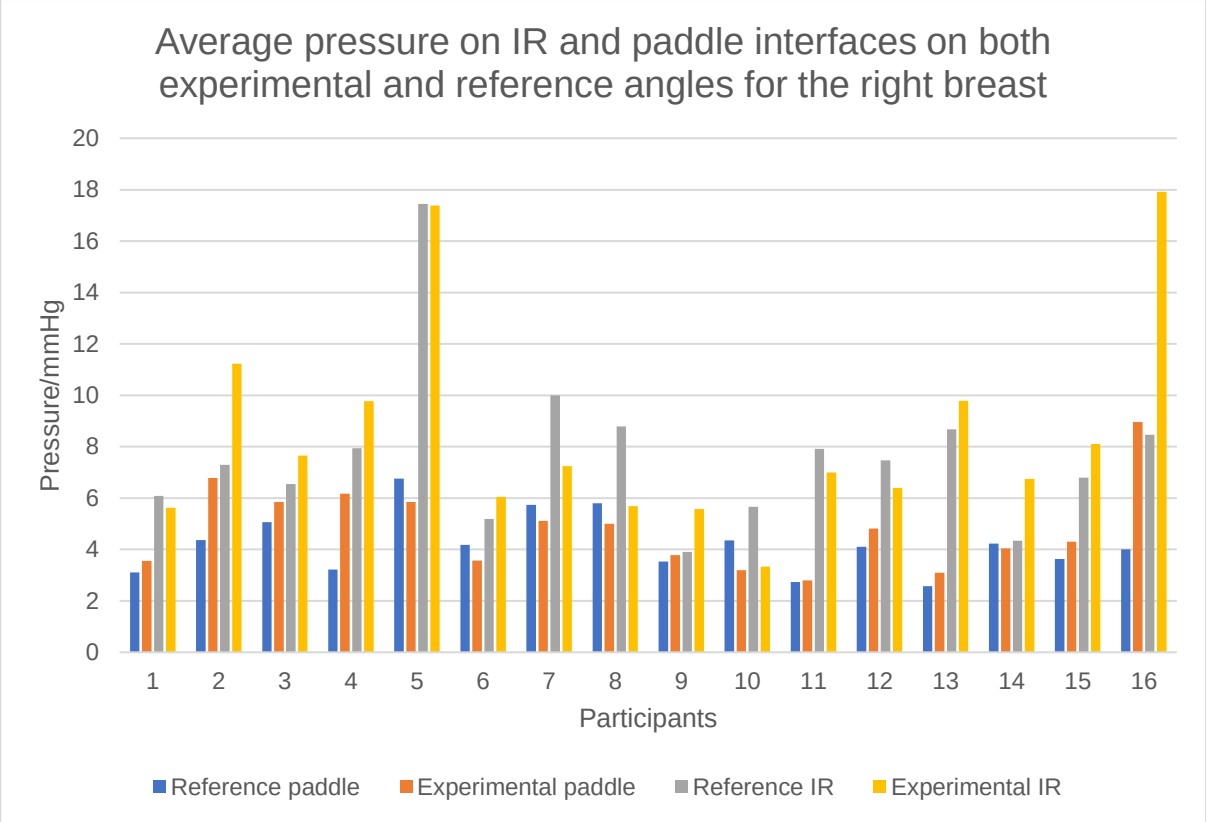

Figure 9 4 Average pressure on compression of the right breast

9.4.2 Peak Pressure

The number of peak pressures (the maximum of 256 mmHg) were recorded by every cell of the pressure mat during compression. The left and right breast compressions from the 16 participants were added together resulting into 32 compressions (**Table 9.3**). Pressure reading were recorded for 10 seconds at a frame rate 1 per second for each compression. The maximum pressure reading of 256 mmHg recorded by each cell was extracted. The highest number of cells recording the peak pressure was 152 for compression on the reference angle. Eight compressions each on both angles recorded no peak pressure reading at all on compression of the breast. From **Table 9.3** the mean for all peak pressure cells was higher for compression on the reference angle 23.53 than that on the experimental angle 22.84.

Table 9 3 Number of peak pressure cells on experimental and reference angles on all 32 compressions

Compressions	Experimental peak pressure cells	Reference peak pressure cells
1	40	20
2	0	0
3	0	10
4	32	23
5	33	34
6	11	30
7	25	16
8	10	51
9	11	11
10	130	152
11	0	0
12	0	0
13	25	26
14	40	63
15	40	0
16	33	40
17	0	0
18	11	11
19	0	0
20	0	20
21	23	11
22	30	30
23	40	10
24	20	21
25	11	20
26	0	20
27	50	51
28	50	33
29	12	10
30	10	0
31	10	0
32	34	40
Average	**22.84**	**23.53**
Max	**130**	**152**
Std Dev	**25.37**	**28.94**
Variance	**644.07**	**837.61**
Std Error	**4.48**	**5.11**
T-test	**-0.48**	

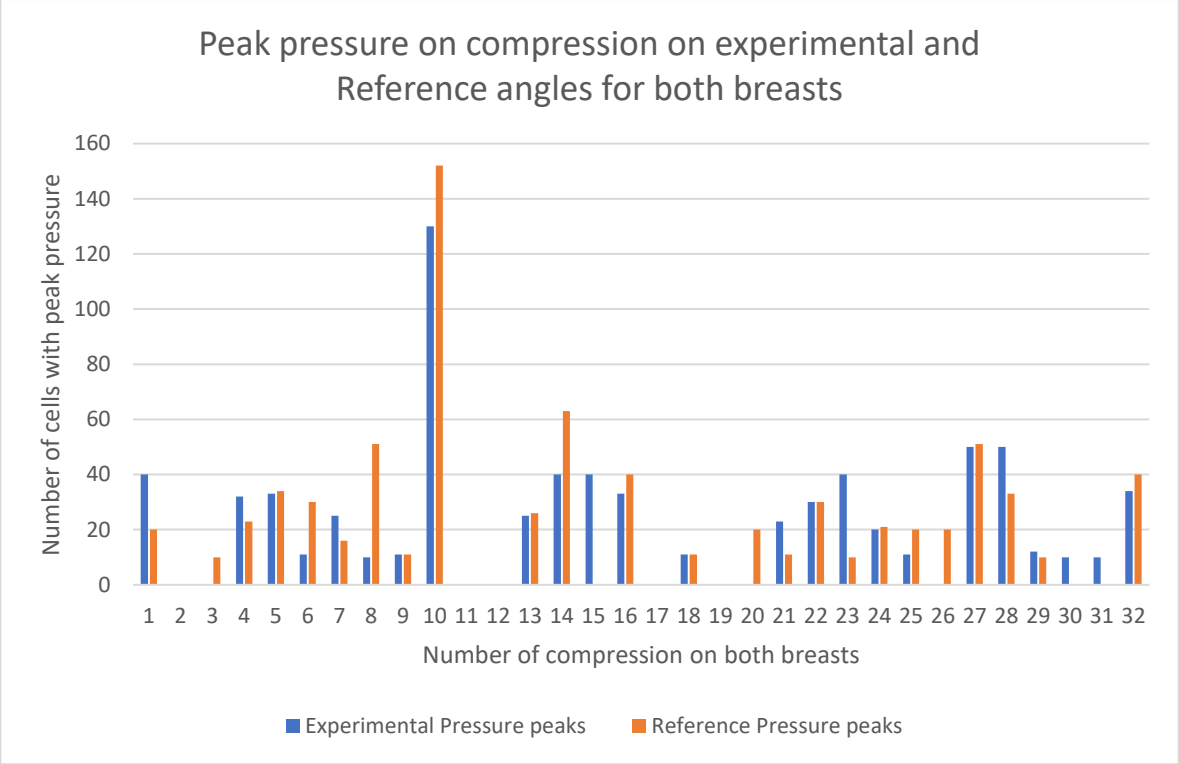

Figure 9 5 Average peak pressure on experimental and reference angles on all compressions

From **Figure 9.5**, compression on the reference angle recorded more peak pressures than the experimental angle. Out of the 32 compressions, the reference angle had 14 compressions recording the maximum peak while the experimental had 10. On 8 of the compressions, they both recorded the same number of peak cells. Eight compressions each on the experimental and reference angles did not record any peak pressure. Compression 10 had a total 152 and 130 cells registering the maximum pressure for all 10 frames for the experimental and reference angles respectively. This number of cells are more than double the next higher peak pressure cells of 60 on compression 14. The higher number of peak pressures recorded on compression 10 was due to the fact that there was a concentration of pressure applied on a section of the breast. On review of pressure recordings, the axilla region produced these peak pressures. For the LMO protocol ,it is not uncommon to experience a large part of compression to the breast. Dustler, Andersson, Brorson, et al. (2012) explained that the pectoral muscle is firmer than breast tissue, and therefore would be

subject to proportionally greater pressure, preventing optimal compression of the breast.

Compression 10 was an outliner and it was still included in the analysis as there were no difference in results when it was excluded. The p value (Table 9.3) from the T test conducted of -0.48 indicated there was no significant difference between peak pressure on experimental and reference angle compressions.

9.4.3 Pressure Uniformity (PU)

Pressure uniformity PU was calculated for each compression using the formular stated in chapter 5 **section 5.4** where:

PU= (A-B)/(A+B).

The closer the PU value is to zero, the better the balance of pressure is between the IR and paddle and vice versa.

PU on left breast compression on both experiment and reference for all participants is represented in **Figure 9.6.** The difference between the two PU is also demonstrated. The most balanced of pressure between the IR and paddle was 0.02 on the experimental angle for participant 8 while the worst balance was -0.62 on the exponential angle for participant 5. Participant 5 recorded the greatest PU difference of 0.51 between the experimental and reference angles.

Table 9 4 Pressure uniformity on compression of left and right breast.

Pressure Uniformity	Left Breast			Right Breast		
Participants	**Ref Uniformity**	**Exp Uniformity**	**Difference**	**Ref Uniformity**	**Exp Uniformity**	**Difference**
1	-0.27	-0.36	0.09	-0.32	-0.23	-0.10
2	-0.16	-0.27	0.11	-0.25	-0.25	0.00
3	-0.21	-0.14	-0.06	-0.13	-0.13	0.01
4	-0.19	-0.16	-0.03	-0.42	-0.23	-0.20
5	-0.11	-0.62	0.51	-0.44	-0.50	0.05
6	-0.20	-0.24	0.04	-0.11	-0.26	0.15
7	-0.10	-0.08	-0.01	-0.27	-0.17	-0.10
8	-0.03	-0.02	-0.01	-0.20	-0.06	-0.14
9	-0.07	-0.07	0.00	-0.05	-0.19	0.14
10	-0.09	-0.04	-0.05	-0.13	-0.02	-0.11
11	-0.33	-0.23	-0.10	-0.49	-0.43	-0.06
12	-0.39	-0.44	0.05	-0.29	-0.14	-0.15
13	-0.17	-0.49	0.32	-0.54	-0.52	-0.02
14	-0.03	0.03	-0.05	-0.01	-0.25	0.24
15	-0.30	-0.25	-0.05	-0.30	-0.31	0.00
16	-0.21	-0.30	0.10	-0.36	-0.33	-0.03
Average	-0.18	-0.23	0.05	-0.27	-0.25	-0.02
Max	-0.03	0.03	0.51	-0.01	-0.02	0.24
Min	-0.39	-0.62	-0.10	-0.54	-0.52	-0.20
Std Dev	0.11	0.18	0.16	0.16	0.14	0.12
Std Error	0.03	0.05	0.04	0.04	0.04	0.03
T-test		**0.201**			**0.527**	

Participant 9 recorded the same PU for both experimental and reference angle therefore there was no difference between the two compressions. **Figure 9.6** indicates that for most of the compression there was more pressure on the IR interface compared to the paddle hence PU below zero.

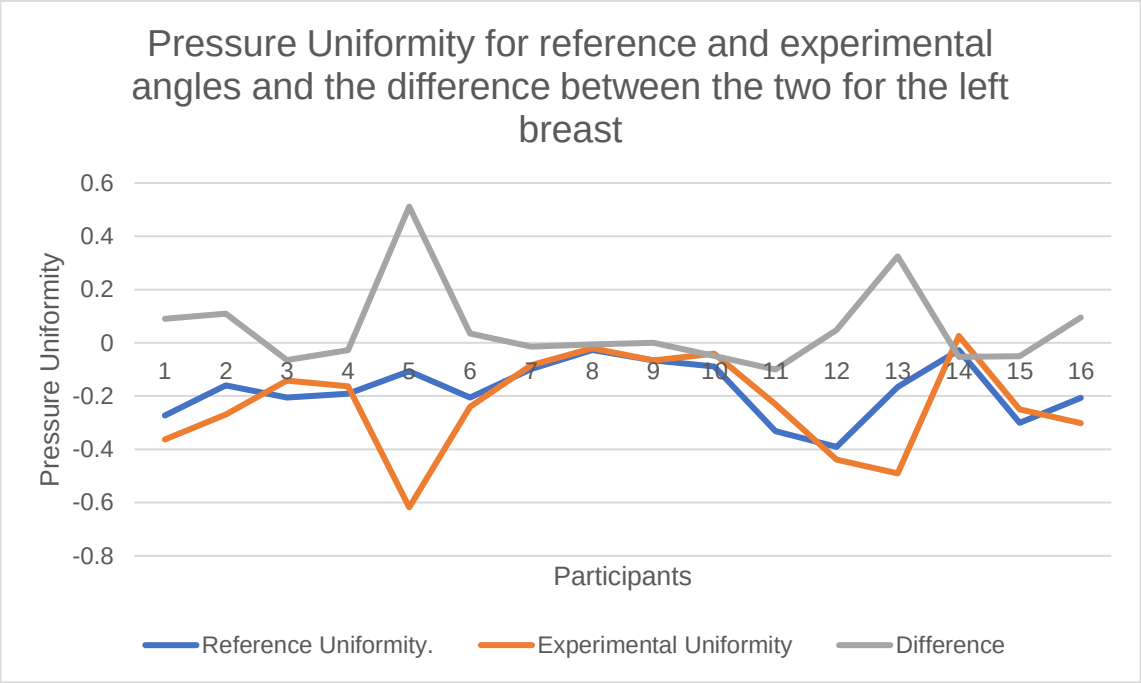

Figure 9 6 Pressure uniformity on compression of the left breast

Right breast compressions recorded the highest balance of pressure of -0.01 on the reference angle of participant 13 with the lowest of balance of 0.54 on participant 13 (**Figure 9.7**)**.** The greatest PU difference between the experimental and reference angle was 0.24 on participant 14. Participant 15 recorded a difference of zero indicating equal PU for both angles. Participant 5 had the greatest imbalance of pressure on both the reference and experimental angles while the most balanced pressure was recorded on participant 14.

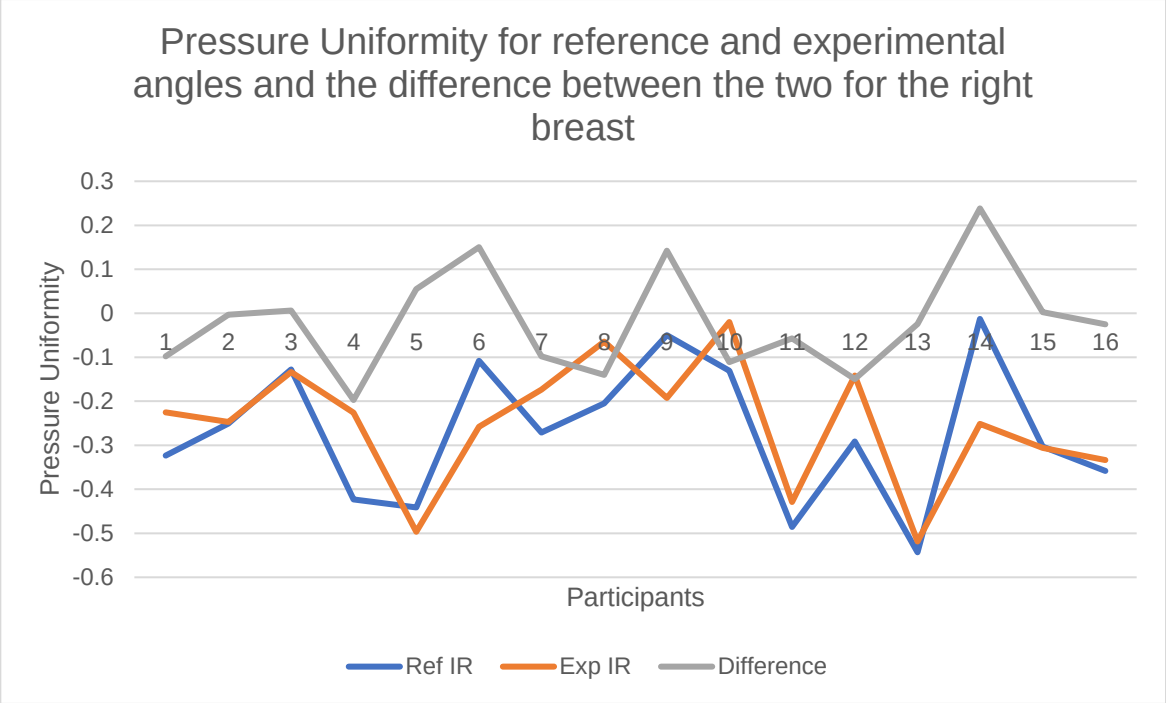

Figure 9 7 Pressure uniformity on compression of the right breast

The t-test conducted to test hypothesis one; on whether there is a significant statistical difference between pressure distribution between the experimental and reference angles resulted in p-value of 0.201 and 0.527 for left and right breast compression respectively (**Table 9.4**).

This indicates that there is no statistically significant difference between the two therefore we cannot reject the hypothesis.

9.5 Hypothesis Two

Null hypothesis H_0 two: There is no significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and it is positioned at a reference angle of 45^0 during MLO projection.

Alternative Hypothesis H_1 two: There is a significant difference between contact area distribution when the IR is positioned parallel to the sternal angle (experimental angle) and it is positioned at a reference angle of 45^0 during MLO projection.

9.5.1 Average Area

The average contact surface area for all participants was greater on the breast/IR interface than breast/paddle interface on all compressions. It could be due to the anatomy and shape of the breast, more of the breast was registered on the breast/IR interface. Some parts of the axilla could just be lying just beneath the compression paddle covered with the mat without having actual contact with it. There will be no readings on the mat if there isn't a significant surface contact pressure applied to the mat. On the left breast, the average paddle area was 26.88 cm^2 for reference angle and 24.44 cm^2 for the experimental angle. The breast/IR interface recorded an average of 32.02 cm^2 and 33.91 cm^2 for reference and experimental angles respectively. Surface contact area for the right breast for reference and experimental angles on breast/paddle interphase was 27.74 cm^2 and 29.60 cm^2 with that on breast/IR interface being 38.06 cm^2 and 37.32 cm^2. There was more contact surface area on breast/IR interface than breast/paddle interface on all participants.

On left breast compression, there was a decrease in breast/paddle interface contact surface area from compression on the reference angle to the experimental angle on 13 out of 16 participants (**Table 9.5**). The largest difference between the angles for breast/paddle interface surface area was 8.39 cm^2 on participant 2. On breast/IR interface, there was a decrease in surface area contact on 9 out of the 16 participants from reference angle to the experimental angle. However, there was a large increase in area on participants 5 and 9 with an increase from 34.19 cm^2 to 55.48 cm^2 and 27.1 cm^2 to 47.73 cm^2 respectively,

Compression of the right breast resulted in an increase in paddle contact area from reference to experimental angles in 9 participants, while the IR recorded an increase in half (8) of participants.

