A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer

Detecting Breast Disease using Palpation

Veitch, Daisy

DOI
10.4233/uuid:d4b385c9-6d47-44f6-a959-4125825e7f06

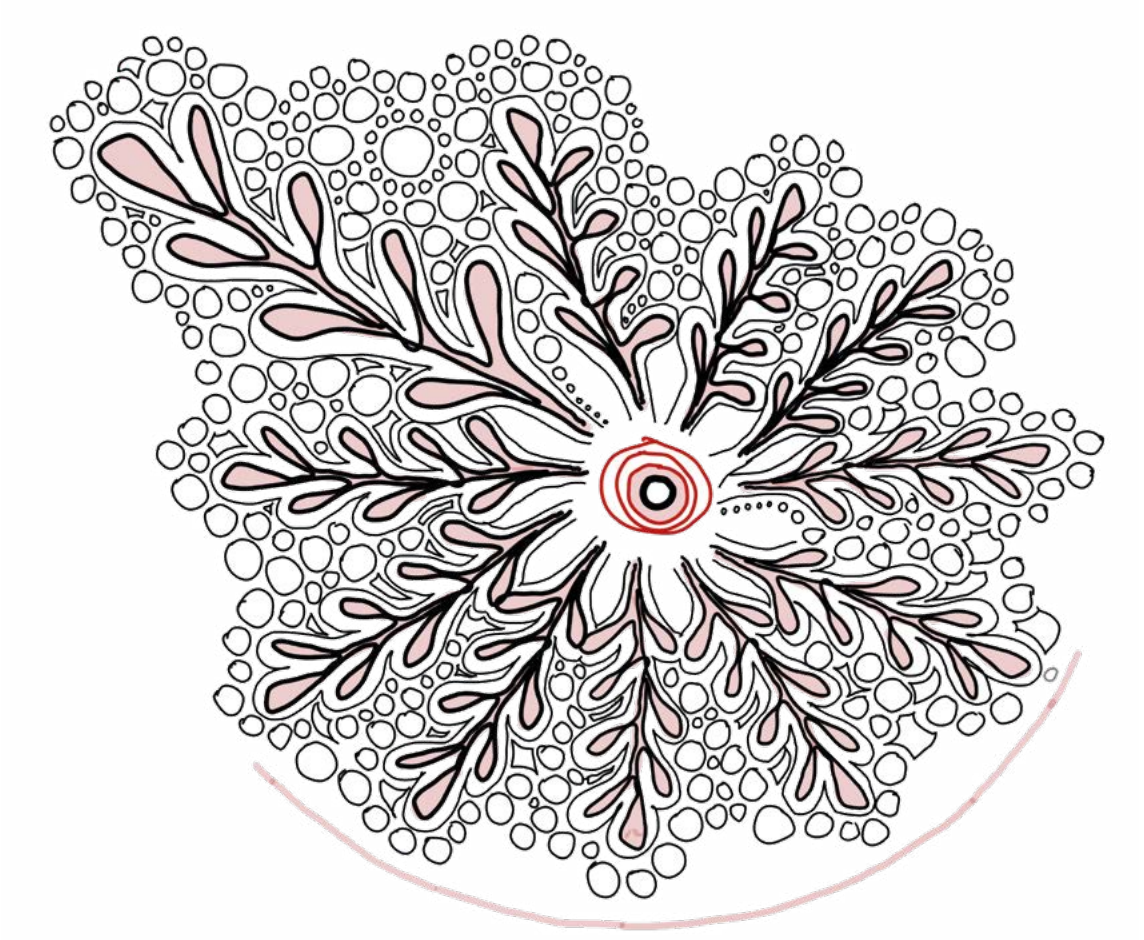
Publication date
2019

Document Version
Final published version

Citation (APA)
Veitch, D. (2019). *A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer: Detecting Breast Disease using Palpation*. [Dissertation (TU Delft), Delft University of Technology]. https://doi.org/10.4233/uuid:d4b385c9-6d47-44f6-a959-4125825e7f06

Important note
To cite this publication, please use the final published version (if applicable).
Please check the document version above.

A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer



Daisy Ellen Veitch

A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer

Daisy Ellen Veitch

A Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff to Diagnose Breast Cancer

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus, Prof.dr.ir. T.H.J.J. van der Hagen,
Chair of the Board for Doctorates
to be defended publicly on
Monday 9 December 2019 at
10:00 o'clock

by

Daisy Ellen VEITCH
born in Adelaide, Australia

This dissertation has been approved by the promotors.

Composition of the doctoral committee:

Rector Magnificus,	Chairperson
Prof.dr.ir. R.H.M. Goossens,	Delft University of Technology, promotor
Dr.ir. J.F.M. Molenbroek,	Delft University of Technology, copromotor

Independent members:

Prof.dr. T.J.M. van der Cammen	Delft University of Technology
Prof.dr. K.M. Robinette	Oklahoma State University, USA
Prof.dr. G.J. Kleinrensink	Erasmus Medisch Centrum
Dr. C.M.G. Keyzer-Dekker	Erasmus Medisch Centrum
Prof.dr. B.F. van Eekelen	Delft University of Technology

Keywords: breast cancer, simulation model, biofidelic, lifelike teaching, clinical breast examination, breast disease

Thesis, Delft University of Technology, Delft, The Netherlands
ISBN/EAN: 978-94-028-1848-2
This research was funded by SHARP Dummies Pty Ltd
Cover design by Lilian Fellner
Printed and distributed by Ipskamp Printing

Contents

At a glance

When breast cancer is detected early, and is in the localized stage, the 5-year relative survival rate is 100%. (Australian Institute of Health and Welfare 2019)

There is a survival advantage in detecting breast cancer early and treating it quickly (Australian Institute of Health and Welfare, 2019; Cancer Australia, 2004, updated 2009; McDonald, Saslow, and Alciati, 2004; National Breast Cancer Foundation, 2019). Clinical Breast Examination (CBE) is a method which can fast track symptomatic women with a breast lump to scarce medical specialist resources to speed the investigation into their putative cancer and facilitate early treatment if needed. Yet too many medical students and doctors feel they could improve their skills in clinical breast examination. Realistic breast models will help the necessary training (Saslow et al. 2004). But knowing what skills need to be transferred and how to design physical breast models are very different things. What are the important skills in identifying and discriminating breast masses by touch and how do simulation models and a validated testing tool assist skill acquisition? Here's a good example of the creation and development of a successful design from the following brief: to make physical breast models realistic enough to be integral to training and a subsequent testing package, where medical personnel acquire, maintain and improve the skills required to detect possible breast cancer by palpation.