Table 9 5 Average contact surface area on all compression.

AREA	LEFT						RIGHT					
#	Ref paddle	Exp paddle	Difference	Ref IR	Exp IR	Difference	Ref paddle	Exp paddle	Difference	Ref IR	Exp IR	Difference
1	28.39	26.^{0}	1.94	33.55	29.68	3.87	27.1	26.45	0.65	35.81	30.65	5.16
2	35.81	27.42	8.39	36.45	32.26	4.19	29.68	30.97	-1.29	36.77	38.06	-1.29
3	30.65	30.32	0.33	39.35	35.16	4.19	26.45	31.29	-4.84	29.35	32.26	-2.91
4	22.9	27.1	-4.2	29.03	33.55	-4.52	19.68	22.9	-3.22	30.65	30	0.65
5	28.06	21.94	6.12	34.19	55.48	-21.29	40.97	41.29	-0.32	66.77	61.9	4.87
6	27.10	26.77	0.33	33.23	36.77	-3.54	32.26	37.1	-4.84	44.19	45.16	-0.97
7	22.90	20.32	2.58	29.68	28.06	1.62	27.1	25.81	1.29	33.55	28.39	5.16
8	26.13	23.87	2.26	31.61	28.71	2.90	29.03	25.48	3.55	31.61	22.58	9.03
9	27.74	27.74	0.00	27.10	47.74	-20.64	25.16	24.84	0.32	25.16	28.71	-3.55
10	15.16	12.90	2.26	12.58	12.58	0.00	17.74	14.52	3.22	15.81	12.26	3.55
11	24.84	23.87	0.97	37.42	31.94	5.48	26.13	25.16	0.97	43.23	39.68	3.55
12	29.68	28.71	0.97	35.16	44.84	-9.68	32.26	30.65	1.61	48.06	36.13	11.93
13	31.94	26.77	5.17	39.35	40.65	-1.30	32.58	37.74	-5.16	53.87	58.06	-4.19
14	20.97	17.42	3.55	20.97	19.68	1.29	17.42	20.32	-2.9	24.19	26.45	-2.26
15	40.00	32.26	7.74	51.94	41.61	10.33	41.29	46.45	-5.16	56.13	65.16	-9.03
16	17.74	17.10	0.64	20.65	23.87	-3.22	19.03	32.58	-13.55	33.87	41.61	-7.74
Average	26.88	24.44	2.44	32.02	33.91	-1.90	27.74	29.60	-1.85	38.06	37.32	0.75
Maximum	40.00	32.26	8.39	51.94	55.48	10.33	41.29	46.45	3.55	66.77	65.16	11.93
Minimum	15.16	12.90	-4.20	12.58	12.58	-21.29	17.42	14.52	-13.55	15.81	12.26	-9.03
Std Dev	6.30	5.27	3.19	9.09	10.75	8.79	7.25	8.16	4.30	13.26	14.46	5.80
Variance	39.75	27.73	10.17	82.63	115.64	77.34	52.49	66.66	18.53	175.73	209.18	33.69
Std Error	1.58	1.32	0.80	2.27	2.69	2.20	1.81	2.04	1.08	3.31	3.62	1.45
T-test		**0.0079**			**0.4023**			**0.1054**			**0.6140**	

The average area on both the IR and paddle interfaces on compression of the left breast for experimental and reference angles are illustrated in **Figure 9.8**. On the paddle interface there was an increase in surface area contact from in all participants but one (participant 4) from experimental paddle to reference paddle. The highest paddle area difference was 8.39 cm^2 on participant 2 while the lowest difference was 0.33 cm^2 on participant 3. There was no difference in surface area for participant 9.

Average surface area on the IR were considerable higher than surface area recorded on the paddle for all compression. Seven participants had more paddle surface area contact on the experimental angle than the reference angle and 9 had more surface area recorded on the paddle reference angle than the experimental angle (**Table 9.5**)**.** The highest breast/IR area difference was 21.29 cm^2 and the lowest recorded was 1.63 cm^2. Participant 10 recorded no difference in surface area at all for both experimental and reference IR.

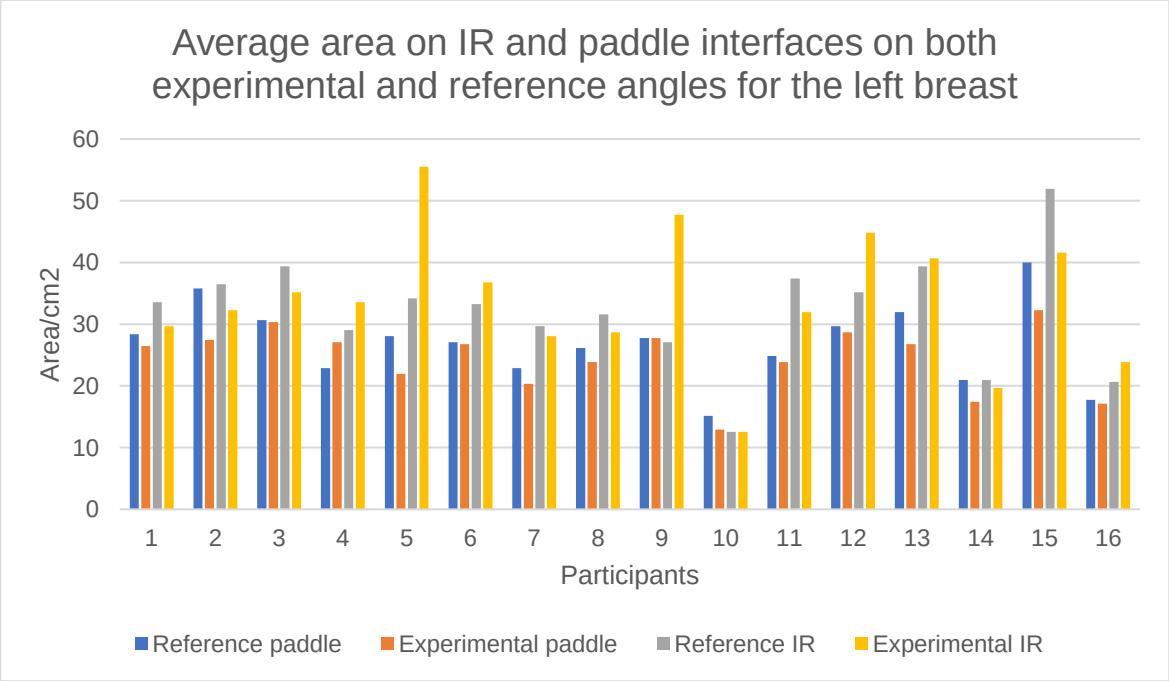

Figure 9 8 Average area on compression of the left breast

The right breast experimental paddle compression recorded the highest and lowest surface area of 46.45 cm^2 and 14.54 cm^2 respectively against reference paddle of 41.26 $cm^2$and 17.42 cm^2 (**Figure 9.9**). Nine out of the 16 participants had more paddle contact surface area on the experimental angle than the reference angle with the remaining 7 recorded more surface contact area on the reference angle. Reference IR compression highest surface area was 56.13 cm^2 with the lowest being 15.81 cm^2. while experimental recorded the highest of 65.16 cm^2 and lowest of 12.26 cm^2.

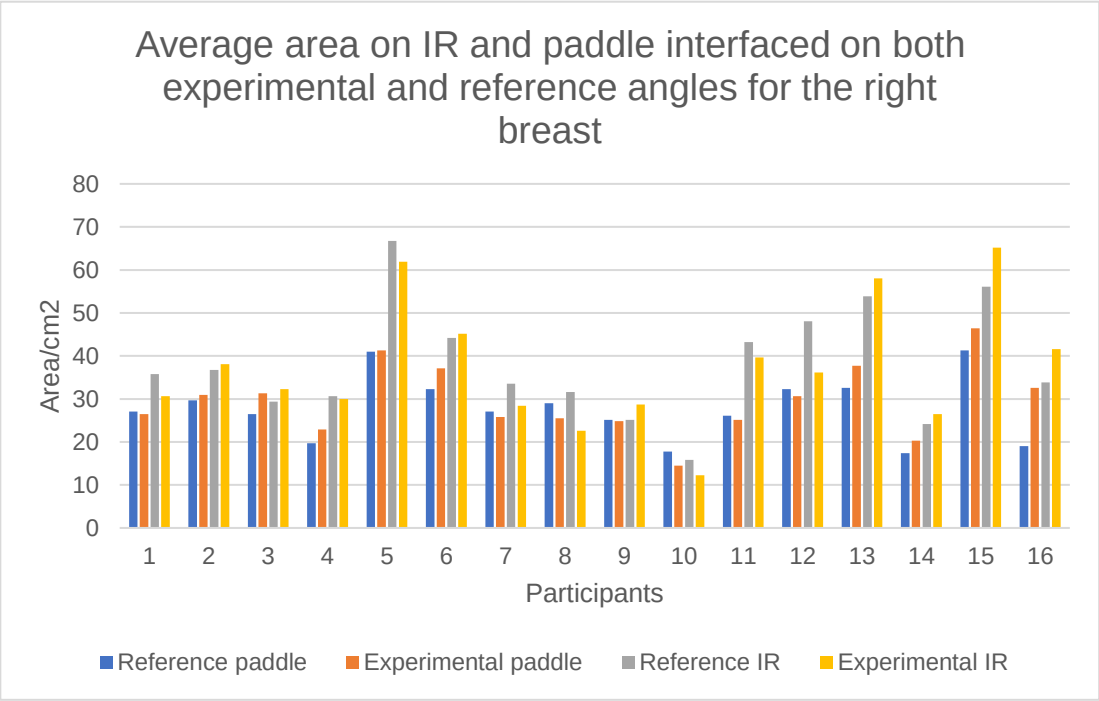

Figure 9 9 Average area on compression of the right breast

In summary, on the left breast the difference of the average breast/paddle surface area from the reference angle to experimental angle for all participants was 2.33 cm^2. This implies there was more breast coverage on the paddle on the reference angle compression than the experimental angle. On the other hand, the reference angle recorded less breast/IR surface area than the experimental angle. The difference between the two angles was -1.90 cm^2 indicating more breast/IR surface are on the experimental angle.

The difference in average breast/paddle surface area for the right breast was -1.85 cm^2 indicating more surface area on compression of the breast on the experimental angle than that of the reference angle. The opposite is true for average breast/IR surface area. The reference angle recorded more surface area with the average difference between the two angles being 0.75 cm^2.

The t-test results on the average paddle surface area on the left breast for both reference and experimental angles was p =0.0079 (**Table 9.5**). This indicates a significant difference between the mean area for the two angles. On the other hand, average IR surface area on the left breast for experimental and reference angle had significance of p =0.4023.

A p-value of 0.1054 was the result of the t-test on average area on reference and experimental angle paddle compression. Reference and experimental IR had p=0.6140. For the right breast there was no significant difference of surface on neither the IR or paddle interface for both experimental and reference angles.

9.5.2 Area Uniformity (AU)

Area uniformity was calculated using the formula stated in chapter 5 **section 5.4** where:

AU = (C-D)/ (C+D).

The closer the AU value is to zero the better the balance of area between the paddle and the IR and verse versa.

Compression on the left breast recorded the worst AU of -0.43 on the experimental angle on participant 5 while the best of 0.01 was recorded on the reference angle on participant 9. (**Figure 9.10**). The AU of 0.00 was achieved on compression on the reference angle of participant 14, signifying a perfect balance of surface area contact between the paddle and IR. The AU difference between experimental and reference angles ranges from minimum of 0.01 and maximum of

0.13. Participant 8 recorded a difference of 0.00 indicating the same contact surface area on compressions on both angles.

The greatest AU difference between compressions on the experimental and reference angles was 0.33 on participant 5.

Table 9 6 Area uniformity on all compressions

Area Uniformity	LEFT			RIGHT		
#	Ref Uniformity	Exp Uniformity	Difference	Ref Uniformity	Exp Uniformity	Difference
1	-0.08	-0.06	-0.03	-0.14	-0.07	-0.06
2	-0.01	-0.08	0.07	-0.11	-0.10	0.00
3	-0.12	-0.07	-0.05	-0.05	-0.02	-0.04
4	-0.12	-0.11	-0.01	-0.22	-0.13	-0.08
5	-0.10	-0.43	0.33	-0.24	-0.20	-0.04
6	-0.10	-0.16	0.06	-0.16	-0.10	-0.06
7	-0.13	-0.16	0.03	-0.11	-0.05	-0.06
8	-0.09	-0.09	0.00	-0.04	0.06	-0.10
9	0.01	-0.26	0.28	0.00	-0.07	0.07
10	0.09	0.01	0.08	0.06	0.08	-0.03
11	-0.20	-0.14	-0.06	-0.25	-0.22	-0.02
12	-0.08	-0.22	0.13	-0.20	-0.08	-0.11
13	-0.10	-0.21	0.10	-0.25	-0.21	-0.03
14	0.00	-0.06	0.06	-0.16	-0.13	-0.03
15	-0.13	-0.13	0.00	-0.15	-0.17	0.02
16	-0.08	-0.17	0.09	-0.28	-0.12	-0.16
Average	-0.08	-0.15	0.07	-0.14	-0.10	-0.05
Max	0.09	0.01	0.33	0.06	0.08	0.07
Min	-0.20	-0.43	-0.06	-0.28	-0.22	-0.16
Std Dev	0.07	0.10	0.11	0.10	0.09	0.05
T-test		**0.025**			**0.003**	

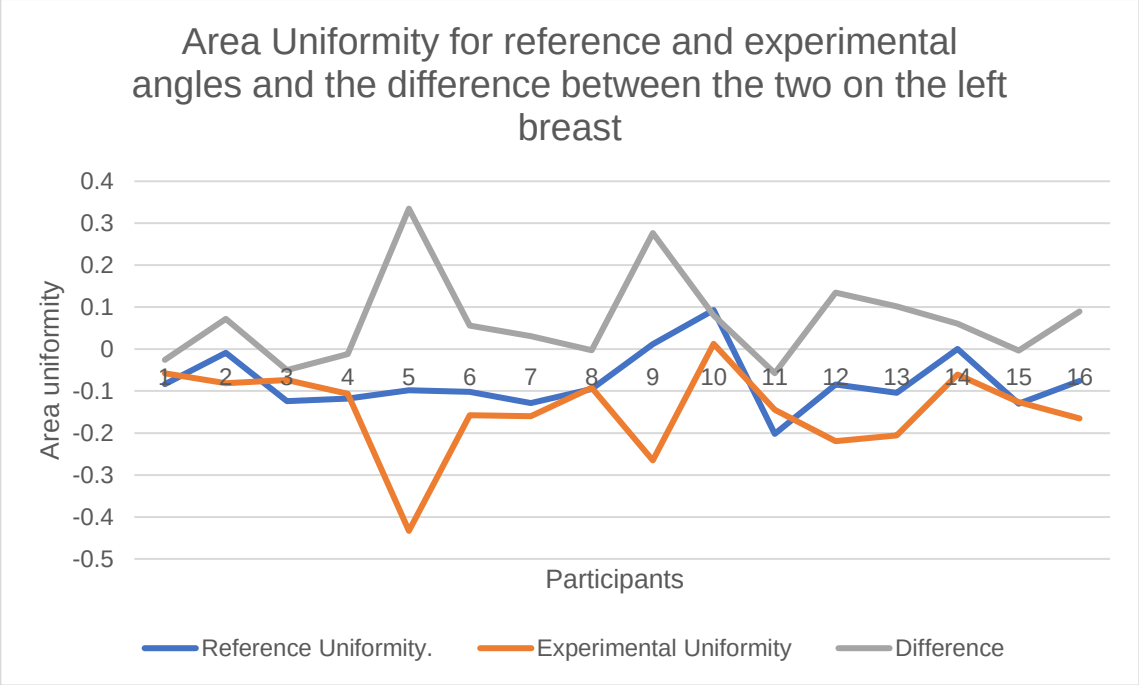

Figure 9 10 Area uniformity on compression of the left breast

The AU on compression of the right breast registered the highest and lowest of 0.28 and -0.02 respectively (**Figure 9.11).** There was more contact surface area on the paddle interface compared to the IR interface on majority of compressions. Reference angle compressions had 14 out of the 16 participants having AU negative figure denoting more contact area on the paddle to that of the IR. It recorded an average AU of -0.14 on reference angle for all participants while the average for the experimental angle was -0.10 on the right breast.

The highest and the lowest difference between the AU of the experimental and reference angle as demonstrated in **Figure 9.11** are -0.16 and -0.02 respectively. The highest difference of -0.16 was recorded on participant 16.

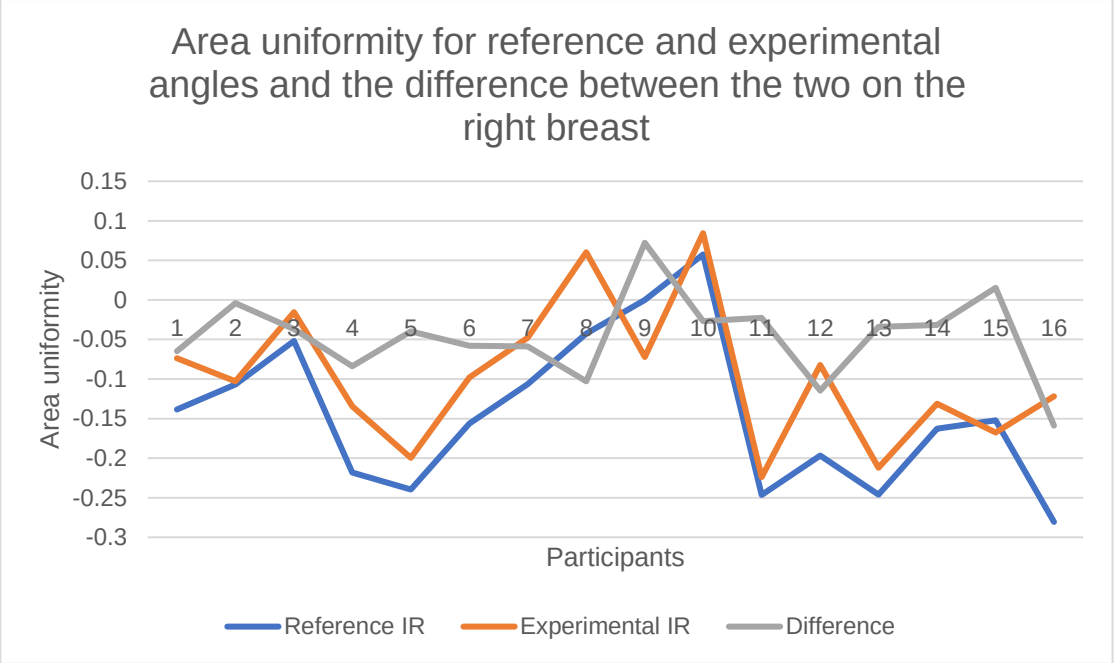

Figure 9 11 Area uniformity on compression of the right breast

The result of the t-test to ascertain if there was statistically significant difference between AU for the experimental and reference angles had p≤0.025 for the left breast and p≤0.003 for the right breast (**Table 9.6**).

The low p-value (p≤0.025) of surface area for compression on experimental and reference angles of the left breast indicates there is a statistical difference in contact surface area when compressions are made on these angles therefore **the null hypothesis was rejected.**

For the right breast, the lower p-value (p≤0.003) shows there is a significant statistical difference between surface area on compression of the breast on the experimental angle and reference angle. For this reason, **the null hypothesis was rejected on this occasion.**

9.6 Pain Score Analysis- Hypothesis Three

Participants completed an 11-point pain NRS questionnaire (**Appendix XIII**) to rate any pain/discomfort experienced during compression. In this section, both descriptive and inferential statistics were used. Descriptive statistics in the form of tables and graphical representation such as graphs and charts while confidence interval and Mann-Whitney U-test were used for inferential statistics. The correlations between height and sternal angle, then sternal angle and BMI of participants were also tested using Pearson's correlation.

With 11-point NRS pain rating 0=no pain, 5=moderate pain and 10=worst possible pain **Figure 9.12** however, it is difficult to interpret the clinical importance of changes from baseline on the scale such as a 1- or 3-point decrease on a 0-10-point scale (Farrar et al., 2001). According to Moore et al. (1996) the criteria to define the level of change that best represents a clinical importance improvement have usually been determined based on face validity. Meanwhile Farrar et al. (2001) established in their study that a reduction of approximately two points or a reduction of approximately 30% in the PI-NRS represents a clinically important difference.

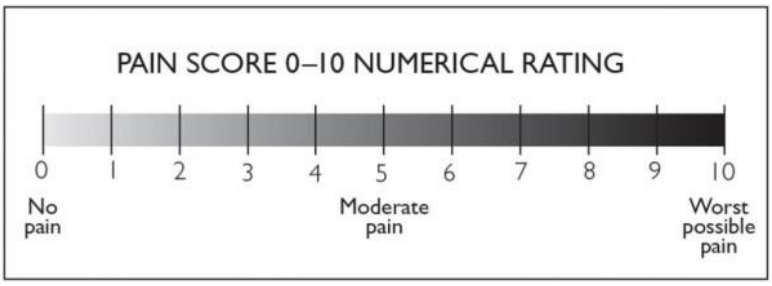

Figure 9 12 11-point pain NRS demonstrating the numerical implication of the numbers.

9.6.1 Descriptive Statistics

Pain score data was collected from all 16 female participants, age ranged 41 to 68 years with the mean age of 52.5 years and SD of 6.5. From **Table 9.7**, the steepest

sternal angle of 70^0 was recorded on participant 10 who also was the second tallest in the group with the height of 167 cm.

The average pain score on the experimental angle and reference angle on the left breast was 4.38 and 5 respectively, while the average on the right breast for experimental and reference angle was 3.44 and 4.56 respectively.

Table 9 7 Pain score on compressions by participants

Participants	Sternal angle/^{0}	Right experimental Pain rate	Right reference pain rate	Left experimental pain rate	Left reference pain rate
1	67	3	3	5	5
2	65	4	5	4	4
3	60	5	4	3	4
4	60	1	9	1	9
5	53	2	4	7	9
6	60	6	9	9	10
7	65	2	2	1	2
8	70	1	0	0	1
9	62	2	1	3	4
10	70	6	7	8	6
11	62	4	3	5	4
12	58	2	1	2	3
13	56	2	8	8	2
14	60	5	5	6	7
15	58	2	6	2	4
16	64	8	6	6	6
Average	**61.88**	**3.44**	**4.56**	**4.38**	**5**
Std Dev	**4.76**	**2.06**	**2.83**	**2.80**	**2.65**

The right experimental angle compression recorded the highest and lowest pain score of 8 and 1 with the reference angle scoring the highest and lowest of 9 and 0 respectively (**Figure 9.13**). Majority of participants (81%) pain score difference between the experimental and reference angle ranged from 1 to maximum of 3. However, the biggest difference was scored by participant 4 with a pain score of 9 and 1 for the reference and experimental angles respectively, the difference of 8 points. The second biggest difference was 7 points from participant 13 who score 8 and 2 for experimental and reference angles respectively.

Participant 8 recorded zero for no pain on the reference angle compared to 1 for the experimental angle.

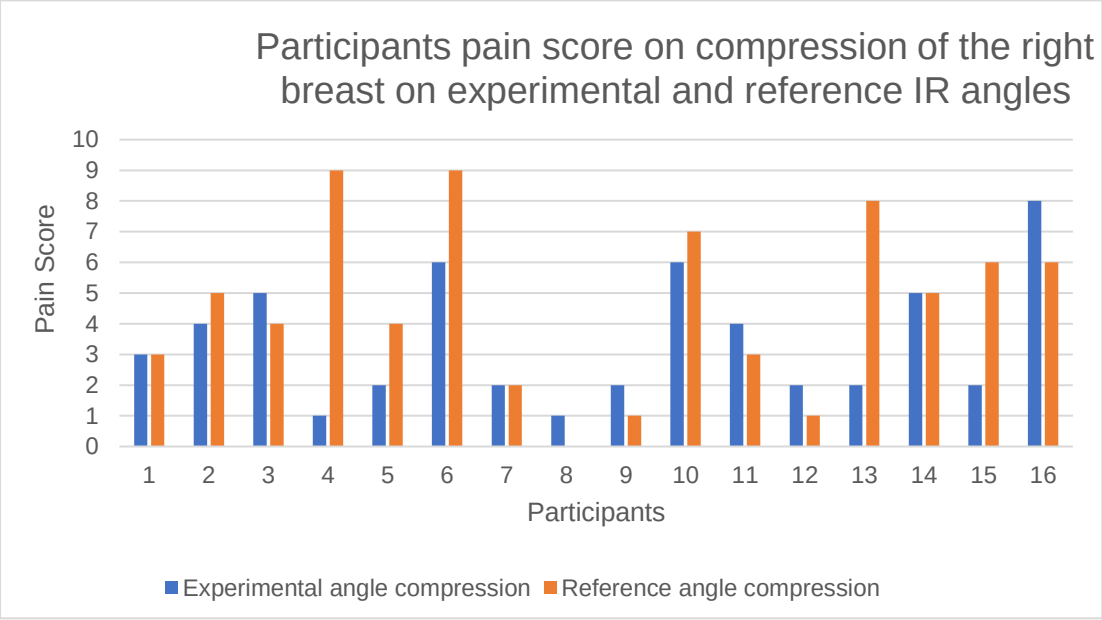

Figure 9 13 Demonstrating the pain experienced by participant on compression of the right breast on experimental and reference angles.

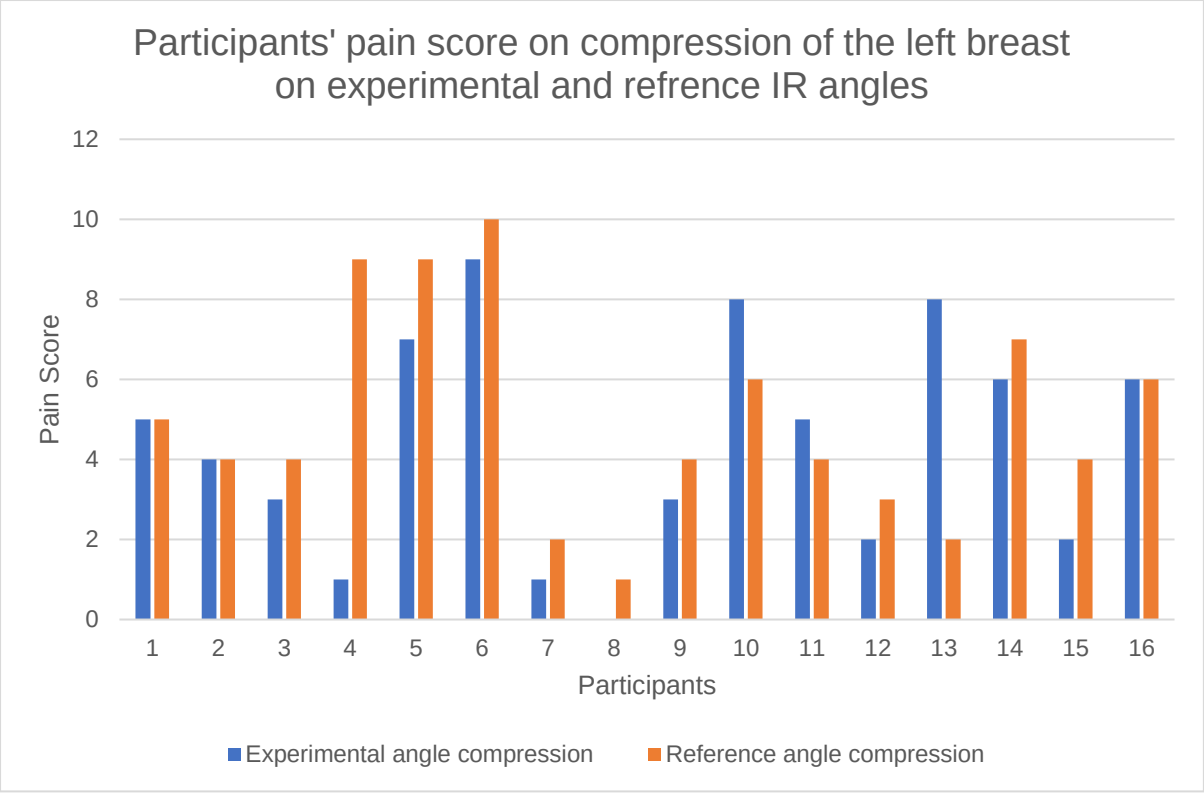

Figure 9 14 Demonstrating the pain experienced by participant on compression of the left breast on experimental and reference angles.

For left breast compressions. the maximum pain of 10 was scored on the left breast on the reference angle by participant 6 and a high score of 9 was given for the experimental angle as well (**Figure 9.14).** No pain with a score of zero was given by participant on the experimental angle and 2 for reference angle. The greatest score difference between the two angles on the same participant (participant 13) was 6.

On the average, the 69% of women marked their pain at 5 or below for compression on the experimental angle while 56% marked it on more than 5.

The right and left breast compressions were combined for both the experimental and reference angles that resulted into a total of 32 compressions in **Table 9.8**. The difference between the pain score of the two angles were established by subtracting reference pain score from experimental pain score. A difference of a negative figure suggests less pain experienced on the experimental angle. A positive figure indicates more pain experience on the experiment angle while zero indicates no difference in pain between the pain experienced on the experimental and reference angles.

In 13 out of the total 32 compressions scores, there was a decrease in pain score from compression on the reference angle to the experimental angle. This means 41% of the response on pain$ experience from compressions found less pain on the experimental angle than that on the reference angle. A total of 10 responses (31%) found no difference in pain experience on compression on either angle. Out of the 32 compressions score, 9 (28%) experienced more pain on the experimental angle to that on the reference angle.

Table 9 8 Combined right and left compression pain score on both experimental and reference angles.

Compressions	Experimental angle compression	Reference angle pain score	Difference in pain score
1	3	5	-2
2	4	4	0
3	5	4	1
4	1	9	-8
5	2	9	-7
6	6	10	-4
7	2	2	0
8	1	1	0
9	2	4	-2
10	6	6	0
11	4	4	0
12	2	3	-1
13	2	2	0
14	5	7	-2
15	2	4	-2
16	8	6	2
17	5	3	2
18	4	5	-1
19	3	4	-1
20	1	9	-8
21	7	4	3
22	9	9	0
23	1	2	-1
24	0	0	0
25	3	1	2
26	8	7	1
27	5	3	2
28	2	1	1
29	8	8	0
30	6	5	1
31	2	6	-4
32	6	6	0
Mean	**3.91**	**4.78**	**-0.88**
Standard deviation	**2.47**	**2.71**	**2.74**

The mean difference of pain score between the two angles was -0.88 with the SD of 2.74. A negative mean value indicates less pain experienced on the experimental angle to that experienced on the reference angle.

9.6.2 Mathematical Statistical Analysis

The correlation between height and sternal angle, then sternal angle and BMI was tested using Pearson's correlation. The correlation between sternal and BMI is demonstrated in **Figure 9.15.** BMI decreases with increasing sternal angle and the statistical output below indicates that the Pearson's correlation coefficient was -0.773

Pearson correlation of BMI and sternal angle = -0.773

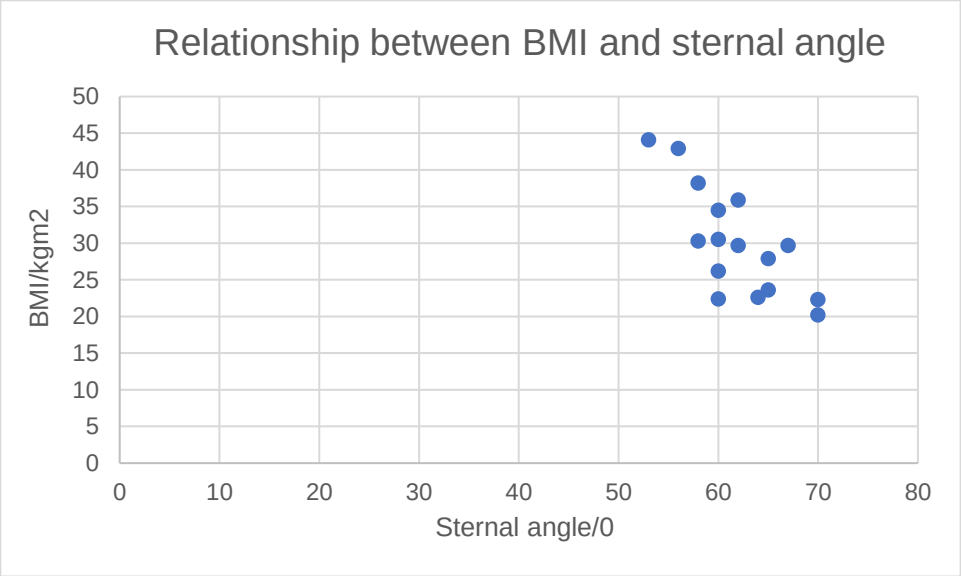

Figure 9 15 Correlation between BMI and sternal angle for all participants

A negative coefficient in this case has shown a downward sloped which represents the decrease in BMI with increasing sternal angle. This represents a fairly strong negative relation between sternal angle and BMI of participants.

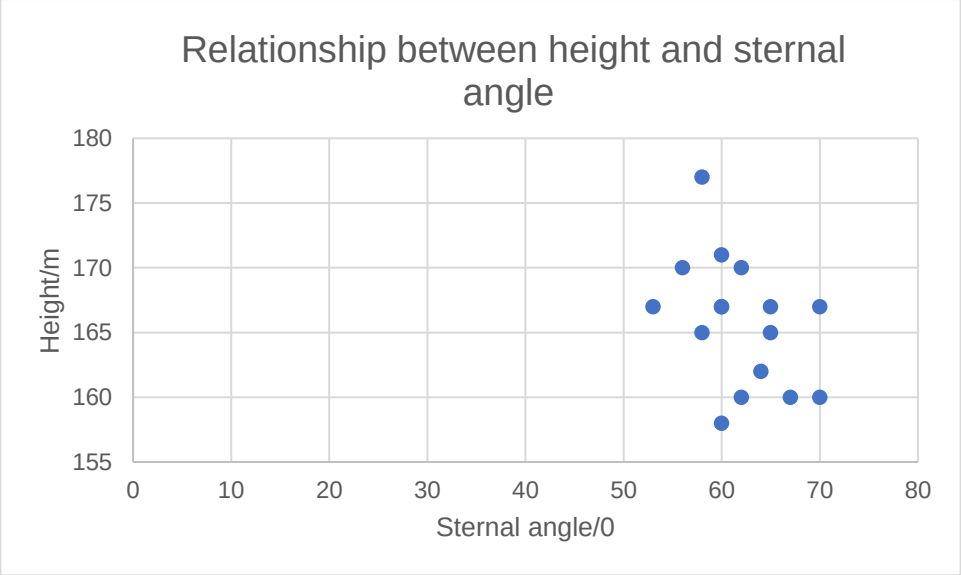

Figure 9 16 Correlation between height and sternal angle for all participants

There was however a weak negative correlation between sternal angle and height of participants (**Figure 9.16**). The Pearson's correlation coefficient was -0.407.

Pearson correlation of height and sternal angle = -0.407

To test hypothesis three stated in chapter one **section 1.13**, the inferential statistical tool used for the analysis of pain score was Mann-Whitney U-test. Confidence interval (CI) was calculated beforehand for compressions scores on the left and right breast for all participants.

Hypothesis H0 three: There is no significant difference between pain experienced for compression on the reference angle and the experimental angle.

Table 9 9 Pain score statistical analysis for participants with confidence interval

Participants	Right experimental pain score	Left experimental pain score	Left reference pain score	Right Reference pain score
1	3	5	5	3
2	4	4	4	5
3	5	3	4	4
4	1	1	9	9
5	2	7	9	4
6	6	9	10	9
7	2	1	2	2
8	1	0	1	0
9	2	3	4	1
10	6	8	6	7
11	4	5	4	3
12	2	2	3	1
13	2	8	2	8
14	5	6	7	5
15	2	2	4	6
16	8	6	6	6
Mean	3.44	4.38	5	4.56
Standard Error	0.52	0.7	0.66	0.71
Standard Deviation	2.06	2.80	2.65	2.83
Confidence Level (95.0%)	1.10	1.49	1.42	1.51
Upper CI (95%)	**4.54**	**5.87**	**6.42**	**6.07**
Lower CI (95%)	**2.33**	**2.89**	**3.59**	**3.06**

The confidence level of the mean pain score on experimental angle compression of the right breast was 1.10 while that of the left breast was 1.49 (**Table 9.9**). Compression on the reference angle recorded a higher confidence interval of 1.51 and 1.41 on both the right and the left breast respectively. The upper and lower CI recorded for the right on experimental and reference angles on the right are 4.54 and 2.33 while that of the left breast was 5.87 and 2.89. There was an increase in both upper and lower CI on compression on the reference angle. The left breast had upper and lower CI of 6.42 and 3.59 respectively and the right breast had 6.07 and 3.06.

For the experimental angle, there is a 95% chance that the pain score on right compression of the breast falls between 2.33 and 4.54 whereas that of the left

breast falls between 2.89 and 5.87. The range of left breast compression pain score falls below the moderate score of 5 on the pain scale questionnaire while the upper limit on the right breast falls just above moderate pain score.

For compressions on the reference angle, there was a 95% chance that the pain score on compression of the right falls between 3.06 and 6.07 while whereas that of the left breast falls between 3.59 and 6.42.

Table 9 10 CI for all compressions on experimental and reference angles

Compressions	Experimental angle pain score	Reference angle pain score
Number of compressions scores	32	32
Mean	3.91	4.78
Standard Error	0.44	0.48
Standard Deviation	2.47	2.71
Confidence Level (95.0%)	0.89	0.98
Upper CI (95%)	**4.79**	**5.76**
Lower CI (95%)	**3.02**	**3.81**

The overall compressions scores of both right and the left breast were combined to result in 32 pain scores each for experimental and reference angles (**Table 9.9**). The overall experimental angle pain score had an upper and lower CI of 4.79 and 3.02 which implies there is a 95% chance that the actual pain score for this angle falls within 3.02 and 4.79 (**Table 9.10**). The range of pain score values for the experimental angle falls below the moderate pain score of 5 on the pain scale questionnaire.