Prototype and final design

The successful methods used in the development of the breast models and Tactile Landscape (TL) are described in length in Chapters 3, 4, and 5 that are in the form of published papers – see structure of the thesis in Chapter 1. In the end there are 6 models that vary in softness and lumpiness each relating to cases that teach each concept as well as offering hands-on experience. One of the series of breast models developed is shown in Figure 0.1. There are also simulated pathology representing cancer, fibroadenoma and cysts. All these components were recombined in new ways to create the TL testing object. The models and the TL have been validated in preliminary trials described in Chapters 4, 5 and 6.

Figure 0.1 *Finished breast model that is quite soft with a medium amount of nodularity.*

Future development

The teaching package needs to be created and tested. The TL needs further testing with a wider variety of students at different locations. Although the breast simulators represented more than 80% of women, for completeness a seventh breast simulator needs to be added to the range of normal that is extremely soft.

List of abbreviations

BCS/MD	Bachelor of Clinical Sciences/Doctor of Medicine
BMI	Body Mass Index
BSE	Breast Self-Examination
CAESAR	Civilian American and European Surface Anthropometry Resource Project
CAD	Computer-Aided Design
CBE	Clinical Breast Examination
CNC	Computer Numerical Control
CPR	Cardiopulmonary Resuscitation
CS	Competence Score
DS	Difference Score
FEA	Finite Element Analysis
GP	General Practitioner
IDBM	Identification and Discrimination of Breast Masses
IEA	Intimate Examination Associate
MRI	Magnetic Resonance Imaging
RAH	Royal Adelaide Hospital
SHARP	Surface Human Anatomy Replication of People
TL	Tactile Landscape
USAF CARD	Lab United States Air Force Computerized Anthropometric Research and Design Laboratory

List of Daisy Veitch's publications included in this PhD

Publications are grouped into peer-reviewed journals, conference proceedings and discipline publications and listed in reverse date order, newest first.

Peer reviewed journals

D Veitch, R Goossens, H Owen, J Veitch, J Molenbroek, M Bochner (2019), "Evaluation of Conventional Training in Clinical Breast Examination (CBE)", WORK: A Journal of Prevention, Assessment & Rehabilitation 2019;62(4): 647-656. doi: 10.3233/WOR-192899.

D Veitch, M Bochner, J Molenbroek, R Goossens, H Owen (2019), "Breast Cancer Detection: The Development and Pilot Study of a "Tactile Landscape" as a Standardized Testing Tool", Simulation in Healthcare 2019; Jun;14(3): 201-207. doi: 10.1097/SIH.0000000000000365.

D Veitch, M Bochner, L Fellner, C Leigh and H Owen (2018), "Design, development and validation of more realistic models for teaching breast examination", Design for Health, available online at https://www.tandfonline.com/doi/citedby/10.1080/24735132.2018.1451454?scroll=top&needAccess=true

D Veitch, M Bochner (2014), "Development of a Realistic Model for Teaching Breast Examination", The Breast 23(4):S2–S3.

D Veitch, R Dawson, H Owen and C Leigh (2011), "The development of a lifelike breast cancer patient simulator using anthropometric data" Ergonomics Australia – HFESA 2011 Conference Edition, 2011 11:45.http://www.ergonomics.org.au/resource_library/journal.aspx
Paper was the winner of Ken Provins award 2011

Conference proceedings

D Veitch, L Fellner, M Bochner, (2018) "Realistic breast models: can they be used for rural clinician training and accreditation?" PeARLs, The Muster 2018, Mount Gambier, South Australia.

D Veitch, R Goossens, J Molenbroek, H Owen, M Bochner, (2018) "Refining the language of touch/feel in developing evidence-based simulation manikins to teach Clinical Breast Examination (CBE)", video abstract, 22th World Congress on Ergonomics – International Ergonomics Association (IEA), Florence, Italy

D Veitch, C Leigh, M Bochner, (2014), "Development of realistic model for teaching breast examination", Presentation and extended abstract, Australiasian Society for Breast Disease, Gold Coast, Queensland, Australia.

D Veitch, R Dawson, H Owen and C Leigh, (2012), "Using 1D and 3D Anthropometric Data to Develop a Biofidelic Breast Cancer Patient Simulator", Asian Workshop on 3D Body Scanning Technologies, Tokyo Japan.

Discipline publications

D Veitch (2019), Clinical Breast Exam, Asian Hospital & Healthcare Management

Acknowledgements

The authors would like to thank the promotor Prof.dr.ir. Richard Goossens and copromotor Dr.ir. Johan Molenbroek from TUDelft for their unwavering support. We would like to thank Prof Harry Owen, for his input of excellent ideas, Dr Melissa Bochner for her substantial assistance in the research, Mr Christopher Leigh for input in material selection and model building techniques, Ms Lilian Fellner for her ongoing support in all aspects, Ms Rachel Dawson for her input in the initial stages, Dr James Veitch and Prof.dr. Kathleen Robinette for their editing and statistical advice, Dr Jeff Hudson for the CAD images (Chapter 3, 4 and 5), Mr David Summerhayes for assistance in preparation of the other images (used throughout the thesis), Mr Schonn-Pierre Hirst (filming the video clip), Dr Henry Fellner for input in the initial material selection process (Chapter 4), Mr Donovan Allen for assistance in the design of the Tactile Landscape, Dr Martin McAvoy for editing, Ms Griselda Raisa Susanto for research support, Dr Frank van der Meulen for some early statistical advice, Dr Randell Brown for organizing and interpreting the MRI (Chapter 4), staff at TU Delft for the preparation and milling of the CAD model shown in Figure 4.3 (Chapter 4), the many volunteers who assisted in the clinical trials (Chapters 4, 5 and 6) and staff at the Royal Adelaide Hospital Women's Health Centre who generously gave their time for the collection of data (Chapter 4, 5 and 6).

Chapter 1 — Introduction

Medical context

"Breast cancer is the most common cause of cancer death in women worldwide, estimated to be responsible for around 458,500 female deaths in 2008 or nearly one in seven (around 14%) of all cancer deaths in women." (Cancer Research UK 2013)

There is a survival advantage in detecting breast cancer early (Cancer Australia 2004, updated 2009, McDonald, Saslow, and Alciati 2004, Australian Institute of Health and Welfare 2019). Western countries facilitate early detection with screening programs, usually mass screening mammography. For example Australia experienced a reduced death rate in women with breast cancer after mammography screening was introduced in 1995 (Australian Institute of Health and Welfare 2019).

Although some countries like India use CBE for screening, in most places it is either not recommended or there is no recommendation either for or against its use in screening programs due to its low specificity and sensitivity for detecting breast cancer (Saslow et al. 2004, Keating and Pace 2015). However, CBE is useful when women present with breast symptoms in the primary health setting. This is because CBE is not just about detecting cancer – it is also about diagnosing and reassuring women who have symptoms that are not cancer. Kollias et al. (2001) found of symptomatic women with a definitive diagnosis, 82.7% were benign breast cases. This means there is a large burden of care for women who have symptoms that are not cancer and CBE is the first line in medical care for this group of women.