The upper and lower CI pain scores recorded for the compression on the reference angle were higher compared to that of the experiential angle. The range was 3.81 for lower CI and 5.76 for upper CI. For this range, there is a 95% chance that the actual pain score for the compression on the reference angle fall within 3.81 and 5.76. The upper limit though was just above the moderate pain score on the pain scale questionnaire.

To test for statistical difference between pain experienced for compression on the experimental and reference angles, a Mann-Whitney U-test was then conducted. The test was done separately on right and left pain score values (16 on each) and then both were combined to generate 32 pain core values for analysis.

Left breast pain score recorded a z score of -1.225 and a 2-tailed p-value of:

$$p \leq 0.221$$

For pain score recorded on compression on the left breast, the 2-tailed p-value of 0.211 indicates no significant statistical difference between pain scores for compression and the reference and the experimental angles, therefore the **null hypothesis cannot be rejected**.

The right breast pain score recorded z- score of 0.00 with a p-value of:

$$p \leq 1.00$$

For pain score recorded on compression on the right breast, the 2-tailed p-value of 1.00 indicates the pain score on both angles are the same. There is no significant statistical difference between pain scores for compression and the reference and the experimental angles, therefore the **null hypothesis cannot be rejected**.

A z score of -0.471 was recorded from the total of 32 pain score (right and left breast) recorded on both the experimental and reference angles.

The 2-tailed *p*-value from Mann-Whitney test was:

$$p \leq 0.637$$

With the standard alpha level of 0.05 used, there is no statistically significant difference between pain score experience recorded on the experimental and reference angles therefore the **null hypothesis cannot be rejected**.

9.7 Discussion

Mammography has been established as the gold standard for breast cancer screening and reduces breast cancer mortality by 20% (Independent Uk Panel On Breast Cancer, 2012; Marmot et al., 2013). The procedure has several advantages as the modality of choice over other imaging modalities (Dumky et al., 2018; Henderson et al., 2015; Ohuchi et al., 2016) however, it is associated with pain and discomfort (Davey, 2007; Moshina et al., 2020; Nelson et al., 2020; Uchiyama et al., 2012) .

Optimum positioning of the breast is vital as all the breast need to be imaged so no abnormality is missed. The MLO position is the only mammographic view that has the whole breast imaged (Amendoeira, 2013; Public Health England, 2020b). For this reason, getting positioning right is crucial so no aspect of the breast is missed on mammogram. The angle of the IR plays an important role in optimising image quality and Spuur et al. (2010) emphasise that incorrect IR angle selection does result into wide pectoral muscle width and short length excluding the inferior lateral aspect of the breast and decreasing pectoral muscle length.

Mammography positioning usually is modified to suit client's body habitus. This is done not only to produce optimum images but to make the procedure as comfortable as possible as well for the client (Popli et al., 2014). Peart (2005) is of the opinion that practitioners will have to understand how to modify positioning to suit all body types; small/large breast women, men, post-surgery, patient with pectus excavatum or barrel chest, wheelchair and stretcher patients. Each breast has a different position on the thorax, however all are positioned on the front wall of the chest between the 2nd and the 6th rib (Tortora & Derrickson, 2006). Because of the individual chest structure, each breast is positioned differently. Currently, there is no precise way of choosing the angle of IR for MLO protocol, therefore there is significant variation in the IR angle used (Bedene et al., 2019; Spuur & Poulos, 2009).

Mercer, Hill, et al. (2015) suggest that for an effective compression force balance on MLO position, the sternal angle and the IR should be parallel to each other. It is expected that when the IR is parallel to the angle of the sternum, there is an even distribution of pressure through the breast as well the optimisation of breast footprint from both the paddle and IR. An even distribution of pressure could also result in less pain/discomfort associated with the mammography.

This research investigated the distribution of pressure and area on compression of the breast on two IR angles, reference, and experimental angles. The study is first of its kind to study the pressure balance and contact surface area distribution in the MLO projection.

9.7.1 Pressure Distribution for Breast Compression on Experimental and Reference Angles.

Application of compression plays a vital role during mammogram as it is one of the important factors that affects image quality (Kopans, 2007; van Lier et al., 2021). Compression immobilises the breast, separate overlapping breast tissue, reduce scattered radiation and ultimately reduce radiation dose to the breast (Amendoeira, 2013; Balleyguier et al., 2018; Jeukens et al., 2019; Serwan et al., 2021). It has been established that most of the pain/discomfort experience during mammography is due to the compression applied (Katarzyna Feder & Grunert, 2017; Whelehan et al., 2021), Therefore it is important pressure applied during compression is evenly distributed throughout the breast so as to prevent its' concentration on just a part of the breast.

The most frequently used IR angle is 45^0 (Popli et al., 2014) which was the reference angle used in this work, meanwhile different body habitus means that this angle is not suitable for every client attending for mammography. Popli et al. (2014) recommends that the IR is angled to 45^0 to begin with, then this is personalised to the client as per size of the breast for up to $\pm 10^0$. On the other hand, Dronkers et al. (2001) are of the view that, in tall slender women the angle from the vertical be slightly smaller (steeper) while in smaller, more opulent women

the angle from the vertical should be slightly greater. However, there is a suggested relationship between the breast and the sternum where mammography is concerned; Different body habitus presents with different sternal angle therefore the sternal angle of participants was established by the use of digital inclinometer.

As hypothesised the result of the study indicated there was no statistically significant difference between contact pressure distribution when the IR was positioned parallel to the sternal angle and at the reference angle of 45^0. Although the difference between pressure balance on these 2 angles was not statistically significant, compression on the experimental angle produced a better pressure balance compared to the reference angle on majority of compressions (See **Table 9.3**). This goes to support Mercer, Hill, et al. (2015) view that, for an effective compression force balance on MLO position, the sternal angle and the IR should be parallel to each other. Importantly this study has emphasised the fact client should be assessed first and mammographic technique modified to suit different body habitus as recommended by various literature (Bedene et al., 2019; Brnić & Hebrang, 2001; Moshina et al., 2022; Popli et al., 2014).

The average PU for all compressions (negative numbers) showed more pressure registered on breast/IR interface than on breast/paddle interface. This is in contrast with the PU from the phantom study (positive numbers) which indicated more pressure on phantom breast/paddle interface than phantom breast/IR interface (see **Table 5.7**). The reason for this could be that human study, there was a lot more pressure recorded at the thoracic and axilla regions on participants compared to that of the phantom. During positioning participants were able to lean onto the IR better than the phantom could be positioned because of the limited mobility of the phantom model. Additionally, silicone breast implant has similar compression characteristics as breast tissue as demonstrated by Hauge et al. (2012) therefore, another reason for the difference in pressure distribution between the phantom and human study may be due to the fact that the same compression force of 10 daN was used for all compressions for the phantom study while it was varied for the human study. Compression force of 10 DaN was applied throughout for the phantom as this amount of force provided enough contact surface area on

the pressure mat. The force applied for the human study varied between participants and depended on how much the individual could take. The other issue is the difference in the nature of breast tissue and the pectoral muscle included on compression could cause more pressure to be registered on the breast/IR interface than the breast/paddle interface. Eklund et al. (1994) reported that the pectoral muscle can limit the compression of anterior breast tissue if it is prominently included during compression of the breast. According to Dustler, Andersson, Brorson, et al. (2012), the pectoral muscle is firmer than breast parenchyma, becoming more so when compressed and this effect could become more pronounced as compression increases. The difference in the structure of the breast and the pectoral muscle could have resulted in more pressure registered on the breast/IR interface than the breast/paddle interface.

The PU for the right breast on reference angle was -0.27 and that on the experimental angle was -0.25. The experimental angle provided a greater pressure balance on the right breast which implies pressure was better distributed between the paddle and IR. A perfect balance of pressure would have PU of zero hence the closer the PU value is to zero, the better the balance of pressure on compression. This result is supported by the study undertake by Smith, Szczepura, et al. (2015), for CC projection. They found out that by raising the IR by 2 cm relative to the IMF increases the breast footprint on the IR and gives a better pressure balance between breast/IR and breast/paddle interfaces.

Several studies have recommended various technique to consider during mammographic positioning to suit clients' body habitus (Anja et al., 2019; Brnić & Hebrang, 2001; Dronkers et al., 2001; Moshina et al., 2022; Popli et al., 2014; Smith, Szczepura, et al., 2015) for optimum positioning. Majority of these research based the IR selection on breast size and body shape of the clients (tall, short, slim etc) however, this is the first study that has actually used the sternum as a point of reference for the selection of IR angle for MLO projection. Similar to this work, Brnić and Hebrang (2001) compared the efficacy of breast compression between 2 IR angles, a standard IR angle of 45^0 and an alternative angle of 60^0 in 52 women. The reference angle of 45^0 was used because it was suitable for

majority of patients in routine daily practice while no explanation was provided for using the alternative angle of 60^0. They recommended 60^0 IR for MLO especially for small and pendulous breasts as this angle provided a better compression of the breast and reduced absorbed glandular dose by 25%. The limitation of this study was there was no justification given for using an alternative IR angle of 60^0. Modification of mammographic positioning should ideally be based on obtaining optimum images and to suit clients' body habitus and the selection of an IR angle for an individual could be based on these factors.

Anja et al. (2019) based the selection of the IR angle not only on the size of the breast but also on the size and shape of the chest. They recommend the use of IR angle of 55^0 for patients with longer thoraxes and small breasts and 35^0 for those with shorter thoraxes and large breasts. The IR angle of 35^0 is the gentlest angle to be recommended so far though it is within the range suggested by Popli et al. (2014) of $\pm10^0$ from starting angle of 45^0. The recommended angle for MLO varies between countries, normally between 45^0 and 60^0 (Brnić & Hebrang, 2001; Moshina et al., 2022; Public Health England, 2020b).

The average pressure was greater on the reference angle than that of the experimental on the left breast for both the breast/paddle and breast/IR interfaces with the difference of 0.76 mmHg. This could be as a result of imbalance of the distribution on the reference angle resulting in increased pressure readings. Ideally, there should be a uniform distribution of pressure throughout the breast for optimum compression. Optimum compression is vital component in mammographic image quality (Kopans, 2007; van Lier et al., 2021) This is particularly important as early detection of breast pathology is image quality dependent (Serwan et al., 2021) and has multiple benefits. The benefits of optimum compression include reduce radiation dose to the breast, overlapping of breast tissues and motion blurring as well as produce better image contrast and improve image quality. (Branderhorst et al., 2015; De Groot, Branderhorst, et al., 2015; Jeukens et al., 2019; Serwan et al., 2021).

The average number of cells that recorded peak pressure for compression on the experiment and reference angles were 22.84 and 23.53 respectively. The results indicated no statistical difference in peak pressure on compression on on these two angles. Peak pressure indicates greater amount of pressure on particular parts of the breast on compression. For the MLO projection, it has been shown that the distribution of pressure on the central breast varies as the axilla area receives a concentrated amount of compression force (Dustler et al., 2020a, 2020b). Dustler and colleagues adds that because of the stiffness of the pectoral muscle, it absorbs a substantial portion of the applied compression force consequently, only a small fraction of the applied force is distributed to the clinically important central breast.

The inclusion of the pectoral muscle and other juxtathoracic structures substantially affects pressure distribution and prevents proper compression of the breast (Dustler, Andersson, Fornvik, et al., 2012). To help reduce high proportion of compression force in this area Dustler et al. (2020a) recommended the use of flexible plate in an effort to redistributes pressure to the central breast to achieve better compression. For this reason, the flexible compression paddle was used for this research work.

It is important to mention that the Xsensor pressure mat could only read and record maximum pressure of 256 mmHg therefore, if there were pressures beyond this point which was highly likely, there was no record of that. The restricted pressure sensing range of the mat was one of the limitations of this study. The peak pressure results obtained from this study could have been influenced by the restricted readings of the pressure mat. For future research work pressure mapping system with the capacity to read and record a wide range of pressure is required.

This study did not investigate peak pressure areas on various parts of the breast on compression. Only the number of peak pressure unit which was 256 mmHg for compressions on both angles were compared. High pressure values in

future research could give more insight on areas of the breast where there is a concentration of force on compression and the relation to pain experienced.

Modification of mammographic positioning is carried out ideally to suit patient's body habitus and to obtain optimum images, as such, selecting IR angle based on the individuals' sternal angle is a novel approach. Positioning the IR angle perpendicular to the sternum is expected to provide an even distribution of pressure between the IR and the paddle. An even distribution of pressure throughout the entire breast leads to uniform breast tissue thickness and improving image contrast and quality, with an associated reduction in radiation dose, geometric/motion blurring and tissue superimposition (Serwan et al., 2020). The results from the study showed that PU was generally lower on compressions on the experimental angle compared to the reference angle. A lower PU indicates better pressure distribution therefore positioning the IR parallel to the angle of the sternum for clients. The result supports the fact that modifying technique to suit clients body habitus could result into optimum positioning (Dronkers et al., 2001; Moshina et al., 2020; Popli et al., 2014).

Although pressure balance was better on compression on the experimental angle compared to that on reference angle, the difference was not statistically significant enough. This could be because of the small sample used for the research. Future studies to follow on this feasibility study should use a larger sample size. The other reason for no statistical difference may be due to the inability of the pressure mat system to read and record a wide range of pressure values.

9.7.2 Area Distribution for Breast Compression on Experimental and Reference Angles.

Average contact surface area for all participants was greater on the breast/IR interface than breast/paddle interface on all compressions (see **Table 9.4**). This could be due to more pressure settling on the breast/IR interface as discussed in the previous section (**section 9.7.1**). Increased pressure on the breast does

reduce the thickness of the breast and the spreads out the breast tissue (Jeukens et al., 2019; Mercer, Szczepura, et al., 2015; Serwan et al., 2021) increasing the amount of breast contact area on the mat. In practice, the natural shape of the breast is distorted with the application of pressure to achieve uniform thickness. According to Serwan et al. (2021), uniform thickness of the breast upon compression results into a homogenous signal over the entire image which contributes to improved image quality and reduced radiation dose to the breast. In addition, greater surface area on the breast/IR interface could be because participants were positioned better as they could lean on the IR resulting into more of the axilla area being in contact with the mat. Unlike in the phantom study where there was restriction in the movement of the torso, participants could easy lift their arms and lean their upper body onto the IR.

On the other hand, there was a decrease in area on breast/paddle interface on the left (26.88 cm^2 to 24.44 cm^2) and breast/IR interface on the right (38.06 cm^2 to 37.32 cm^2.). This could be due to how the breast was positioned for compression. It is a common practice to find practitioners positioning slightly different on either side of the breast. One side could be slightly easier to position and could produce slightly better imager, however both images are comparable. This phenomenon has not been researched or established though aas it is only anecdotal.

Contrary to the hypothesis stated, the results from AU indicated there was a difference between contact area distribution when the IR was positioned parallel to the sternal angle and positioned at a reference angle of 45^0. The increase of contact area for compression on the sternal angle compared to that of the reference angle resulted in a statistically significant difference between the two compressions with $p \leq 0.025$ for the left and $p \leq 0.003$ for the right breast. This is an important finding as an increase in surface contact area could imply more breast tissue on actual mammogram which is a desired effect that goes towards optimising breast tissue visualisation. Similar findings were reported by Smith, Szczepura, et al. (2015) when they found an increase in IR breast footprint when the IR was positioned 2 cm above the IMF for CC projection. This result could be

attributed to the personalisation of the IR angle to align with the sternal angle of individual participant. It also supports Mercer, Hill, et al. (2015) suggestion that when the IR is positioned parallel to the sternum, there could be optimisation of breast footprint from both the paddle and IR.

Kopans (2007) highlighted that the ultimate goal of mammography is to obtain an optimum image along with maximum breast tissue visualisation. Additionally accurate positioning of the whole breast is a critical aspect of mammography in order to achieve uniformity and reproducibility of images (van Landsveld-Verhoeven et al., 2015).The MLO projection is required to show all breast tissue (Kwok et al., 2004) as it is considered a more superior projection, in comparison to CC (Anja et al., 2019). For this study, there was an increase in surface area from reference to experimental angle on both breast/IR interface on the left breast (32.02 cm^2 to 33.91 cm^2) and breast/paddle interface on the right breast (27.74 cm^2 to 29.60 cm^2). The importance of all the breast to be imaged on the MLO projection cannot be emphasised enough. Research has shown a direct link between mammographic image quality and cancer detection (Bassett et al., 2000) and optimal image quality leads to earlier detection, higher detection rates and fewer interval (O'Leary & Rainford, 2011).

A related recent study by Moshina et al. (2022) investigated the differences in positioning criteria relating to the presentation of the pectoral muscle for women of different heights using a standardised 60^0 IR angulation for MLO projection. In BreastScreen Norway, a 60^0 IR angulation has been used since the program started in 1996 and Norwegian guidelines states that this angle should be used on all mammograms to ensure reproducible mammograms. The study concluded that IR angle of 60^0 might suit most of the female population offered mammographic screening in Norway, but women of a relatively low height (163 cm or lower) might benefit from an IR angle less than 60^0. The study however had limitations, firstly, the height measurement reported by ladies were recorded several years (2006-2016) before the actual mammograms were taken (2016=2019). As mammograms were taken in later life for these women, height measurements could have been higher than the height at the time of actual screening examination as aging might

have been associated with decreasing height in postmenopausal women (Sorkin et al., 1999). The study was unable to investigate the extent of the changes. Moshina and colleagues sorely relied on height measurements recorded years before mammograms were taken. there is the possibility that those measurement were inaccurate therefore could have an impact on the results of the study. Secondly, mammography equipment used was replaced in the middle of the study for up-to-date ones. The new and more advanced mammographic unit might have an effect on image quality. The last but not the least of limitation is the lack of consensus on the measuring of pectoral muscle length. As there was no standard way obtaining these measurements, results indicated major discrepancies. These discrepancies cannot be overlooked as ii might favour women of certain heights than others.

As with this research Moshina and colleagues also aimed to obtain optimum positioning of the breast to aid in the visualisation of all breast tissue. Positioning is the single most important factor in optimising mammographic image quality as without all the breast tissue included on a mammogram all other aspects of the image quality are not relevant. Adequate pectoral muscle length, width and shape on MLO projection are assumed to be of positive influence for visualization of suspicious lesions in the breast, specifically in the posterior inferior area of the breast. (Muttarak et al., 2006). Théberge et al. (2019) emphasised the importance of including the posterior part of the breast as it is an area where breast cancers might be missed.

In an effort to improve tissue visualisation, Bedene et al. (2019) suggested IR angles are personalised to suit body habitus and breast size. They recommend the use of 55^0 IR angle for women with longer thoraxes and small breasts and a 35^0 angle for those with shorter thoraxes and large breasts. This approach is very subjective and lacks any form of standardisation. Ultimately, the selection of an appropriate IR angle solely relies on the judgement of the practitioner.

The average contact surface area was greater on compressions on the experimental angle in majority of participants (9 out of 16) and this reflected in the AU calculated. The difference in average surface area for compression on the experimental to the reference angle was -1.85 cm^2 indicating more surface area on compression of the breast on the experimental angle than that of the reference angle. The increase could only be from using the appropriate IR angle to suit the body habitus of participants. In practice, the increase in breast tissue on mammogram could be the difference in visualising breast abnormality or missing it because it was not included on the image.