In Australia mammography, not CBE, is used for screening asymptomatic women. In symptomatic women, the clinical guidelines state that CBE is performed on women presenting to their GP with breast symptoms. If the GP finds a suspicious lump via CBE, a diagnostic mammogram or ultrasound is indicated (BreastScreen October 2017). This means that CBE is used as a gateway into further investigation and specialist care at a primary health level. Therefore, competence in CBE is required for GPs to act as an accurate filter for further diagnosis and to facilitate timely access to possible treatment.

It is well documented that CBE is less sensitive than mammography in detecting breast cancer. (Goodson 2010, Irwig, Macaskill, and Houssami 2002). In addition, mammography can detect cancer that are too small to be felt by palpation. Due to this a number of countries like the Netherlands do not recommend CBE as a screening tool (Oncoline 2019). In addition many of the features described and taught in CBE such as 'peau d'orange' and skin dimpling are symptoms of advanced breast cancer that are not as commonly seen nowadays due to the advancement of early detection. CBE also has a high rate of false positives. False positives in mammography screening can lead to adverse psychological outcomes and quality of life issues in the false positive group (Keyzer-Dekker 2012, 'Anxiety and quality of life in (benign) breast disease' p20). However NHG Dutch guidelines concur with Australian guidelines about the importance of physical examinations, CBE, when a woman presents with breast symptoms (NHG Nederlands Huisart Genootschap 2016).

There are a large group of women who do not participate in screening for various reasons. Either screening is not available, as in third world countries or rural populations, or they are excluded due to age or by their own choice: for example, 55% of women aged 50-74 in Australia participated in screening mammography in 2016-17(Australian Institute of Health and Welfare 2019). However, if these women become symptomatic and present to their primary healthcare physician (GP) then CBE, when performed well, allows for the judicious use of resources for further investigations that may include diagnostic mammography, ultrasound, targeted ultrasound and specialist referral. Alternatively, CBE may also facilitate patient reassurance with no further investigation required.

CBE is important because sometimes it is the only pillar of the triple test available, and at other times is vital for the breast cancer sufferers who present to the GP or physician with symptoms and have clinically palpable tumours that are either mammographically occult or whose cancer appears as an 'interval cancer'. Interval breast cancers are those that may appear between imaging appointments and potentially have more aggressive features than other breast cancers (Haakinson et al. 2010, Australian Institute of Health and Welfare 2019).

CBE doesn't require any expensive or specialist equipment and is relatively non-invasive, so is affordable for most communities. For part-diagnostic purposes in symptomatic women in a primary healthcare setting, it is a fast track to connect

those with a suspicious breast lump to the additional resources of the triple test. CBE is important to different stakeholders for different reasons (see Table 1.1 below).

Stakeholder	Type of examination	Purpose
Self breast examination	Self-examination	Breast awareness
Breast screen services	Mammogram	Screening
GP	CBE	Part-diagnostic
Medical trainee	CBE	Part-diagnostic
Breast specialist	CBE as part of TRIPLE TEST	Diagnostic

***Table 1.1** The Target Audience for the Breast Model Teaching Package and IDBM testing shaded in grey.*

Despite being widely used over many decades in different situations and for different reasons there is little data about the accuracy of CBE in different contexts. It is important to note that the published figures for accuracy, sensitivity and specificity of CBE overwhelmingly reflect the use of CBE in conjunction with a mammographic cancer-screening program, and that data describing the performance of CBE in the primary health setting is sparse.

The best practice in Australia for diagnosing symptomatic breast cancer is the 'triple test' with a 99% to 100% sensitivity (Ahmed et al. 2007, Irwig, Macaskill, and Houssami 2002, Nigam and Nigam 2013, SA Health 2019).

The triple test is:

1) Clinical Breast Examination (CBE) which includes an oral history, palpation and visual aspects,
2) Radiological imaging including mammography, ultrasound and MRI, and
3) Biopsy/Pathology.

However, the triple test is not always practiced and sometimes only one pillar of the three is used. Sometimes this is because the importance of the triple test is not recognised. For example, mammography is often used as a surrogate for CBE as some GPs are not aware that mammography screening misses some of clinically palpable breast cancers – values vary depending on the type of mammography, definition of a positive mammographic examination,

mammography done with older technology and/or larger screening intervals (Barlow et al. 2002, Cahill et al. 1981, Donegan 1992, Haakinson et al. 2010, Irwig, Macaskill, and Houssami 2002). However, Irwig et al. (2002) reported that 3% of cancers are only detected with fine needle biopsy (FNB) and 1.1 percent, of breast cancers are only detected with CBE and 2.4% are only detected by mammography. The majority of cancers, 73.3% are triple positive (detected by all three tests) while 9.8% are detected with either FNB or CBE or both together but not mammography. It is thought that breast density can visually obscure some cancers so certain breast types are more likely to be mammographically occult – a mammogram does not always visually differentiate the cancer from surrounding tissue (Whitehead et al. 1985, Sala et al. 1998, Boyd et al. 2007). Sometimes the triple test can not be practiced for practical reasons. For example, the location of some communities is so remote from urban hospital facilities that they do not have access to imaging equipment or individuals have to travel vast distances to access equipment. Similarly underdeveloped countries may not have the capability to do the triple test, e.g., no access to medical imaging or limited electricity supply.

This research focuses on capturing expertise from the breast specialist in order to provide a high quality set of simulation models and testing capability to ultimately improve basic training for medical trainees and General Practitioners (GP).

Current training in CBE is not clearly standardised in Australia. We focussed on medical training of MBBS/MD students in South Australia, specifically training given by breast specialists practicing at the Royal Adelaide Hospital. Currently students are offered a 30-minute training in CBE with intimate examination associates (paid actors who allow students to practise intimate physical examinations on them). This is usually accompanied by supervised clinical practice in hospital and medical settings. The number of CBEs during that time will vary depending on each student's placements. There is no formal test for the specific skills of IDBM.

In addition, the opportunities for students to practice in South Australia have changed. Over the last 10 years the number of medical students has increased to meet anticipated workforce deficiencies. In addition, patients are increasingly being managed outside public hospitals. Thus there is an increasing demand for student access to patients in public hospitals, but a corresponding decrease in the number of patients suitable for student learning. Generally, our population

is aging and becoming increasingly obese: the breast is approximately 80% fat, so larger people tend to have bigger breasts, which are more complex to examine. Patients now expect higher quality of care and more accurate diagnosis from their health care professionals. This means medical students and professionals are under increasing pressure to deliver higher quality healthcare with diminishing learning resources.

Students and trainees need to access alternatives to real patients for their training. Good quality medical simulation models with standardised training can relieve these pressures. Then the medical trainees would have the basic essential techniques of CBE before they start practicing on relatively scarce patients. This training could provide, like cardiopulmonary resuscitation (CPR), a path for basic accreditation in CBE and a continuing personal development for General Practitioners, who act as a gateway for breast specialists when it comes to diagnosing breast disease both pathological and benign.

Training programs including silicone breast simulators can improve the rate of detection of lumps in patients. Despite this, medical students typically do not perform well in breast examination tests and report they could improve their CBE skills (Saslow et al. 2004). There are a number of existing breast simulation models on the market (Veitch et al. 2011). It would appear that these models are not serving their intended purpose, even though we know that practicing palpation on breast models improves CBE (McDonald, Saslow, and Alciati 2004; Saslow et al. 2004). There is also clear evidence existing simulation models are not sufficiently authentic and better models are needed (Veitch et al. 2011). The teaching of CBE is not standardised, even when standardisation has been reported to improve sensitivity (Day 2008, Campbell et al. 1994, Saslow et al. 2004).

Most patient simulators lack complexity, and are neither shaped, nor feel, like real people.

This thesis explores not only the barriers but also overcoming the barriers to designing and prototyping breast models for the purpose of teaching and testing IDBM skills as part of competent CBE to address some of the aforementioned issues.

How useful the models are can only be ascertained by determining if students are competent in IDBM. Currently there is no existing test to determine this although this thesis proposes a test – TL.

Simulation (design) context

Type of test	Name	Can it Identify and Discriminate Breast Masses (IDBM) or is it directly useful in either making a model or teaching the student (our desired outcome)?
Biomechanical test	Indurometer	Too narrowly focused (reductionist). Detects absolute hardness, not relative hardness or type of hardness. Doesn't inform the designer about shape of nodularity.
Biomechanical test	Breast movement studies	Doesn't relate directly to feel of breasts or lumps or take into account the different interacting layered properties of the breast.
Finite element analysis	FEA	Not in the physical world. Relates to digital human modelling but totally unrelated to physically detecting breast masses and not directly useful for model construction.
Haptics		Might be used instead of a physical model. Limited by input data i.e. there is no breast density database – often using data from biomechanical tests. Needs further development to be useful to directly teach IDBM.
Virtual reality		Would need to be used in conjunction with a well-developed haptic device.
Augmented reality		Would need to be used in conjunction with well-developed models.
Mechanical Breast Examination	Robot hand	Purportedly replaces the need for CBE – at this stage quite inadequate as the real human hand has very advanced sensors and these have not been replicated. No capability for IDBM
Mechanical device	Bra – First Warning System	Purportedly replaces the need for breast self-examination. Could be downright dangerous, as by the time the bra detected any putative (possible) cancer it might be too late for effective treatment. Might also provide the wearer with a false sense of security delaying their access to appropriate medical treatment.
Silicone models		Useful tools when appropriately matched with the other essential components in good teaching for detecting breast masses described above. However they are not stand-alone products.

Table 1.2 *Summary of the preliminary approaches to this research.*

There are many ideas in the engineering and design world promoted (purported) to assist in the detection of breast cancer, and some are portrayed as alternatives to CBE.

In looking to develop this research we examined a number of different approaches that could potentially deliver the necessary outcomes. These included biomechanical tests, finite element analysis, haptic, virtual reality, augmented reality, mechanical breast examination, a mechanical device (first warning bra), and lastly, silicone models.

Table 1.2 summarises some of the different approaches suggested for solving the problem of designing simulation models for CBE palpation and clearly illustrates how the possible design criteria can impact the product designed in both positive and negative ways.

There is a problem with replicating the breast specialist's skills, as the hand is really multisensory with many types of receptors, not to mention the investigatory and problem-solving capacity of the breast expert's skill-set. For a list of the twenty receptors in the hand, including cutaneous and subcutaneous mechanoreceptors, thermal receptors, nociceptor and muscle and skeletal mechanoreceptor, see Appendix 8 (Kandel et al. 2000).

Tactile skill in CBE is somewhat similar to a chef being trained to detect aromas in food. When someone opens the fridge how does someone know that there is 'off' food present? If you had the task of detecting 'off' food but were not allowed to use your sense of smell, what single chemical test would you use to detect 'off' food in the fridge? This is comparable to being only allowed to use a single mechanical test to detect cancer.

Touch is Mediated by Mechanoreceptors

Tactile sensitivity is greatest on the hairless (*glabrous)* skin of the fingers, the palmar surface of the hand, the sole of the foot, and the lips. Glabrous skin is characterized by a regular array of ridges formed by folds of the epidermis. The finger ridges are arranged in circular patterns called *fingerprints* and contain a dense matrix of mechanoreceptors. These receptors mediate the sensory touch; they are excited by indentation of the skin and motion across its surface. When an object presses against the hand, the skin conforms to its contours. The depth of indentation depends on the force exerted by the object on the skin as well as

its geometry; mechanoreceptors sense these changes in skin contour but differ morphologically in important ways that alter their physiological function.

Source: Kandel, E. R et al. Principles of Neural Science, 4th ed.

Table 1.2 lists methods currently being developed in relation to CBE training but we had to broadly eliminate any method that didn't actually physically train the hands and aid comprehension to inform the student what they were feeling. The most direct method listed above that could directly train the student in line with the required hand-on palpation skills were silicone models. So how realistic, lifelike or biofidelic do the models need to be to be effective?

The language of touch or feel of breast masses

This has not been defined in the literature, so we had to create our own list (from the breast specialists): see Table 1.3 below. "Meaningful feedback" requires a common language that focuses the attention on the important characteristics that make a breast lump normal or suspicious. This also helps to categorise and chunk information regarding the feeling of breast masses so the information can be conveyed more efficiently.

During the interviews with the breast specialists we had this comment that described overall feel: "I really do probably spend more time interrogating different bits of those lumpy breasts just to be confident that really what I'm feeling is a woman's texture and not feeling an individual discrete mass that needs further investigation" (Jenepher Martin 2016[1]).

[1] Private communication with Dr Jennepher Martin via interview 2016

Characteristic	Antonym	Description
Hard/Firm	Soft	Determine firmness through the feeling of texture.
Fixed/Anchored/ Tethered / fixicity/ fluctuaty (suspicious)	Mobile (good sign)	Slide the lump over its deeper and superficial areas to determine its movement. Can lift the skin, not fixed on the skin, and try and move the whole breast around on the chest wall and tense the pectoral muscles and try and move the lump. Immobile on the skin or the chest wall is suspicious. Grab the Cooper's ligament; if the tumor is fixed to the Cooper's ligament, the patient will lift their arms and it will dimple the skin.
Smooth Texture	Lumpy/Granular Recognizing that it is not smooth but it is still normal	Nodularity doesn't have a focal lump or discrete lumps – so lumps are within other lumps.
Dimpling (like a tangle of fibres) (suspicious)	Absence of dimpling (Smooth shape change)	With arm movement or pectoral tensing there are no abnormal depressions occurring on the skin surface.
Blotchy / irregular colour (suspicious)	Normal skin colour gradient	Infection or inflammatory breast cancer – cancer has diffused through to the skin.
Abnormally high localized temperature	Normal temperature	Infection without cancer.
Inverted nipples (normal)	Tethered nipples (abnormal)	Look of a cancer vs an inverted nipple.