9.7.3 Pain Experienced during Compression on Experimental and Reference Angles

Pain/discomfort is associated with mammography (Chen et al., 2012; De Groot, Broeders, et al., 2015; Heine et al., 2010; O'Leary & Al Maskari, 2013; Uchiyama et al., 2012; Whelehan et al., 2021) and it is a significant cause of non-compliance with screening mammography attendance (Ashkar & Zaki, 2017; Poulos & McLean, 2004; Whelehan et al., 2013). The pain/discomfort generally arise from the positioning and compression applied to the breast (Whelehan et al., 2013). Concentration of compression force on a part of the breast due to inadequate positioning could result into more pain during the procedure therefore, it is advisable to get positioning right so there is an even balance of pressure distributed throughout the breast.

Positioning the IR parallel to the sternal angle as suggested by Mercer, Hill, et al. (2015) could results is an even distribution of pressure through the breast and the balance distribution of compression could lead to a more comfortable procedure. Angulation of the IR for MLO projection is practice based, not based on evidence and the practitioner decides on the angle of the IR according to the patient's habitus (Dronkers et al., 2001; Mercer, Hill, et al., 2015).

The pain score measurement tool used was 11-point NRS pain rating 0=no pain, 5=moderate pain and 10=worst possible pain. The average pain score on the

experimental angle and reference angle on the left breast was 4.38 and 5 respectively, while that on the right breast for experimental and reference angle was 3.44 and 4.56 respectively. This result confirms what several studies have concluded on mammography being associated with pain and discomfort (Lee & Uchiyama, 2015; Nelson et al., 2020; Shelby et al., 2012; Uchiyama et al., 2012; Whelehan et al., 2021; Zavotsky et al., 2014). The main source of pain in mammography is mostly due to the compression applied to the breast (Nelson et al., 2020; O'Leary & Al Maskari, 2013) and positioning (Whelehan, 2015). As in this study, Nelson et al. (2020) measured mammography-related pain in two groups of women undergoing regular surveillance using 11-point NRS pain rating scale. Participants scored their perceived pain before compression based on memory, immediately after compression and one week later. The study concluded pain from mammography can develop and extend beyond the examination period. Conversely, Uchiyama et al. (2012) objectively quantified the physical burden on female subjects by measuring the electrical potential generated by the activation of certain muscle groups, including the trapezius and sternocleidomastoid muscles, which are associated with positioning during mammography. The used Visual analogue scale (VAS) for pain measurement and the result suggests that positioning during mammography affects the muscle activity and that the increased muscle activity could be related to the pain.

The average pain by participants was lower on compression on the experimental angle compared to the reference angle. This can be explained by the more even balance of pressure for compression on the experimental angle as discussed in **section 9.4.3**. On compression of the breast a uniform balance of pressure throughout the breast would imply a concentration of pressure on a part of the breast is unlikely, as such experience of pain would be spread out making the examination less uncomfortable. With regards to this, Dustler, Andersson, Brorson, et al. (2012) measured and described the pressure distribution over the breast as a result of applied breast compression in mammography. They also examined compressed breast thickness and experienced pain and correlated these parameters with the pressure distribution. One hundred and three women were subjected to two additional breast compressions of the left breast (standard

force and approximately 50% reduction). Pressure images of the compressed breast were obtained using force sensing sensors placed underneath the compression paddle. Participants then rated their experience of pain on a visual analogue scale immediately following compression. Dustler and colleagues concluded that the distribution of pressure differed greatly between breasts. In a large proportion of breasts, the compression plate did not provide optimal compression of the breast, the compression force being absorbed in juxtathoracic structures. With regards to pain experienced they identified that pain was associated with the independent variables, breast area, mean pressure over dense tissue, and breast thickness. There was also a significant correlation between full and reduced compression, the higher the compression force, the greater the pain experienced. However, there was there was no correlation between pain and breast thickness.

In addition, the mean difference of pain score between the two angles was -0.88 with the SD of 2.74. The negative mean value indicates less pain experienced on the experimental angle to that experienced on the reference angle. It supports the suggestion by Mercer and colleagues (2015) that positioning the IR parallel to the sternal angle could result in an even distribution of pressure through the breast and balance distribution of compression could result into a more comfortable procedure.

The CI calculated for pain experienced for combined compression on the left and right breast on the experimental angle showed that, there was a 95% chance that the actual pain score for this angle falls within 3.02 and 4.79 while there was a 95% chance that the actual pain score for the compression on the reference angle was between 3.81 and 5.76 (see **Table 9.9**). This results confirm Smith (2013) assumption that an image which is symmetrical in both contact area footprint and contact pressure, is likely to provide a more comfortable experience for the participants. Pain experienced on the experimental angle was clearly less than that on the reference angle and the possible explanation could be the even balanced of compression pressure on the experimental angle which is the angle of the sternum

for each participant. This emphasises the importance of modify mammographic positioning to suit clients' body habitus as supported by various research (Dronkers et al., 2001; Moshina et al., 2020; Popli et al., 2014). In addition, the CI does confirm the fact that mammography is associated with pain as mentioned by several studies (Chen et al., 2012; De Groot, Broeders, et al., 2015; Heine et al., 2010; O'Leary & Al Maskari, 2013; Uchiyama et al., 2012; Whelehan et al., 2021). The most important finding from the CI was that compressions on the experimental angle were less painful compared to the reference angle. The PU and AU for compressions on the experimental angle was generally lower compared to that on the reference angle which indicates better pressure and area balance. The CI goes to supports Mercer and colleagues (2015) suggestion that when the IR is positioned parallel to the sternal angle there is an even distribution of pressure through the breast which could result into a more comfortable mammographic procedure. Better pressure and area balance provided a more comfortable procedure.

The combined p-value for both breasts was 0.637. Although the CI for pain experienced on the experimental angle was lower than that experienced on the reference angle, the difference was not great enough to result into statistically significant difference between the two angles, therefore the null hypothesis cannot be rejected. The possible explanation for this could be that the sample size was too small to make a significant difference. Further future work is recommended with a larger sample size.

The reduction of pain was in mammography is vital as it stops some women from attending for breast cancer screening (Whelehan et al., 2013). The impact of decreasing breast compression during digital mammography and DBT on perceived pain and image quality has been investigated by Agasthya et al. (2017). In this two-part study, two groups of women with prior mammograms were recruited. In part 1, subjects were positioned for CC and MLO projections, and four levels of compression force were applied to evaluate changes in breast thickness, perceived pain, and relative tissue coverage. There was no radiation exposure. In part 2, two MLO DBT images of one breast of each patient were acquired at

standard and reduced compression. Blurring artifacts and tissue coverage were judged by three radiologists, and compression force, breast thickness, relative tissue coverage, and perceived pain were recorded. Agasthya and colleagues suggested that mammography and DBT may be possible using half of the compression force used currently, with a significant and substantial reduction in perceived pain with no clinically significant change in breast thickness and tissue coverage.

The findings from this work have shown there is a reduction of pain experienced when the breast is compressed with the IR parallel to the sternum. Any reduction of pain during mammography is good as pain is one of the factors that accounts for acceptance of clinical mammography and even more importantly lower attendance in screening programs (Saunders Jr & Samei, 2008).

9.8 Chapter Summary

This chapter elaborated on results for phase two of this research which was the human study. Data from Xsensor pressure mapping system was transferred into Microsoft excel and these were analysed. Average pressure and area were calculated for all compressions as well PU and AU. The hypothesis set in chapter 1 **section 1.12** were tested.

The average contact area and pressure were greater on the breast/IR interface than breast/paddle interface on all compressions.

There was no statistically significant difference between pressure distribution on the reference angle and the experimental angle therefore the null hypothesis cannot be rejected. There was however statistically significant reference between area balance for compressions made on the reference angle and that made on the experiment angle therefore the null hypothesis was rejected.

Pain score analysis was done using both descriptive and mathematical statistical analysis. The CI range for pain experience on the reference angle was

3.81 for lower CI and 5.76 for upper CI. For this range, there is a 95% chance that the actual pain score for the compression on the reference angle fall within 3.81 and 5.76. That of the experimental angle had an upper and lower CI of 4.79 and 3.02. This implies there is a 95% chance that the actual pain score for this angle falls within 3.02 and 4.79. However, there was no statistically significant difference between pain experienced from compression on the reference angle and the experimental angle, so the null hypothesis cannot be rejected.

Chapter Ten - Conclusion of Thesis

10.1 Chapter Review

This chapter contains summary of the thesis the overall conclusion. The limitations and recommended future work required were stated alongside the novelty of this thesis. The dissemination of this research was also stated.

10.2 Thesis Summary

The primary aim of this PhD thesis was to investigate the relation of the sternal angle in selecting the appropriate IR angle for an optimum pressure and area balance for MLO mammographic projection. Using finding from this thesis, inferences were made about patients. This was to critically assess if positioning the IR parallel to the sternum for individual women will result to a better balance of surface pressure and area between the IR and paddle. In addition, it is to ascertain if compression on the sternal angle provided a less painful/uncomfortable mammographic experience.

10.3 Limitations

While this thesis makes significant contribution to understanding the relation of the sternum and selection of IR and how this subsequently affect clients mammographic experience, it has limitations. Firstly, the sample size was small. The larger sample size might could generate more information. Secondly, only non-symptomatic and women without previous breast surgery participants were invited. As mammography is generally offered either as screening or symptomatic, it is fair to include all women. Again, women who have history of breast surgery for any reason do have follow up or routine screening mammograms so could be included in the study. Male participants were also not invited for the study even though they do attend for symptomatic mammogram. Thirdly, information on peak and low areas of pressure on the breast which were not investigation in this work could provide more insight into effect of compression on different IR angles and whether that will affect the pain/discomfort experienced during the procedure. Further research in this area is necessary to map out the distribution of pressure on both experimental and reference angles.

Last but not the least, this study is limited by the performance of the pressure mapping system. The maximum amount of pressure the Xsensor pressure mat could read and record was 256 mmHg. There is the possibility that greater pressure than 256 mmHg was applied to some parts of the breast but this could not be accounted for. Further study is recommended using a system that could read and record a wider or indefinite range of pressure. Again, pressure points on compression on both the experiment and reference angles needs to be investigated further.

10.4 Recommended Future Work

1. This study should be replicated for a larger sample size to investigate findings.
2. This study should be conducted again with different practitioners positioning participants. The difference in positioning technique could influence the results of the study
3. Dedicated study into the distribution of pressure taking into consideration maximum/peak pressures on aspects of the breast is recommended.
4. Advanced pressure mapping system with a wider range of pressure to be read is required. The system used could only read and record pressure up to 256 mmHg.

10.5 Thesis Novelty

No study has investigated pressure and area balance on compression of the breast with regards to the sternum and selection of IR angle for MLO projection. Consequently, there is no up to date knowledge on the relationship between the sternum and the selection of appropriate IR angle for individual client during mammography. This thesis adds new knowledge to academic/clinical literature as it demonstrates that taking into consideration the sternal angle of women and positioning the IR parallel to the sternum for MLO projection results in a less painful procedure. This finding creates the need for raising awareness of the

pain/discomfort of mammography which could deter some women from attending breast cancer screening.

This thesis has identified in its method a unique technique of assessing pressure uniformity and area uniformity separately. Previous study on CC projection calculated Uniformity Index which involves a combined calculated of pressure and area.

10.6 Summary of Conclusions

The findings of this thesis have demonstrated:

1. For the phantom study, when the IR was parallel to the sternal angle of the phantom model, it was at this angle that the greatest balance of pressure and area footprint was achieved.
2. Although the CI of pain experienced score on the experimental angle was lower than that on the reference angle of 45^0, there was no statistically significant difference between pain on the two angles.
3. There was statistically significant difference between of area balance for compressions made on the reference angle and that made on the experiment angle.
4. There was no statistically significant difference between pressure balance on the reference angle and the experimental angle.

10.7 Research Dissemination

This work has been presented at several conferences, seminars, and workshops (**Table 10.1**). It is proposed that it is written up for publication in peer reviewed journals after the thesis has been submitted.

Table 10. 1 Conference Presentation, papers and posters

No	Title	Status
1	Standardised mammographic positioning and compression protocols for use within breast screening and symptomatic services. **Muniratu Aliu Osmanu,** Claire Mercer, Katy Szczepura	Oral presentation at the Salford Postgraduate Annual Research Conference (SPARC) 2021
2	Standardised mammographic positioning and compression protocols for use within breast screening and symptomatic services ***Muniratu Aliu Osmanu,*** *Claire Mercer, Katy Szczepura*	Conference poster presented at SPARC (2021)
3	Standardised mediolateral oblique mammographic positioning and compression protocol for use within breast screening and the symptomatic services. **Muniratu Aliu Osmanu,** Claire Mercer, Katy Szczepura	Conference poster presented at Symposium Mammographicum 2021 Conference
4	Standardised mediolateral oblique mammographic positioning and compression protocol for use within breast screening and the symptomatic services ***Muniratu Aliu Osmanu****, Claire Mercer, Katy Szczepura, John Thompson*	Conference poster presented at UK Imaging and Oncology Congress, UKOI (2020)
5	Standardised positioning and compression protocol to reduce pain and discomfort in mammography. ***Muniratu Aliu Osmanu****, Claire Mercer, Katy Szczepura, John Thompson*	Oral presentation. University of Salford Radiography Research Seminar Series, 2020
6	Standardised mammographic positioning and compression protocols for use within breast screening and symptomatic services. ***Muniratu Aliu Osmanu,*** *Claire Mercer, Katy Szczepura*	Poster presentation at North-East Postgraduate Conference NEPG (2020)
7	Standardised positioning and compression protocol to reduce pain and discomfort in mammography. ***Muniratu Aliu Osmanu****, Claire Mercer, John Thompson*	Oral presentation at SPARC, 2019
8	Standardised positioning and compression protocol to reduce pain and discomfort in mammography. ***Muniratu Aliu Osmanu****, Claire Mercer, John Thompson*	Oral presentation. University of Salford Breast Imaging Research Seminar (2019).

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12 Appendices

12.1 Appendix I - Summary of selected literature

Author	Title	Objectives/aim	Research method	Sample size	Findings	Limitations
1. **Branderhorst, W.; de Groot, J. E.; Neeter, L. M. F. H.; et al. (2016)**	Force balancing in mammographic compression	To implement a method to measure and minimize the force imbalance. To assess its feasibility as an objective and reproducible method of setting the image receptor height.	Experimental study	Phantom study (13 compressions)	Monitoring the force imbalance and actively adjusting the position of the image receptor throughout the compression may lead to less pain, better image quality and reduced radiation dose.	Study conducted on CC projection only. Results might not replicable when conducted on human as there are natural variation between women
2. **Branderhorst, W; de Groot, Jerry E.; Highnam, Ralph; et al. (2015)**	Mammographic compression - A need for mechanical standardisation	To compare compression practice between imaging site To investigate whether standardisation of pressure could improve compression	Quantitative retrospective study Multi-site study	9,188 (37,518 compressions)	Large differences and high variation in applied force and pressure, both between and within the two sites Pressure standardisation could decrease variation, improve reproducibility, and reduce the risk of unnecessary pain, unnecessary high radiation doses and inadequate image quality.	Screening mammograms were largely used but both screening and symptomatic images were used in one of the sites. This could contribute to compression variation as diagnostic population may be

		protocols				more prone to pain
3. **Cassar Agius E and Naylor S (2018)**	Breast compression techniques in screening mammography – A Maltese evaluation project	To find out how radiographers carry out their breast compression techniques	Quantitative – Descriptive phenomenology	9 radiographers	Radiographers should be flexible in their approach in order to carry out successful compression technique and effectiveness in practice is gained from experience rather than initial training.	Small sample size from a single unit
4. **De Groot J, Branderhorst W, Grimbergen C, Den Heeten G, Broaders M (2015).**	Towards personalized compression in mammography: A comparison study between pressure- and force-standardisation	To compare a conventional 14 daN force-standardised compression protocol with a personalised 10kPa pressure-standardised protocol	Double blinded randomised controlled trial	433	Pressure-standardised compressions resulted in AGD values and a retake proportion similar to force-standardised compressions, while pain was significantly reduced.	Pressure standardised protocol required more forces for women with larger breast. The study compared 10kPa pressure-standardised protocol to a strict implementation of target force of 14 daN and represented the compression level as percentages of the target values. This is not representative of conventional daily practice.

5. **De Groot J, Hopman I, Van Lier M, Branderhorst W, and Den Heeten G (2017)**	**Pressure-standardised mammography does not affect visibility, contrast and sharpness of stable lesions**	**To evaluate whether pressure-standardised mammography affect the quality of image**	**Randomised controlled trial**	**188**	**Pressure-standardised mammography reduces pain and exam variability and there was no difference in image quality.**	**Small sample size**
6. **Den Boer, D.; Dam-Vervloet, L. A. J.; Boomsma, M. F.; et al. (2018)**	Clinical validation of a pressure-standardised compression mammography.	To validate pressure-standardised compression mammography	Correlational research design	39	PSCM can reduce patient discomfort and pain during mammographic compression compared to conventional FSCM as a result of lower average pressure as the same time offer more constant image quality	Small sample size The time between both mammograms were relatively long (1-6 years) and the breast could change during this time.
7. **Dumky Hanna, Leifland Karin, Fridell Kent. (2018).**	The Art of Mammography with Respect to Positioning and Compression—A Swedish Perspective	To describe how radiographers, perceive the examination method used in mammography	Qualitative research using interview	13 radiographers	Radiographers work and think in different manners concerning the methodologies used in mammographic examinations	Small sample size As this is a descriptive study, the opinion expressed are limited to individual interpretation of the procedure.
8. **Dustler, Magnus; Andersson, Ingvar; Brorson, Hakan; et al. (2012b)**	Breast compression in mammography: pressure distribution patterns	To describe the pressure distribution over the breast as a result of applied breast compression.	Mixed method prospective study	103	Pressure distribution differed greatly between breast.	Single unit study with compression plates from only one manufacturer. Sensor system could not read high pressure beyond its saturation point
9. **Dustler, Magnus; Andersson, Ingvar;Fornvik, Daniel ; Tingberg,**	The Effect of Breast Positioning on Breast Compression in Mammography: A	To investigate the difference in compression of the breast	Experimental study	21	The inclusion of the pectoral muscle and other juxtathoracic structures in the MLO projection substantially affects pressure	Study conducted on only MLO view. Small sample size saturation of sensor

Anders (2012a)	Pressure Distribution Perspective	before and after repositioned to exclude 1 cm of the juxtathoracic part.			distribution and prevents proper compression of the breast.	elements and partial area effect that may affect pressure measurement.
10. **Hogg, P; Szczepura, K; Darlington, A; Maxwell, A (2013)**	A method to measure paddle and detector pressures and footprints in mammography	To measure pressures applied to the breast from the IR and the paddle and to measure breast footprint	Experimental phantom study	15 compressions	The greatest IR footprint was achieved at IMF +2 cm	The result could be different if conducted on human
11. **Holland, Katharina; Sechopoulos, Ioannis; Mann, Ritse M.; et al. (2017)**	Influence of breast compression pressure on the performance of population-based mammography screening	To determine the effect of compression pressure in mammography on breast screening outcomes.	Retrospective study Single site study	57,179 (132,776 examinations)	Too much pressure if applied during mammography may reduce sensitivity. In contrast, if pressure is low this may decrease specificity.	Study carried on MLO view only. Computed pressure might not accurately reflect pressure on the breast as the pectoral muscle is also included in the contact area of MLO view. Finding could be more substantial if mammograms of individual women could be obtained who were repeatedly imaged with different compressions.