Table 1.3 *The language of look and feel used by the breast specialist during CBE*

We published a video poster on the topic of the language of feel – see Appendix 3.

Refining the language of touch/feel in developing evidence-based simulation manikins to teach Clinical Breast Examination (CBE)

Daisy Veitch, Richard Goossens, Johan Molenbroek, Harry Owen and Melissa Bochner

Teaching CBE could potentially be standardised by using simulation models that realistically represent the palpation characteristics important to a breast specialist when feeling for breast disease. The models need to provide complex and varied experiences, and so exhibit a range of normal breasts and lesions that provide examples of what an expert means by words such as 'smooth' or 'nodular'; thereby consistent definitions of these words are created for use in breast examination as accurate descriptions of breast texture in the language of feel.

Status: August 2018 – 22th World Congress on Ergonomics – International Ergonomics Association (IEA), Florence, Italy – video abstract
https://www.youtube.com/watch?v=kAC1XJmqWAc
See Appendix 3 for the video poster.

The central question of the thesis

The central question of this thesis is, how to design tools to improve the teaching and testing of identification and discrimination of breast masses (IDBM) through tactile examination.

The research questions

The question is how to make sure the students can detect and differentiate between different breast masses by touch so they can quickly and accurately refer patients to the appropriate services. So the models only need to be realistic enough that they mimic the clinical experience and have specific learning outcomes like understanding the difference in feel between a normal woman's breast texture and an individual discrete mass that requires further investigation.

We formulated 3 research questions to fill the three identified gaps:

1) How to reflect human variation in normal breast durity (hardness/softness) and nodularity in simulation models?
2) How to reflect variation in breast disease pathology in simulation models?

   and

3) How to design a validated testing tool for the tactile component in the teaching of CBE to test how and when students achieve proficiency in the discrimination and identification of various breast masses (IDBM)?

The Gap

To summarize the above a threefold gap was identified,

1) Human variation in normal breast durity and nodularity is not reflected in existing simulation models.
2) Variation in breast disease pathology is not reflected in existing simulation models.
3) There is no validated testing tool for tactile education in Clinical Breast Examination (CBE).

Aims

Therefore, the main aim of this thesis is:

How to design tactile correct (biofidelic) teaching models for training medical staff to diagnose the large varieties of breast disease by touch. Then how to test medical staff have appropriate tactile skills.

Research method

Brief overview of the research method

Method Part 1: Construct and develop a range of suitable physical breast models with varying texture and softness to show normal human variation. Each one representing important cases for teaching. In addition develop individual discrete masses representing cancer, fibroadenoma and cysts to embed in the models that would trigger further investigation when felt. Using the same techniques develop a test object 'tactile landscape' (TL) for assessing students skills in IDBM. Develop a test protocol to accompany the TL. Described further in Chapters 2, 3, 4, 5 and 6.

Method Part 2: Compare the developed breast models for characteristics of categorization for normal durity and nodularity to real patients to determine if they do represent the range of normal – see Chapter 4.

Method Part 3: Conduct an evaluation of conventional training in CBE with existing assessment techniques and adding the new TL as an alternative evaluation method – see Chapter 6.

Assumptions

In absence of a database we are assuming that the population of Australian women tested by the breast surgeons has the same range of breast softness and nodularity as other populations in the world.

We are assuming that the TL tactile landscape testing tool will be a method of assessment that will drive the meaningful feedback required so that students can know if they have successfully identified and discriminated between suspicious and normal breast masses and if not what remediation is required but this hasn't been formally tested in this dissertation.

We are assuming that this training and testing tool will be for students in the first part of the learning continuum and will not replace the need for clinical experience – it will only facilitate the learning of basic skills to provide a better base to commence clinical studies.

Structure of the thesis

This dissertation is by publication so due to its nature some of the elements of the chapters might overlap as publications require appropriate standalone introductions. Each of the Chapters are labelled with the type of publication, either peer-reviewed international journal, extended abstract, video presentation or poster.

Chapter 1 introduces the dissertation by exploring what is known, and also not known. This leads to the identification of the gaps and the aims of the thesis. Here we describe the structure of the thesis. Chapters 2, 3 and 4 address Gap 1. Chapters 4 and 5 address Gap 2. Chapters 5 and 6 address Gap 3. Appendix 1 looks forward to further work in Gap 1 and 3. Chapter 7 concludes with a general discussion and conclusion, contribution to the knowledge, describes the importance of this research, the implications for future research and gives a general summary.

Graphs, Figures and Tables are numbered according to chapter number then chronologically after that e.g. Figure 2.1 refers to the first figure in Chapter 2. Figure number 0.2 is the second figure before the Chapters have commenced.

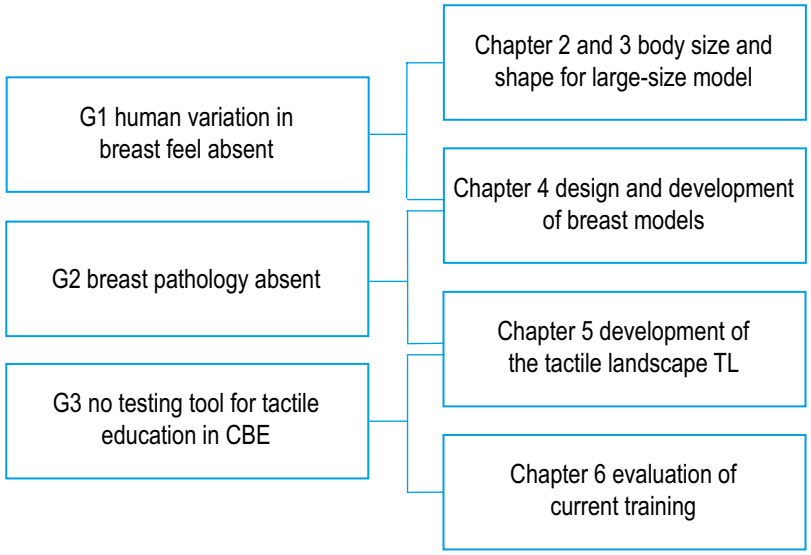


***Figure 1.1** Shows how gaps (G) relates to each of the publications (Chapters).*

Ethics

As in all research involving human subjects in Australia ethics approval was important to ensure no one was harmed in the conducting of the research.

Ethics approval was sought and gained from Southern Adelaide Clinical Human Research Ethics Committee Application number 34.13. There was a second ethics approval HREC/13/SAC/21 granted by the Central Adelaide Local Health Network on behalf of Royal Adelaide Hospital (RAH) adding another research site. Later there was a time extension – see Appendix 2

Chapter 2 — Using size, shape and body scan data to improve biofidelity of patient simulators

This chapter combines two abstracts for two different audiences. The two audiences required different information although the work presented and the authors were the same. One abstract was presented in poster format for the design community, accepted for the HFESA 2010 Annual Conference, October 31 – November 3, 2010 and published November 2010 in *HFESA* as *Size, shape and body scan data to improve the biofidelity of patient simulators.* The authors are Daisy Veitch, Harry Owen and Christopher Leigh.

The second abstract and presentation were presented to the medical community at SimTech 2010 as *Improving the biofidelity of patient simulators*. The authors are Daisy Veitch, Harry Owen, Christopher Leigh. This work was selected as an *Outstanding Abstract* SimTechT and published Dec 2010 in *SimTechT*.

What follows in this Chapter is an amalgamation of both abstracts and poster contents to remove duplication for the thesis reader.

Using size, shape and body scan data to improve the biofidelity of patient simulators

Daisy Veitch, Harry Owen and Christopher Leigh
Daisy Veitch daisy.veitch@gmail.com
Harry Owen harry.owen@flinders.edu.au
Christopher Leigh chrisml01@bigpond.com

Most patient simulators are not shaped like real people. This has implications for transfer of training from simulated patient encounters to clinical practice. Sub-routines of clinical skills can be learnt on quite abstract models but mastering skill sets require lifelike surface anatomy.

More than half the Australian population is overweight or obese but this is not reflected in the current manikin shapes used as patient simulators. This project uses body scan data from a representative population to create more realistic

models. These data were originally collected as an anthropometric base for other industries to solve design problems related to use of products by the general population.

This chapter describes the background, methods, results and conclusions for the production of large-size female breast models for breast examination to train medical students in detection of breast cancers.

Background

Training programs including artificial (usually silicone) breast simulators can improve the rate of detection of lumps in patients by healthcare workers (Saslow et al. 2004) Despite this, medical students and trainees typically have low performance scores for breast examination. Most patient simulators, including soft breast models are not shaped like real people. Sub-routines of clinical skills can be learnt on quite abstract models but mastering skill sets requires lifelike look and feel.

Anthropometry is used to create biofidelic manikins for other industries such as the clothing industry and we have explored how these data can be applied to improving a breast examination simulator.

Methods

We examined size, shape and body scan data that can be applied to making patient simulators. These data were used to investigate how current manikins would need to be modified to reflect the predominant shape of patients. (See Figure 2.1)

Results

SHARP Dummies and University of Adelaide undertook a National Size and Shape Survey of 1265 adult Australian women in 2002. The results of this survey, along with those of the Civilian American and European Surface Anthropometry Resource Project (CAESAR®) incorporating 1D and 3D data

from 937 whole body scans, enabled us to create a manikin representative of a real world patient and compare them.

Conclusions

Instruction strategies that meet learning needs of students have been identified as an important future challenge in improving breast cancer education (Fiche J, et al. 2010).

A training model for clinical breast examination needs to facilitate

- Learning elements of the clinical skill
- Authentic practising of the whole skill
- Accommodating variation (e.g. size and shape of breast and lumps)
- Coping with complexity (e.g. nodular breasts, lumps in lymph nodes)
- Demonstrating competence

Currently available breast examination simulators do not model the shape of patients encountered. This will impede development of confidence and competence of healthcare workers that need these skills. Also, realism of feel will require anatomically-correct, multilayer construction of a soft breast with detectable underlying features.

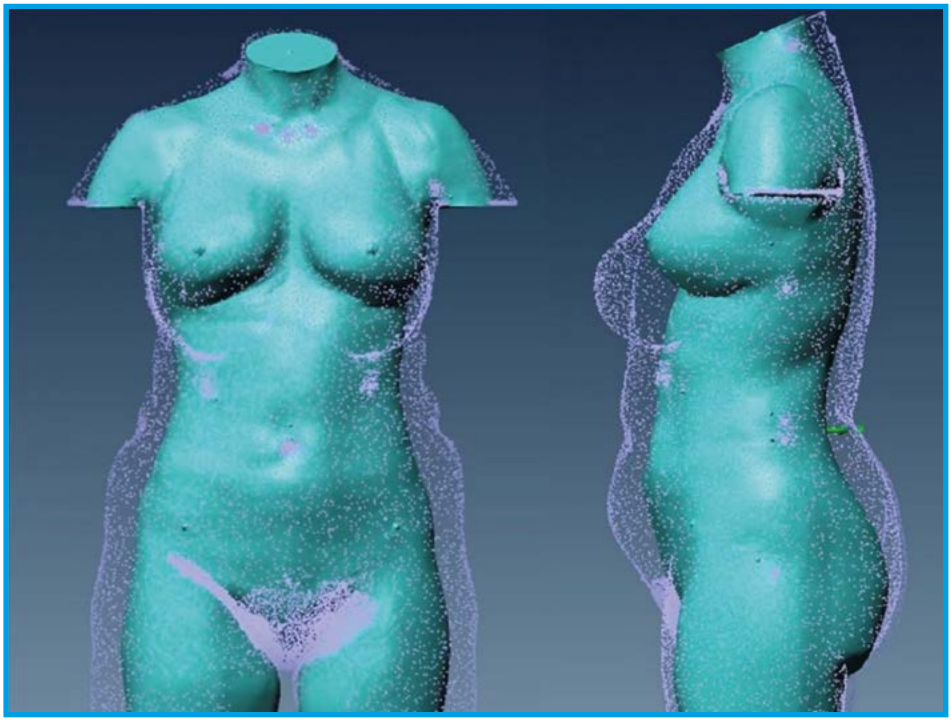


Figure 2.1 *Comparison of regular (turquoise) and large size (lilac dots) body shapes from 3D body scan data. Using biofidelic manikins to show allometry: software tools such as Integrate or Polyworks allow*
3D comparisons.

The allometric phenomenon – data points from a body scan of an obese patient superimposed on the scan of a woman of ideal bodyweight to show how obesity and cup size changes the relative dimensions of the body.