12. **Katarzyna Feder; Grunert, Jens-Holger (2017).**	**Is individualizing breast compression during mammography useful? - Investigations of pain indications during mammography relating to compression force and surface area of the compressed breast**	**To determine how the presence of pain during mammographic pressure could be reduced.**	**Experimental study**	**199 (756 images)** **30 for pilot study**	**Women with larger breasts tolerated greater compression force compared to those with smaller breast, therefore the need for individualised examination depending on the size of breast.**	**Only symptomatic women were used for the study which might skew the result to a painful side.** **Absence of specified minimum compression force meant might results into inter-individual differences in the examiners' procedure**
13. **Mercer C, Hogg P, Cassidy S and Denton (2013b).**	Does an increase in compression force really improve visual image quality in mammography? – An initial investigation	To investigate how IQ varies with different levels of compression force levels	Retrospective, longitudinal comparative study	36 (500 images)	There was no difference in visual IQ when different amounts of compression are applied. and it was speculated that not be necessary to use high levels of compression force when lower amounts may suffice.	Small sample size Single centre study
14. **Mercer C, Szczepura, K, Kelly J, Millington S, Hogg P. (2015)**	A 6-year study of mammographic compression force: Practitioner variability within and between screening sites.	To investigate practitioner compression force variation over a six-year cycle in 3 screening units	Retrospective longitudinal comparative study	975 (11,700 images). Multiple sites study	There were large variations in the application of compression force across all the sites and these variations could impact negatively on clients experience	The study was conducted with analogue images. With digital images now widely in use, it may have slightly alter the result of the study.
15. **Mercer, C. E. ; Hogg, P. ; Lawson, R. ; et al. (2013a)**	Practitioner compression force variability in mammography: a preliminary study	To determine whether the absolute amount of breast pressure varies between and within practitioners	Retrospective comparative study	488	Large Practitioner variation in compression was identified and these were grouped into those who used low, intermediate and high compression	Single site study. As it was retrospective data, personal details of clients were not accessed e.g. breast tenderness, menopause previous

						breast surgery etc.
16. **Murphy Fred, Nightingale Julie, Hogg Peter, Robinson Leslie, Seddon Doreen, Stuart Mackay Stuart. (2015)**	Compression force behaviours: An exploration of the beliefs and values influencing the application of breast compression during screening mammography	Investigate compression behaviours od practitioners. To understand 'how' and 'why' practitioners apply compression	Qualitative studies with focus groups interview	41 practitioners.	A wide variation in the application of compression force, thus offering a possible explanation for the difference between practitioner compression forces found in quantitative studies. The culture and the practice of the units themselves influenced beliefs and attitudes of practitioners in compression force application.	Small sample size. By seeking the practitioners own perspective, the validity of the findings were limited to their interpretation of their compression force practice.
17. **Nightingale J. M, Murphy F.J, Robinson L, Newton-Hughes A, Hogg P. (2015).**	Breast compression – An exploration of problem solving and decision-making in mammography	To explore the problem-solving process applied to the application of breast compression force from the practitioners' perspective.	Qualitative studies with focus group interview	41 practitioners 6 mammography educators	Seven consecutive stages contributed towards compression force problem solving: assessing the request; first impressions; explanations and consent; handling the breast and positioning; applying compression force; final adjustments; feedback. The application of compression should no longer be considered as one single task, but is now recognised as a seven-stage problem solving continuum.	These are practitioners' perspective on compression force and were limited to their interpretation.
18. **Smith H. (2013) Unpublished work (Dissertation)**	An analysis of the compressed breast area and image receptor/compression paddle pressure balance in different mammographic projections	To determine whether: Medio-Lateral Oblique (MLO) 45º or (MLO) 55º gives increased image receptor (IR) foot print; IR at intra-mammary fold	Quantitative study	16 participants (32 images)	Raising the IR by 2cm relative to the IMF improved pressure balance and increased footprint. No significant difference is observed in the MLO view when comparing the pressure images at 45^0 with 55^0	Small sample and conducted at a single unit

		(IMF) or IR at +2cm relative to IMF gives increased IR foot print and better pressure balance for Cranio-Caudal (CC).				
19. **Smith H, Szczepura C, Mercer C,Maxwell A and Hogg P (2015)**	Does elevating image receptor increase breast receptor footprint and improve pressure balance?	To explore the right position on the IR in relation to the breast.	Quantitative study	16 participants (32 images)	Breast footprint increases significantly when the IR is raised by 2 cm from the inframammary fold (IMF)	Small sample and conducted at a single unit Only CC position was assessed.
20. **Waade, Gunvor G.; Moshina, Natalia; Sebuodegard, Sofie; et al. (2017)**	Compression forces used in the Norwegian Breast Cancer Screening Program	To investigate the force used in the Norwegian breast cancer screening programme	Retrospective randomised controlled study	17,951 examinations 14 breast centres	A wide variation in applied compression force was observed between the breast centres in the NBCSP. This variation indicates a need for evidence-based recommendations for compression force aimed at optimizing the image quality and individualizing breast compression.	Information on radiation dose would have provided a valuable insight

12.2 Appendix II - University Ethics Application

This form should **only** completed by staff and PGRs from the **School of Health Sciences** and the **School of Health &Society**. For queries, please contact Health-ResearchEthics@salford.ac.uk

For all other schools, please visit http://www.salford.ac.uk/ethics

School Research Ethical Approval FILTER Form

No research can be started without full, unconditional ethical approval. There are a number of routes for obtaining ethical approval depending on the potential participants and type of study involved – please complete sections A, B and C to determine which is the most appropriate route for your research study.

A. Only complete this section if your study relates to Teaching & Learning Research (STAFF ONLY)		
1.	Is the proposed study being undertaken by a member of **UoS staff**?	Select
2.	Is the purpose of the study to evaluate the effectiveness of UoS teaching and learning practices by identifying areas for improvement, piloting changes and improvements to current practices or helping students identify and work on areas for improvement in their own study practices?	Select
3.	Will the study be explained to staff and students and their informed consent obtained?	Select
4.	Will participants have the right to refuse to participate and to withdraw from the study?	Select
5.	Will the findings from the study be used **solely** for internal purposes? *e.g. there is no intention to publish or disseminate the findings in journal articles or external presentations*	Select

If you have answered **YES to ALL** of Qs.1-5 your study does not require UoS ethics approval as the work sits under enhancing quality of teaching and learning.

If you have answered **NO to ANY** of Qs.1-5 you should complete the checklists below to determine which route you should use to apply for ethics approval of your study.

To find out if your study requires ethics approval through NRES, please

B. National Research Ethics Service (NRES)		
1.	Will your study involve research participants identified from, or because of their past or present use of services (adult and children's healthcare within the NHS and adult social care), for which the UK health departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?	YES
2.	Will your research involve collection of tissue or information from any users of these services (adult and children's healthcare within the NHS and adult social care)? This may include users who have died within the last 100 years.	NO
3.	Will your research involve the use of previously collected tissue or information from which the research team could identify individual past or present users of these services (adult and children's healthcare within the NHS and adult social care), either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?	NO
4.	Will your research involve research participants identified because of their status as relatives or carers of past or present users of these services (adult and children's healthcare within the NHS and adult social care)?	NO

If you have answered **YES to ANY of these questions** then you should complete this application form for University of Salford ethics review, and you will normally receive a response within 4-6 weeks of submission. Once you have obtained UoS approval, you will then need to complete and submit the relevant NHS National Research Ethics Service (NRES) form. Further information and details on how to

If you have answered **NO to ALL of the questions above** then please complete the checklist below to determine whether your application is eligible for Proportionate

C. Proportionate Review or Full Review Checklist		
1.	Expose participants to high levels of risk, or levels of risks beyond those which the participant is likely to encounter in their everyday activities? These risks may be psychological, physical, social, economic, cause legal harm or devalue a person's self-worth. *For example, untrained volunteers exposed to high levels of physical exertion; participants purposefully exposed to stressful situations; research where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.*	YES
2.	Involve the administration of drugs, medicines or nutritional supplements as part of the research design?	NO
3.	Include adults who may be classed as vulnerable? *For example, adults with learning disabilities or mental illness; drug/substance users; young offenders; prisoners/probationers; those in a dependent relationship with the researcher.*	NO
4.	Include children or young adults (below 18 years of age)?	NO
5.	Involve the discussion or disclosure of topics which participants might find sensitive or distressing? *For example, sexual activity; criminal activity; drug use; mental health; previous traumatic experiences; illness; bereavement.*	NO
6.	Use questionnaires which focus on highly sensitive areas? *For example, illegal activity; criminal activity; disclosure and analysis of findings based on sensitive personal information as defined by Data Protection Act e.g. racial or ethnic origin; political opinions; religious beliefs; trade union membership; physical or mental health; sexual life.*	NO
7.	Incorporate interviews or focus groups which involve the discussion of highly sensitive areas? *For example, illegal activity; criminal activity; disclosure and analysis of findings based on sensitive personal information as defined by Data Protection Act e.g. racial or ethnic origin; political opinions; religious beliefs; trade union membership; physical or mental health; sexual life.*	NO
8.	Involve high levels of risks to the researcher? *For example, lone working at night; interviewing in your own or participants homes, observation in potentially volatile or sensitive situations.*	NO
9.	Involve deliberately misleading participants in any way?	NO
10.	Involve recruiting participants who have not been provided with a participant information sheet and asked to sign a consent form? *Please note that for questionnaire based studies where the questionnaire is completed by the participant, a consent form is generally not required as consent is implied by the completion of the questionnaire. Applicants conducting **questionnaire-only** studies should answer NO.*	NO
11.	Involve the collection and/or use of human tissue from healthy volunteers? *Under these circumstances human tissue is as defined by the Human Tissue Act 2004 - "Any, and all, constituent part/s of the human body formed by cells." Research studies involving the use of plasma or serum are not covered by the HTA.*	NO
12.	For research accessing and analysing existing datasets: will the dataset include information which would allow the identification of individual participants?	N/A

If you have answered **NO to ALL** of Qs.1-12 then your study is eligible for Proportionate Review.

Please note that if the assigned reviewer finds that your application has been wrongly

Submitting your Application

PGR Students – please ensure that your completed and **FULLY ANONYMISED** application is reviewed and submitted by your supervisor.

Supervisors – please submit the student's application from your University email account where possible. This serves as your approval for the application to be sent for review. Please include the name of your student in the body of the email (and cc them in when submitting the application).

Staff – please submit the **FULLY ANONYMISED** version of your application from your University email account where possible.

School Research Ethics Approval Application Form CHECKLIST

School	SCHOOL OF HEALTH SCIENCES
Course of Study	PhD
Title of proposed research project	
Has this project received external funding?	NO If **YES**, please provide name of Research Council or other funding organisation: Click here to enter text.
Do you use non-human genetic materials from outside UK for your research?	NO If **YES**, has this been collected since the 12th October 2014? Select

Please select which type of review is required: Full Review

The following checklist MUST BE COMPLETED. It is designed to help you to ensure that you have submitted all the supporting documents with your ethics application form. This information is necessary for the committee to be able to review and approve your application. Please complete the relevant boxes indicating whether a document is enclosed and, where appropriate, include the **date and version number** allocated to the specific document *(in the header/footer).* Additional documents can be recorded in the boxes provided.

Document	Enclosed?	Date	Version No.
Application form	**Mandatory**	13/12/19	1.1
Risk Assessment Form	**Mandatory**	13/12/19	1.1
Protocol	NO		
DBS Check	NO		
Participant Invitation Letter	YES	13/12/19	1.1

Participant Information Sheet	YES	13/12/19	1.1
Participant Consent Form	YES	13/12/19	1.1
Participant Recruitment Material – *e.g. copies of posters, newspaper adverts, website, emails.*	YES	13/12/19	1.1
Organisation Management Consent/Agreement Letter	YES	13/12/19	1.1
Research Instrument, non-validated questionnaire	YES	13/12/19	1.1
Draft interview guide/Topic guides for participants	YES	13/12/19	1.1
Additional 1	Select		
Additional 2	Select		
Additional 3	Select		

School Research Ethics Approval Application Form CHECKLIST

School	SCHOOL OF HEALTH SCIENCES
Course of Study	PhD
Title of proposed research project	
Has this project received external funding?	NO If **YES**, please provide name of Research Council or other funding organisation: Click here to enter text.
Do you use non-human genetic materials from outside UK for your research?	NO If **YES**, has this been collected since the 12th October 2014? Select

Please select which type of review is required: Full Review

Document	Enclosed?	Date	Version No.
Application form	**Mandatory**	13/12/19	1.1
Risk Assessment Form	**Mandatory**	13/12/19	1.1
Protocol	NO		
DBS Check	NO		
Participant Invitation Letter	YES	13/12/19	1.1
Participant Information Sheet	YES	13/12/19	1.1
Participant Consent Form	YES	13/12/19	1.1
Participant Recruitment Material – *e.g. copies of posters, newspaper adverts, website, emails.*	YES	13/12/19	1.1
Organisation Management Consent/Agreement Letter	YES	13/12/19	1.1
Research Instrument, non-validated questionnaire	YES	13/12/19	1.1
Draft interview guide/Topic guides for participants	YES	13/12/19	1.1
Additional 1	Select		
Additional 2	Select		
Additional 3	Select		

School Research Ethics Approval APPLICATION Form

Is this a resubmission?
Yes ☐ No ☒ If YES, please indicate Reference Number (if known) Click here to enter text.

Staff/PGR Student experience/qualifications:	MUNIRAU ALIU OSMANU
School	SCHOOL OF HEALTH SCIENCES
Course of study: *(PGR use only)*	PHD MEDICAL IMAGING

Expected end date of project:	JUNE 2022

Risk Assessment
*A risk assessment of the project is mandatory and **MUST** be submitted with the application.*

Is a DBS check required?
Yes ☒ No ☐ *If 'Yes', then please submit your current DBS form with the application. NB. This document will only be viewed by the Health Research Ethics Administrator for verification purposes.*

Have you read the Lone Worker Policy?

Yes ☒ No ☐

The form must be completed electronically; the sections can be expanded to the size required. To assist you with the completion of this form there are *Guidance notes for completing your application* which explain what is required for each section.

1. Title of proposed research project: *(refer to the guidelines in section 1)*	The development of standardised MLO positioning and compression protocol for use within breast screening and symptomatic services

2. Project Summary *(refer to the guidelines in section 2)*

Mammography is the main diagnostic tool for breast cancer screening and the aim is to obtain optimum image quality along with maximum tissue visualisation (Jiani Yu et al, 2017). Most patients find mammograms uncomfortable and this is due to challenges in positioning and the compression applied to the breast during the procedure (O'Leary& Al Maskari, 2013). Positioning and compression are entirely controlled by the practitioner and can influence image quality and the patient's experience (Popli, 2014). Mammographic imaging is carried out in the CC (Cranio-Caudal) and MLO (Medio-Lateral Oblique) positions as standard and can be undertaken for either symptomatic patients or as part of a screening programme. Selection of the angle of the image receptor (IR) with respect to MLO positioning depend on body habitus of the patients; Lee (2003) recommends using a reference angle of 45^0 though it is questionable that this is suitable for all patients.

The aim of the research is to develop an evidence-based protocol that enables practitioners to complete personalised positioning that may help reduce pain and discomfort associated with the procedure. This will be achieved by an experimental methodology in a clinical setting.

It is to note that standardisation for the CC position has already been developed through the work of Smith, Szczepura, et al. (2015). Therefore, this work will be based on only the MLO protocol.

3. Project Objectives *(refer to the guidelines in section 3)*

The introduction of this evidence-based protocol will enable mammographers to offer patient centred care and aim to improve patient experience. The objectives include:

a) To develop a method, using the sternal angle, to allow selection of the correct image receptor (IR) angle for mediolateral oblique (MLO) projections on healthy volunteers.
b) Using the Xsensor pressure map system, determine the pressure and area balance for MLO position with two different IR angles (1 on Reference angle of 45^0, the other on Experimental angle measurement of the sternum) on healthy volunteers.
c) Use the evidence created in this project to make recommendations for standardised positioning and compression protocols in mammography.

4. What is the rationale which led to this project? *(refer to the guidelines in section 4)*

The introduction of digital mammography and the implementation of a robust quality assurance (QA) programme results in good consistency and control of most technical factors that affect image quality - such as exposure, resolution, noise, and contrast. Two critical factors that still affect image quality are positioning and compression, both still being controlled by the operator (Popli, 2014); this leads to inter- and intra-operator variability, thus impacting on the consistency of the service provided (Mercer et al, 2013).

There are general guidelines for optimum positioning of a client for mammography (Public Health England, 2017) but the expertise of the practitioner plays a crucial role in producing optimally positioned breasts Positioning is the single most important factor in optimising mammographic image quality. (IQ) (Popli, 2014). Without all the breast tissue included on a mammogram, all other aspects of IQ assessment are irrelevant.

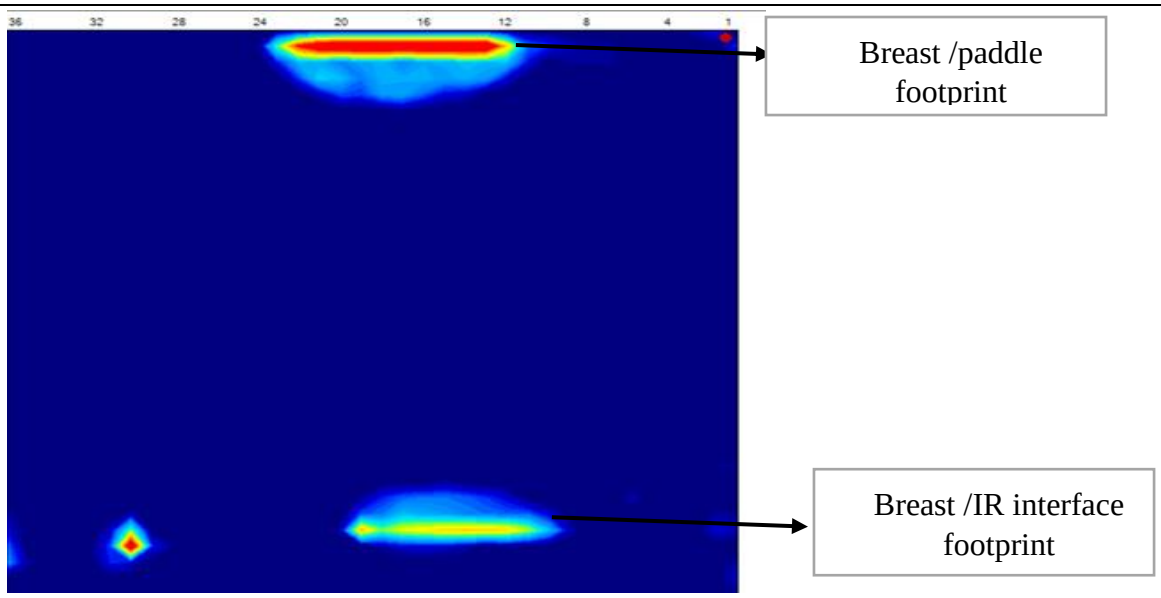
The aim of the research is to develop an evidence-based protocol for practitioners to assist with mammographic positioning as currently this does not exist.

Currently, guidelines for the level of compression to apply to the breast during mammographic examinations (Public Health England, 2017) are sparse and lacking in evidence. As a result, the amount of compression applied is subjective and this can lead to inconsistencies (intra-operator) and variations between practitioners (inter-operator) (Mercer et al, 2015). The impact of this is that the same patient could have a different experience each time they attend for breast screening.