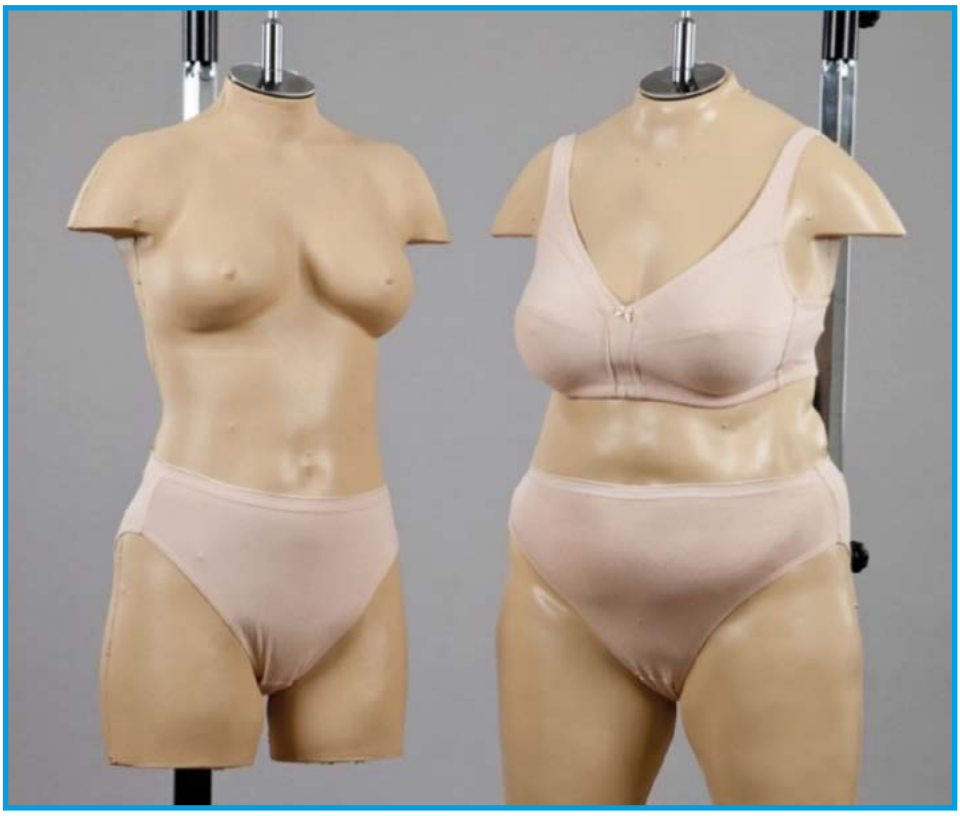


Figure 2.2 *Regular size manikin on left and large size manikin on right.*

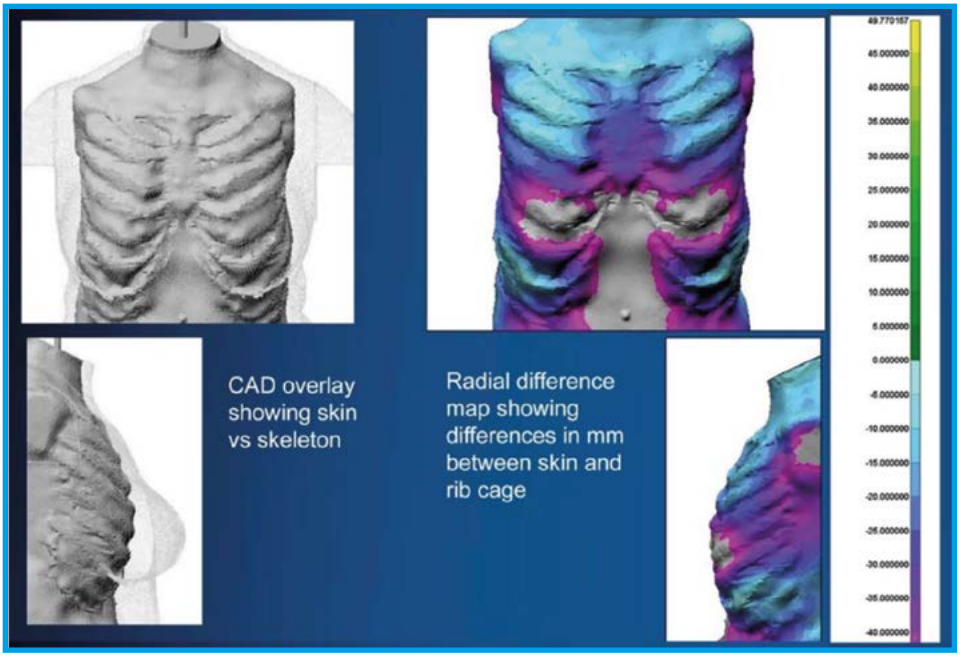


Figure 2.3 *Left above: CAD overlay showing skin vs skeleton – Radial difference map showing differences between skin and rib cage.*

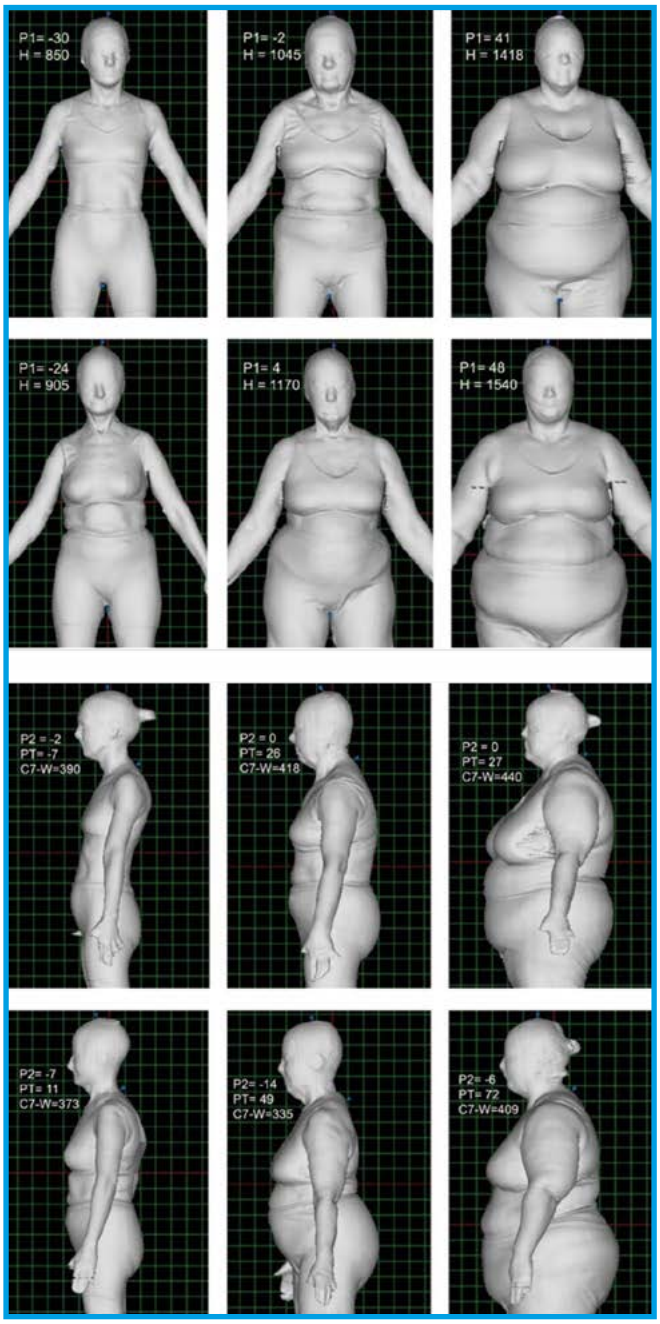


Figure 2.4 *Images of body scans showing increased circumferences from left to right.*