A further confounding factor is that it is unlikely that each patient will be screened by the same practitioner on each subsequent screening attendance, therefore subjectivity leads to different positioning techniques and varying amount of compression. A standardised protocol will provide a consistent experience for the client.

Smith el al (2015) have completed similar work, but focussed on the craniocaudal (CC) position, which is the other projectional image that is acquired during mammography. They investigated the impact of changing the height of the image receptor (IR) with respect to the inframammary fold (IMF). It was concluded that by raising the IR by 2 cm relative to the IMF, it increased the breast footprint on the IR and gives a better pressure balance between breast/IR and breast /paddle (**Figure 1**). This indicates that more breast tissue was covered when the IR was raised by 2 cm compared to when it is at the level of IMF and below it. In addition, there was an even and similar distribution of pressure from the breast/paddle interface and Breast/IR interface.

Figure 1. Breast footprint pressure balance recorded on Xsensor pressure mat



While Smith et al (2015) changed the height of the image receptor (IR) for the CC position, this current research will investigate the optimal angle of the IR for the MLO position. Smith's study was conducted on the craniocaudal (CC) projection **(Figure 2)** with regards to the height of the IR, this research will involve MLO projection **(Figure 3)** with respect to the angle of the IR.

Figure 2. Patient being positioned for CC (Nightingale Centre, 2018)

Figure 3. Patient being positioned for MLO (Nightingale Centre, 2018)

This research will utilise some of the methodological choices and techniques applied to the development of the CC protocol, while developing new skills and knowledge from the investigation of the MLO position. Smith et al (2015) were granted ethical approval from the University of Salford and the University Hospitals of Morecambe Bay NHS Foundation Trust and recruited 16 participants. Breast compressions were applied at different IR heights and pressure distribution was recorded at each of these heights using the Xsensor pressure mapping system. The same method will be adapted for this study with pressure readings recorded for the MLO projection at 2 different IR angles. These conditions have been nominated as the 'Reference angle' and 'experimental angle'. The reference angle is 45° and is the currently recommended by Lee, (2003). The experimental angle will be derived from measurements of the sternal angle measured with digital inclinometer.

To clarify the rationale for this, although a reference angle of 45° is currently recommended, there are variation from 40-55° and it is also recommended that the IR is parallel to the sternum of the individual (Hogg, 2015). This varies according to a patient's body habitus and requires a precise measurement method to achieve the 'experimental angle'. However, it is critically important that the pressure balance and area is compared for the reference angle and the experimental angle to ensure that the experimental angle is offering an improvement in technique. Using only an inclinometer would not be sufficient.

A phantom study preceding the proposed work has already been completed, the

results from this study can be found in **Appendix VIII**. In summary it shows that when the IR angle matched the sternal angle, there was a more even pressure balance and breast contact area from both the IR and paddle. Hogg et al (2015) suggests that, for an effective compression force balance on MLO position, the sternal angle and the IR should be parallel to each other. This implies that, when the IR angle is parallel or close to the angle of the sternum, there is an even distribution of pressure at the superior and inferior aspect of the breast. In addition, it provides a more effective compression, potentially leading to less discomfort. This methodological approach will be followed for the volunteer study.

5. Research Methodology (*refer to the guidelines in section 5)*

This study will take a mixed methods approach utilising both experimental techniques and participant questionnaires.

Sixteen asymptomatic volunteers will be recruited to take part in the study. The exclusion criteria are:

- Men
- Women with any breast symptoms or who have any concerns with the breast
- Women with history of previous breast surgery
- Women with Breast Augmentation: Implants or Injectable fillers
- Women with a Pacemaker in situ
- Women undergoing treatment for breast cancer
- Women who do not have the ability to consent
- Women with ongoing pain or restricted movement of the shoulder/upper limb
- Women with open wound on the thorax or contagious disease

The inclusion criteria are as follows

- All women between the ages of 40 and 80 years (This age range falls within the national screening age 50-70 and symptomatic mammography begins at 40)
- Women with no previous breast surgery
- Women who have the ability to give consent
- Women with no breast implants or pacemaker in situ
- Women who are not currently taking part in another study
- Women with no ongoing breast pain

The study population will be female members of staff of Tameside NHS Hospital. Only females will be recruited because more than 98% of mammographic examinations undertake are done on females and breast cancer screening is not available to men.

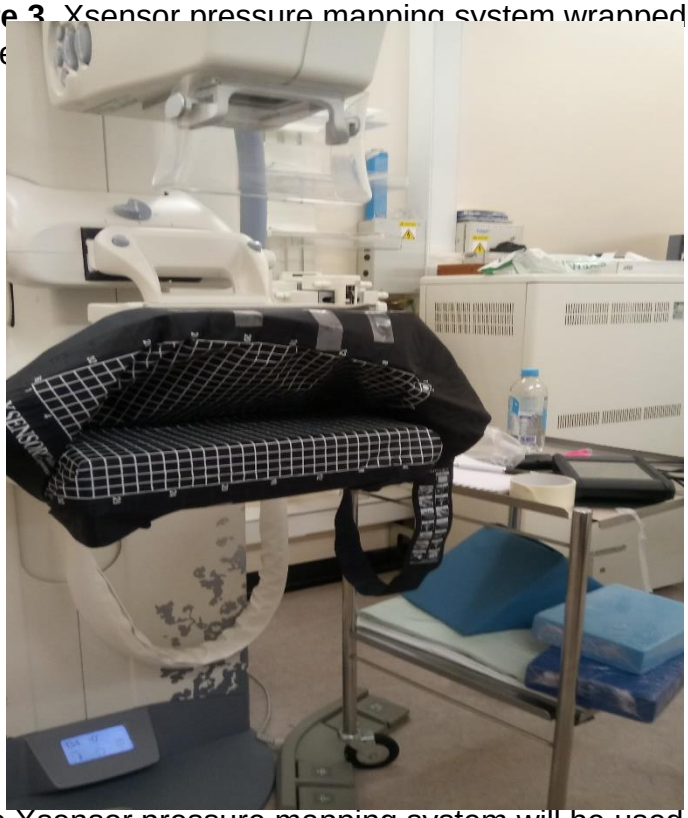
Participants will spend an average of an hour in the mammography room on the day of participation. After the procedure is explained and a signed consent (Appendix III) is taken, they will be asked to undress from the waist up and remove all jewellery. During the procedure if the researcher detects any current signs of symptoms (e.g. lumps, inverted nipple dimpling) the participant will be withdrawn immediately from the study and will be advised to see their GP as

soon as possible.

The angle of the sternum will be measured by placing a digital inclinometer device on the sternum and the reading recorded.

Participants will then be positioned for conventional MLO projection with Xsensor pressure mapping system secured on the mammographic unit with tape to cover the surfaces of the IR and the compression plate **Fig 3.**

Figure 3 Xsensor pressure mapping system wrapped around the IR and the paddle



The Xsensor pressure mapping system will be used to read and record pressure distribution on each compression. This equipment is routinely calibrated every couple of years by the manufacturer and is not due for a while. In additions the Xsensor has been successfully used in a similar study (Smith et al, 2015). The mat will be disinfected using wipes after each participant to ensure effective infection control procedures are followed.

Each participant will receive 4 compressions, 2 on each breast. From the 16 participants, 64 sets of data will be generated (4 compressions (right and left, experimental and reference angle) x 16 participants). There will be no exposure to radiation. The first set of compressions will be performed at the reference angle of 45° for MLO positioning. The second set of compressions will be performed at the experimental angle derived from the inclinometer measurements on the sternum. Inclinometer measurements will be taken 3 times and the average angle used. SD of all measurements will be recorded.

Compression force will vary between participants as individuals will have different tolerance to breast compression, however it will be kept consistent for individual participants for all 4 compressions. It is important to give the same compression for all 4 compressions for each participant in order to assess the effects of the change of angle on the pressure distribution for the same participant.

The compression, for every participant, will be limited within the range of 8-13 daN (decanewton, daN, is a unit of force in the International System of Units, defined as 10^1 newtons using the SI prefix system. Hogg et al (2013) completed a calibration study and recommended compression force within this range to control the pain/discomfort and the pressure applied during mammography. They examined the relationship between pressure and breast thickness on 940 breast compressions from 235 patients. From the results, the authors proposed a standardised cessation force of 90-130 N. They argued that breast compression to the point of rapid resistance increased the potential for pain and discomfort per applied Newton. At this point, the benefit of applying additional force ought to be questioned.

Each pressure map reading requires 10-15 seconds of compression. There will be a break of 1-2 minutes between compressions. This allows the researcher to change the angle of the IR as well as offer a short rest for the participant. Each participant will be allocated 1 hour to allow for set up and measurement the correct angle, and application of compression for 4 MLO positions. Two experienced female Health and Care Professions Council (HCPC) registered mammographers (the researcher and a member of staff) will be required, one to perform the positioning and compressions and the other to record the data.

Participants will be asked to score their pain on a validated 11-point numerical rating scale (NRS) (**Appendix VI**) after each compression that is, compression at the 'reference angle' and the 'experimental angle'. Participants will provide separate pain score after each compression. This will also give an insight into the pain/discomfort from the clients' perspective. This is a validated pain tool and they will rate the degree of pain/discomfort for compression experienced for each compression. Chauny, Paquet, Lavigne et al (2016) investigated the challenges when using 11-point NRS **(APPENDIX VI)** The conclusion was that, NRS has good discriminant power and is less biased by specific baseline pain intensity values when used with slope of relative pain intensity difference (SlopePID). This pain score has been utilised effectively in a study by Nelson et al (2020) in an observational study of mammography pain. Nelson et al (2020) investigated patient's experience of pain relating to mammography and compared pain score between different groups of patients.

The tool has been recently assessed in a study assessing pain in mammography and is a well-established tool for evaluating acute pain intensity (Chauny, Paquet, Lavigne et al (2016).

Statistical analysis

The data from the Xsensor pressure mapping device will be analysed using SPSS. The data obtained from the Xsensor will allow us to calculate –

1. Area of breast in contact with the compression paddle and area of breast in contact with image receptor
2. The maximum pressure applied to any part of the breast; minimum pressure applied to any part of the breast
3. The average pressure applied from above the breast; average pressure applied from below the breast
4. Index of pressure/area above and below the breast expressed on a scale between -1 and +1, where '0' represents perfect balance.

A paired T test will be run on the data in order to compare the following-

5. Area on image receptor at 45° against area on image receptor at experimental angle – a comparison of 64 datasets
6. Pressure from paddle onto the breast at angle 45° against pressure from paddle onto the breast at experimental angle – a comparison of 86 datasets

As in the phantom study (Appendix X), Uniformity Index (U.I) will be calculated.
U. I= (A-B)/ (A+B)

6. Please describe your recruitment strategy, and stipulate how many participants will be recruited and/or involved in the study, and give the rationale for this number *(refer to the guidelines in section 6)*

Asymptomatic women between the ages of 40- 80 will be invited to take part in the study using the inclusion and exclusion criteria stated above. As there has not been any research work done on angle of MLO with respect to pressure distribution, the sample size of 16 is appropriate with respect to the similar study carried out by Smith et al (2015), which looked at the height of IR during CC projection (also recruited 16 participants).

Emails will be sent out within the Hospital Trust and the University of Salford **(APPENDIX I)**. Interested volunteers will be asked to contact the researcher for further information.

Volunteers who express an interest in participating in the study will be sent the participants' information sheet **(APPENDIX II)** by email, which contains the study information. The participants' information sheet will be written clearly so that it would be clearly understood by non-medical or non-healthcare people.
Volunteers who agree to participate in the study will be requested to sign a consent form **(APPENDIX III).** Records of these will be kept in a locked cabinet, within the Hospital Trust and can only be accessed by the researcher and members of the research team within the Trust.

In regard to the consent form it will be indicated that the volunteers had the right to withdraw from the study, without giving any reason for doing so at any time. In this case the volunteer would have their data already collected deleted from the study records.

7. If working with outside organisations, please describe how you plan to obtain organisational agreement for your project *(refer to the guidelines in section 7)*

I will be liaising closely with the staff and management of the breast unit in order to carry out the study. An ethical agreement has been submitted and agreed by the ethical review board of the Hospital for approval before the start of the research**.**

Ethics approval will be sought from the hospital following University of Salford

ethics approval.

Management of Tameside and Glossop NHS Trust has granted approval for the research to be undertaken at the hospital (**Appendix IV**)

8. Please identify which Ethical Framework you will be adhering to. *(refer to the guidelines in section 8)*

Will adhere to the NHS and University of Salford research ethics framework. An ethics application will be submitted to NRES as well

9. Please describe the data protection issues that you need to address? *(refer to the guidelines in section 9)*

1. Participant will be anonymised to prevent identification. Research code will be provided to each participant and these will be known only to the researcher to ensure their identity remain anonymous and confidential.
2. Names and contact details of participants will be stored on a password protected computer and accessed only by the researcher
3. Computer and other devices to be used for data handling will be password protected to prevent easy access. These details can only be accessed by the researcher
4. Data collected including consent form and questionnaire will be anonymous and coded and hard copies of these will be stored in a locked filing cabinet within a locked room which is only accessible to the researcher.
5. Any data to be transported on laptops and USB sticks will be anonymous, identified only by a code and encrypted to protect against lost.
6. Any publication of data will be written in such a way which disguises the identity of participants.
7. Data collected will be stored and achieved for a minimum of 6 years.

10. Please describe how other ethical issues will be considered *(refer to the guidelines in section 10)*

All the patients who fall within the study inclusion criteria will be included where possible. However, patients from minority groups such as disabled patients and those who are non-English speaking will be excluded if they meet the inclusion criteria. Due to time and financial constraint, there will be no access to interpreter for non-English speaking participants

11. Please identify if reimbursements and/or incentives will be provided to participants *(refer to the guidelines in section 11)*

There will be no incentive provided to participants

12. Please describe the dissemination strategies for your project findings *(refer to the guidelines in section 12)*

Research work aimed to be published in various journals including *Radiography* journal and British Journal of Radiology. Results will be presented at conferences, seminars and workshops. In addition, it will be presented to research participants and the school of Health and Society at an event.

13. References – provide a full list of all references used

Chauny, J., Paquet, J., Lavigne, G., Marquis, M., & Daoust, R. (2016). Evaluating acute pain intensity relief: Challenges when using an 11-point numerical rating scale. *PAIN, 157*(2), 355-360.

Hogg, P. P. e., Kelly, J. e., & Mercer, C. e. (2015). Digital mammography: a holistic approach. In: Cham, Switzerland: Springer.

Jiani Yu et al (2018). Women's Awareness and Perceived Importance of the Harms and Benefits of Mammography Screening: Results From a 2016 National Survey. JAMA Intern Med. 2017;177(9):1381-1382. doi:10.1001/jamainternmed.2017.2247

Lee L, Strickland V, Wilson R, Roebuck E (2003). Fundermentals of mammography. 2nd edition.ed. London: Churchill Livingtone. Ltd; p 31-46.

Mercer, CE, Hogg, P, Cassidy, SF, & Denton, E. (2013). Does an increase in compression force really improve visual image quality in mammography? An initial investigation.

Nelson, D. J., England, A., Cheptoo, M., & Mercer, C. E. (2020). A comparative study of pain experienced during successive mammography examinations in

patients with a family history of breast cancer and those who have had breast cancer surgery. *Radiography, 26*(1), 76-81. doi:https://doi.org/10.1016/j.radi.2019.08.007

NHS Breast Screening Programme (2017) Guidance for breast screening mammographers. Third edition. December 2017 Public Health England leads the NHS Screening Programmes

O'Leary, D. & Al Maskari, Z. Breast Cancer Res (2013) 15(Suppl 1): P15. https://doi-org.salford.idm.oclc.org/10.1186/bcr3515

Popli, M., et al (2014). Breast Positioning during Mammography: Mistakes to be Avoided. *Breast Cancer: Basic and Clinical* Research 2014:8 119–124

Public Health, England (2017). NHSBSP Guidance for breast screening mammographers. Third Edition. Public Health England.

Taylor, K and Wallis, M (2017) Mammographic image quality in relation to positioning of the breast: A multicentre international evaluation of the assessment systems currently used, to provide an evidence base for establishing a standardised method of assessment. *Radiography* Volume 23, Issue 4, November 2017, Pages 343-349

NB: Projects that involve NHS patients, patients' records or NHS staff, will require ethical approval by the appropriate NRES. The School Research Ethics Panel will require written confirmation that such approval has been granted. Where a project forms part of a larger, already-approved project, the Research, Enterprise and Engagement Ethical Approval Panel for should be informed about, and approve, the use of an additional co-researcher.

NB: The ethical and efficient conduct of research by PGR students is the direct responsibility of the supervisor.

I certify that the above information is, to the best of my knowledge, accurate and correct. I understand the need to ensure I undertake my research in a manner that reflects good principles of ethical research practice.*

*By submitting your application via email you are confirming that you will comply with the above.

*Please note that whilst the School indemnifies PGR student research projects, the supervisor is signing that they are satisfied that the student has considered the ethical implications of their work and agrees for the PGR student's project to proceed subject to approval by the ethics panel.***

**By submitting your student's application you are confirming that you will comply with the above.

12.3 Appendix III - University of Salford Ethics Approval Letter

University of Salford MANCHESTER

Ethical Approval Panel

Doctoral & Research Support
Research and Knowledge Exchange,
Room 827, Maxwell Building,
University of Salford,
Manchester
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk

6 March 2020

Dear Muniratu,

RE: ETHICS APPLICATION HSR1920-038 – 'The Development of a Standardised Positioning and Compression Protocol for Use Within UK Breast Screening and Symptomatic Services.'

Based on the information that you have provided, I am pleased to inform you that your application HSR1920-038 has been approved to go forward to NRES (HRA).

Once you have received it, please submit a copy of the NRES (HRA) approval letter to Health-ResearchEthics@salford.ac.uk so that it can be placed on your application file.

If there are any changes to the project and/or its methodology, then please inform the Health Research Ethics Support team as soon as possible.

Yours sincerely,

Professor Andrew Clark

12.4 Appendix IV - Management Approval Letter- Version 1.1 14-12-

NHS
Tameside and Glossop Integrated Care
NHS Foundation Trust

Helen Johnson
Radiology Manager
Tameside and Glossop Integrated
Care NHS Foundation Trust
Fountain Street
Ashton under Lyne
Lancashire
OL6 9RW
11/02/19
Email: helen.johnson@tgh.nhs.uk

To Whom it may Concern,

RE: [redacted] Sigma Paddle Research

I write to confirm trust support for Muniratu to undertake the clinical component of her PhD research thesis within our Radiology Department.

We have a well established educational relationship with Salford University, and her research work regarding the impact that the use of the sigma paddle might have in relation to the pain a woman may experience during mammogram examination, follows on from MSc research recently undertaken by our Clinical Specialist Breast Radiographer here at Tameside last year looking at strategies to reduce pain during this examination.

Muniratu has been working clinically with us as a bank Mammographer for many months to establish herself as part of our team and we are happy to support her research in order to facilitate future developments in practice.

Kind Regards

Helen Johnson
Radiology Manager

12.5 Appendix V - Confirmation of Capacity and Capability at Tameside and Glossop Integrated Care NHS Trust

RE: IRAS 274519. Confirmation of Capacity and Capability at Tameside and Glossop Integrated Care NHS Foundation Trust
Study Title: The development of a standardised mammographic positioning and compression protocol for use within UK breast screening and symptomatic services
Trust R&D Reference Number: BR/2020/512
PI- Muniratu Osmanu

This email confirms that **Tameside and Glossop Integrated Care NHS Foundation Trust, Tameside General Hospital** has the capacity and capability to deliver the above referenced study. Please find attached our completed Organisation Information Document as confirmation

We agree to start this study on a date to be agreed when you as sponsor give the green light to begin.

The current documents are as follows:

Document	Version	Date
IRAS Application Form: 274519/1459071/37/690	17/06/2020	Signed 28/10/2020
REC approval letter	20/NW/0307	10/07/2020
HRA approval letter	274519	19/11/2020
Letters of invitation to participant [Invitation letter (email)]	V1.0	18/06/2020
Participant consent form [Consent form]	V1.1	31/10/2020
Participant information sheet (PIS) [PIS]	V1.1	31/10/2020
Research protocol or project proposal [Research Proposal]	V1.1	31/10/2020
Validated questionnaire	1.0	18/06/2020

Local study team;

- Please ensure you notify the R&D office when you recruit your first patient to this study at Tameside Hospital.

- Please ensure you conduct the study in accordance with the TGH research standard operating procedures on http://tis/Pages/randd_sopspolicies.asp . Please also find attached the research study site file aide memoire.

If you have any further queries, please do not hesitate to contact me.

May I wish you the best of luck with your research.

Kind regards
Rebecca

Rebecca Roberts
Research and Governance Manager
Research Office, 2nd Floor Charlesworth Building,
Tameside and Glossop Integrated Care NHS Foundation Trust,
Tameside General Hospital, Fountain Street, Ashton Under Lyne, OL6 9RW
0161 922 4451
Email: rebecca.roberts@tgh.nhs.uk
rd@tgh.nhs.uk

End of document

12.6 Appendix VI - HRA and Health and Care Research (HCR) Approval Letter.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Claire Mercer
University of Salford
School of Health and Society
L614, 6th Floor, Allerton Building
M5 4WT

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

19 November 2020

Dear Dr Mercer

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**The development of a standardised mammographic positioning and compression protocol for use within UK breast screening and symptomatic services**
IRAS project ID:	**274519**
Protocol number:	**N/A**
REC reference:	**20/NW/0307**
Sponsor	**University of Salford**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **274519**. Please quote this on all correspondence.

Yours sincerely,

Rachel Katzenellenbogen
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: Dr Claire Mercer

12.7 Appendix VII - Risk Assessment Question Sheet for COVID-19

	QUESTION	YES	NO
1	Do you or any member of your household/family have a conformed diagnosis of COVID-19? If YES, the procedure will be delayed until the appropriate time has passed		
2	Are you or any member of your household/family waiting for a COVID-19 test results? If YES, the procedure will be delayed until the appropriate time has passed		
3	Have you travelled internationally in the last 10 days? If YES, the procedure will be delayed until the appropriate time has passed		
4	Have you had contact with someone with a conformed diagnosis of COVID-19, or has been in isolation with a suspected case in the last 10 days? If YES, the procedure will be delayed until the appropriate time has passed		
5	Do you have any of the following symptoms? ❖ High temperature or fever ❖ New, continues cough ❖ A loss or alteration to taste or smell? If YES, advice will be given on who to contact NHS 111		

12.8 Appendix VIII - Risk Assessment Checklist for Covid during Data Collection

Covid risk assessments checklist for data collection

TASK	YES	NO
Mammography room clean and tidy		
Mammography unit cleaned before start of procedure		
All equipment and tools (inclinometer, pressure mat, weighing scale) cleaned before start of procedure		
All surfaces wiped down before procedure		
Researcher wearing face covering		
Researcher washed hands before start of procedure		
Researcher in full PPE before contact with participant (hand gloves, apron)		
Negative lateral flow test for researcher		
Participants wearing face covering		
Participant sanitise their hands before entering the unit		
Mammography unit cleaned after procedure		
All equipment and tools cleaned after procedure		
All surfaces wiped down after the procedure		
Researcher washed hands after procedure		
Participant sanitise hands before leaving the unit		

12.9 Appendix IX - Participant Invitation Letter (Email) Version 1.1 14-12-19

Research Governance and Ethics Committee Approval (RGEC) Ref. NO:

……

A research study is being planned to investigate the pain/discomfort associated with mammography as a result of the positioning and compression applied during the procedure. The study's aim is to standardise positioning and compression for the individual to allow for a reproducible experience every time a woman attends for mammography.

For this study we need healthy participants to be positioned for one of the positions completed as part of a mammography examination; radiographic images will not be taken and there will be no exposure to ionising radiation. Each breast will be compressed twice, in two different positions. This will take place at the breast unit of Tameside and Glossop Hospital and will take approximately one hour.

You will not be able to be included in this study if you:

- Had previous breast surgery
- Have had breast augmentation (including implants)
- Have a pacemaker
- Are undergoing treatment for breast cancer
- Do not have the ability to consent
- Have had any previous skin tears or other skin problems on the breast; this study may aggravate the condition.

If you would like more information or are interested in taking part, please do not hesitate to contact me on ([redacted])

You will then be sent a participant information sheet and data sheet which will provide you with more details about the study.

Best Regards,

(Signature to be inserted once ethics approval has been granted)

PhD Student (address to be inserted once ethics approval has been granted)

12.10 Appendix X- Participant Information Sheet- Version 1.1 14-12- 19

Title of study:

Standardised positioning and compression protocol in mammography for use within UK breast screening and symptomatic services.

We are investigating the discomfort and pain associated with mammography. We are inviting you to take part in our research study to find out a standardised (best) position protocol for use in mammography.

If you are interested in taking part then you should read the rest of this information sheet before you decide to participate. You should be aware of the rationale, benefits, limitations and what would be involved for you. Please take your time and read the attached information. If you have any questions and need more explanation, please do not hesitate to contact the lead research (contact details at the end of this document).

What is the purpose of the study?

The purpose of the research is to develop an evidence-based protocol that enables practitioners to complete personalised positioning that may help reduce pain and discomfort associated with the procedure. Mammography is the gold standard tool for the screening and diagnosis of breast cancer. Positioning and compression are the two factors that are directly associated with pain and discomfort experienced during mammography. As a result of women having different body habitus, mammographic positioning will have to modified each time to suit individual client. In changing technique to suit individual's body habitus, the procedure is likely to be painful and this does have impact on patient's experience. Current evidence suggests that the compression applied during mammography is practitioner dependant and therefore it can be subjective. This research will look at standardising compression pressure to eliminate the possibility of over compression and give clients a consistent and repeatable mammographic experience.

Why have you been invited?

All women aged 40-80 employed by Tameside and Glossop NHS Hospital and the University of Salford have been invited to take part in this research. This is because this age group are most likely to receive a mammogram as part of the National Health Service Breast Screening Programme (NHSBSP) or as part of a symptomatic attendance. From the women invited, we will recruit 16 healthy volunteers.

You must not take part in the study if: -

1. You have had any breast surgery in the past
2. You are fitted with a pacemaker
3. You have any current breast symptoms
4. You have any skin tears or other skin problems on the breast
5. You are currently being investigated for breast cancer

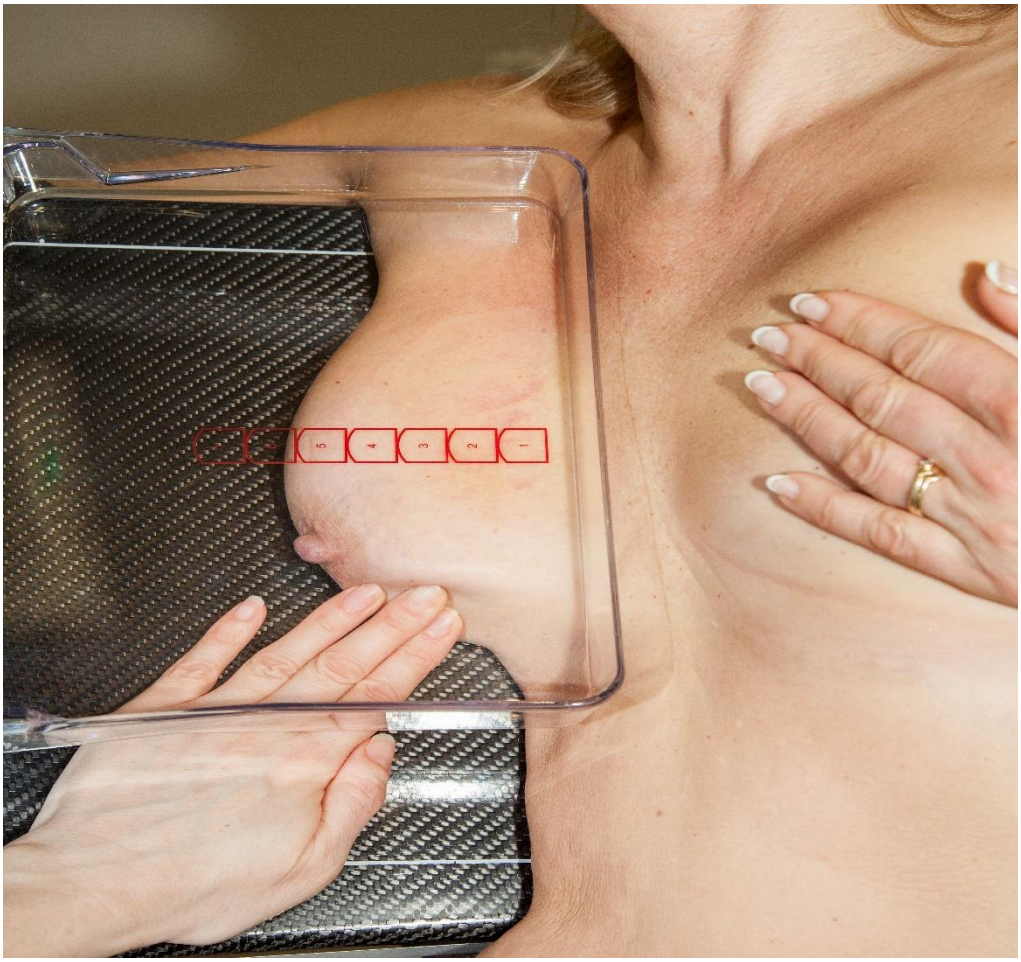
Do you have to take part?

You are the only one who decides whether to take part in this study or not. We will provide you of all the information that you require. You can also withdraw from study at any time. If you withdraw up to 3 months after data collection you can also opt to have all your study data destroyed.

What will happen to me if I take part?

If you are one of our study participants, you will need to attend the Tameside Breast Unit and your visit will last for approximately an hour. You will meet the research team and will have the opportunity to ask any further questions. If you agree to participate, we will then proceed to take your weight and height. Two female mammographers will be present in the mammogram room to perform and record the procedure. You will be asked to undress to the waist. A device will be place on your chest to measure your sternal angle and a pressure sensitive material will be wrapped around the mammography machine. This will be connected to a computer so that information about the pressure applied to the breast can be recorded and analysed. The mammography machine will then be used to compress your breasts 4 times (2 on each side) as represented in **Figure 1.**

Figure 1. Breast being compressed obliquely (Nightingale Centre Manchester University NHS Foundation Trust, 2012).



The compression force applied to each breast is within the range used in standard mammography techniques. Each compression will last 10 to 15 seconds, this is slightly longer than the compression normally takes in routine mammography. This is so that stable readings can be made using the pressure mattress attached to the mammogram machine. Small changes to the position of the mammography machine will be made each time we compress your breast. There will be a break of about 2 minutes in between each breast compression to allow the data to be recorded on to the computer. You will not be exposed to ionising radiation at any stage of the study. At the end of the procedure, you will be required to fill in a questionnaire to rate the scale of your pain with relation to the procedure. All the information recorded will be kept confidential. Your name will not be used in the research in any way.

Expenses and payments?

Participating in this research is voluntary, and no payment will be made to the participants.

What will you have to do?

All you have to do is attend the breast unit at the date and time agreed via email. Be prepared to stay for one to two hours. If you develop any breast symptoms (i.e. pain) during or after participation you must inform us immediately.

What are the possible disadvantages and risks of taking part?

The compression force we will be using is within the range of that applied during standard mammography procedure. However routine mammography can cause skin reddening and tingling; this is not unusual and will quickly diminish. If your breasts are normally very tender, it may not be appropriate for you not to participate. If you bruise easily, the compression could cause bruising.

The equipment we are using will only be available to us at specific times. It is therefore important that you attend at the time agreed. If you think this will be difficult you must let the researcher know as soon as possible.

What are the possible benefits of taking part?

The information we gain from the study will help to increase the understanding of breast positioning and compression in mammography.

Ultimately this study could help to identify a technique which will give us a more consistent and reproducible mammography experience as well as providing a more comfortable procedure.

What if there is a problem?

It is unlikely that anything adverse will happen. However, if you have any concerns about this study, please contact the lead researcher ([redacted]) or one of the research supervisors, [redacted] or [redacted]. However, if you remain dissatisfied, please contact Dr Andrew Clark. L521 Allerton Building. University of Salford. Salford. M6 6PU E: a.clark@salford.ac.uk. T: 0161 295 4109

Will your taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name removed so that you cannot be identified.

When you attend the breast unit to participate in the study you will be allocated a unique number. In accordance with the Data Protection Act 1998 all the information that we collect about you when you attend will be linked to your unique number, not your name.

Each time we compress your breast, information from the pressure sensitive material will be transferred to a computer. This electronic data will be stored on a password protected computer known only by the researcher.

A master list identifying participants to their unique number will be held on a password protected computer accessed only by the researcher.

Paper data will be stored in a locked cabinet, within a locked office, accessed only by the researcher.

Only the research team involved in this study will have access to identifiable data. The information we collect will be kept for a minimum of 3 years.

What will happen if you don't carry on with the study?

If you withdraw from the study all the information and data collected from you, to date, will be destroyed and your name removed from all the study files.

What will happen to the results of the research study?

The outcome of this study will form part of a PhD thesis but you will not be identified in the publication. Any new and significant results will be published in peer reviewed academic journals and presented at scientific conferences. We will contact you as soon as the study is complete and give you the opportunity to see the results.

Who is organising or sponsoring the research?

The University of Salford, Manchester, UK

Further information and contact details:

If you need more information or enquires about this research, please contact (insert name and details after UoS ethics approval granted)

Research Supervisor- [redacted]

12.11 Appendix XI - Research Participant Consent From- Version 1.1 14-12-19

Title of study: Standardised positioning and compression protocol in mammography for use within UK breast screening and symptomatic services.

Name of Researcher: (name to be inserted once ethics approval granted)

Ethics REF NO:

Please complete and sign this **form after** you have read and understood the participant information sheet. Read the statements below and answer yes or no, as applicable in the box on the right-hand side.

(*Delete as appropriate*)

1. I confirm that I have read and understand the participant information sheet version 1for the above study. I have had opportunity to consider the information and ask questions (face to face and by email).	Yes/N
2. I understand that my participation is voluntary, no financial benefit and that I am free to withdraw at any time, **without giving any reason**. If I decide to withdraw. I understand that the information I have given will be destroyed (provided that you withdraw in a period of 3 months from your data collection).	Yes/N
3. My participation in this research will involve being positioned for mammogram However there will be no images taken which have been explained to me by the researcher.	Yes/N
4. I understand that my data will be used in the researcher's thesis, academic publications and conferences presentations. However, I understand my data will be anonymised and will be stored by code on a password protected University computer. My data will be given a unique participant identifier code and no identifiable information will be retained.	Yes/N
5. I agree to take part in the study.	Yes/N

Name of participant: ……

Date: ……

Signature: ……

Name of researcher: ……

Date: ……

Signature: ……

Name of researcher taking consent	(to be inserted after UoS ethics approval granted)
Researcher e-mail address	(to be inserted after UoS ethics approval granted)
Research supervisor	[redacted]
Supervisor e-mail	[redacted]

11.12 Appendix XII- Data Collection Sheets- Version 1.1 14-12 19

Project title: Standardised positioning and compression protocol in mammography for use within UK breast screening and symptomatic services.

Today's Date:	Participant number:	
Date of birth:	Gender:	Phone Number

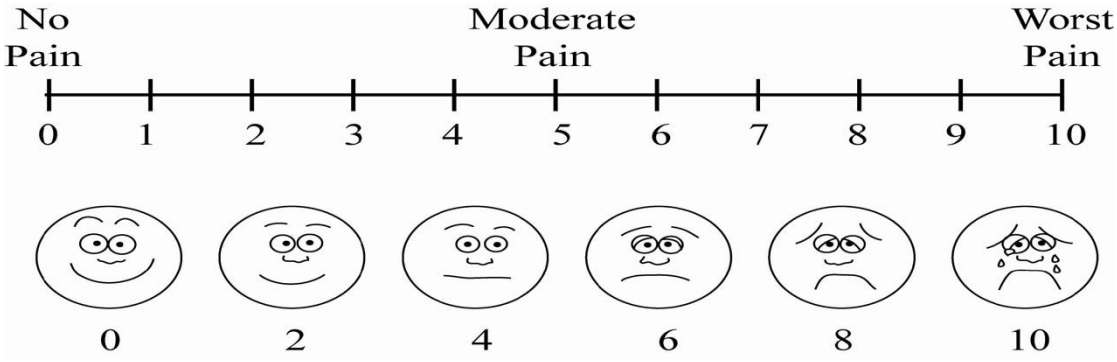
1. Have you had any previous breast surgery?	Yes	No
2. Do you have any current breast symptoms?	Yes	No
3. Do you have breast implant?	Yes	No
4. Are you fitted with a pacemaker?	Yes	No
5. Are you currently being investigated for breast cancer?	Yes	No
6. Do you have any skin tears or other skin problems on or around the breast?	Yes	No

Height:	Weight:	BMI	Breast size

12.13 Appendix XIII -Patient Experience of Pain- Version 1.1 14/12/19

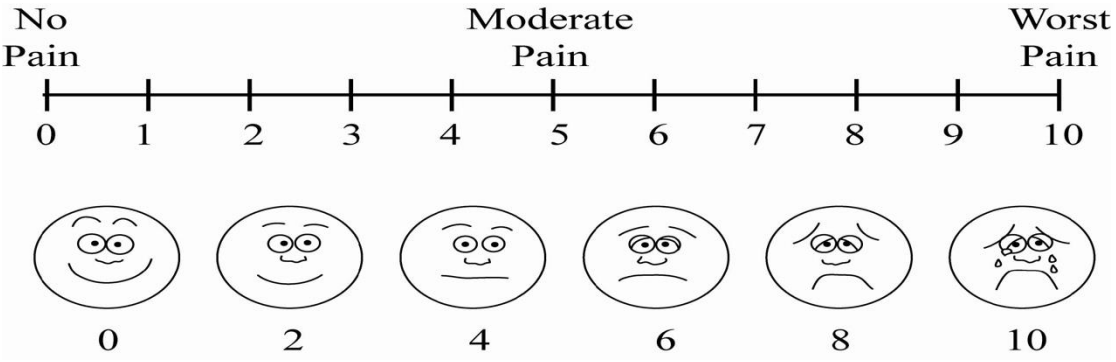
Was the first compression painful? Yes No

Please score it from 0-10 immediately just before the compression was released.



Was the second compression painful Yes No

Please score it from 0-10 immediately just before the compression was released.



Any sign of skin damage? Redness Skin tear

Bruise Lump Nil

Site of visible skin damage ……

Patient comments relating to pain