Figure 2.5 *Simulation model incorporating most commonly occurring large-size body shape, skeleton, skin, adipose tissue and breast tumours. Completed prototype manikin made from silicone skin, soft adipose tissue, rigid rib cage, nodular lumps and tumors.*

Chapter 3 — The development of a lifelike breast cancer patient simulator using anthropometric data

Daisy Veitch, Rachel Dawson, Harry Owen and **Christopher Leigh**
Status: Published Nov 2011 - Ergonomics Australia
Paper was awarded the Ken Provins Award for best paper (peer-voted).
Veitch, D., Dawson, R., Owen, H., & Leigh, C. (2011). The development of a lifelike breast cancer patient simulator using anthropometric data.
Ergonomics Australia – HFESA 2011 Conference Edition.

Abstract

Background: Early detection significantly reduces breast cancer mortality. Yet, many medical students and doctors report they could improve their skills in clinical breast examination (CBE). Training programs using silicone breast simulators improve the lump detection rate. Despite this, medical students and trainees typically perform low in breast examination scores. This indicates current simulation models provide insufficient CBE training. In this study, we have improved breast examination simulators by applying anthropometric data and selecting one very commonly occurring shape in the female population as a model.

Aims: To provide a breast model representative of the large-size female population and more varied scenarios for breast lump palpation.

Method: Comparing the 2002 National Size and Shape Survey of 1,250 adult Australian women, Australian Bureau of Statistics data, and the Civilian American and European Surface Anthropometry Resource Project (CAESAR®), we selected individuals anthropometrically representative of the surveyed population. Combining one woman's body scan, computer-aided design, rapid prototype techniques, and the latest biofidelic (lifelike) silicone technology we created an anatomically correct representation of a real world patient. This model requires trainees to learn that breast examination can be complex and involves a multifaceted approach.

Results: A prototype representing women with larger breast size and a relatively high body mass index (BMI) was developed. The individual selected was a large-size woman of approximate BMI 30, 82kg and large cup size (D); by our analysis more than 50% of women are C cup or above.

Conclusions: Confident and competent breast palpation requires a life-size model that looks and feels lifelike. Currently available breast examination simulators do not model the size and shape of patients encountered. This impedes developing confidence and competence in healthcare workers who need these skills. Lifelike look and feel require an anatomically correct, multilayered soft breast construction, incorporating palpable anatomical underlying features, including tumors.

Background

Early detection of breast cancer significantly improves outcomes for patients by both increasing survival rates and reducing the invasiveness of treatment required (McDonald, Saslow, and Alciati 2004, Saslow et al. 2004). High quality mammography is the gold standard of screening in asymptomatic women and can detect some cancers before they have become palpable. However clinical breast examination (CBE) is still a core component of breast cancer detection and management in symptomatic women (Irwig, Macaskill, and Houssami 2002). The way CBE is taught and performed in Australia is not standardised (Thistlewaite 2007), even though standardisation has been reported to improve sensitivity and accuracy of lump detection (Saslow et al. 2004). This is why a standard breast patient simulator model needs to be used. In an extensive review of the performance and reporting of CBE undertaken for the American Cancer Society, McDonald et al. (2004) concluded "… it is reasonable to suggest that increased proficiency in CBE that leads to detection of smaller tumors may contribute to enhanced survival from breast cancer."

A comprehensive CBE must include palpation, i.e., feeling the breasts correctly and with as little tissue as possible between the finger pads and the patient's rib cage. But there is no standardised procedure, and it is thought this impacts adversely on cancer detection (McDonald, Saslow, and Alciati 2004). Competence (lump detection and identification), and confidence in CBE skills, are improved by structured teaching that involves the use of silicone breast models and teaching associates (Steiner, Austin, and Prouser 2008).

Many medical students and doctors report they could improve their skills in CBE. Why? Most breast simulators are small and although patients in general and breasts in particular are getting larger (see below) no current simulators are large. The way a CBE should be conducted on a large-breasted, or obese, patient has some differences to that on someone small-breasted or not overweight (Silk and McTigue 2011). Special patient positioning is used to minimise tissue thickness when palpating a large breast (Saslow et al. 2004, Barton, Harris, and Fletcher 1999), and also the breast area is larger, so the examination takes longer (Silk and McTigue 2011). A recent commentary on simulation in medical education summarised the research thus: "…the recall of information and its application are best when it is taught and rehearsed in contexts similar to real life…" (Kahn, Pattison, and Sherwood 2011). Consequently, we studied the anthropometric data on Australian and North American populations to determine what large-size patient simulators should be developed for optimal education and assessment.

Training programs using silicone breast simulators improve the lump detection rate (Saslow et al. 2004). Despite this, medical students and trainees typically perform low in breast examination scores (Saslow et al. 2004). This indicates current CBE training is deficient. There will be many reasons for this, but lack of practice on an appropriate simulator will be an important one. Learning how to palpate the breast requires a life-size model that looks and feels authentic. For example, it has been reported that students do not use enough pressure during palpation. Varying amounts of pressure should be used to identify and locate lesions in the breast. This means that the materials used in a simulator need to deform in a similar way to real breast tissue and should be on a chest wall so that the trainee can feel ribs and know they are using appropriate pressure to identify the deepest lesions. Breast palpation includes the axilla and above and below the clavicle, so the model requires these structures if the whole sequence is to be learnt.

It is important that medical students learn CBE well during medical school. In a study of medical practitioners, it was revealed that individuals who felt they had been taught digital rectal examination well in medical school were more likely to perform this examination on their patients (Hennigan et al. 1990). The knowledge gained from this study may be generalised to the practice of CBE as yet another type of intimate examination. Current evidence reveals that healthcare workers do not feel confident in CBE and would welcome further

training (McDonald, Saslow, and Alciati 2004). Studies of medical students have revealed similar trends, with students reporting they feel underprepared and require further training (Kann and Lane 1998). In this study, we have developed a breast examination simulator by applying anthropometric data and selecting the most commonly occurring shape in the large-size female population as a base to build the model.

Method

The need for a biofidelic model of large-size women does not answer the question of how such a model is to be designed. The purpose of this section is to describe the process by which such a design was achieved. This required combining anthropometric data of several kinds from a variety of sources. The statistical analysis of these data informed the design process.

Anthropometric trends and analysis

In the last 30 years, obesity has become a major public health issue (Access Economics 2006) and more than half the adult population in Australia, and in many other countries, are now overweight or obese. The effect of increasing weight on diabetes and cardiovascular disease is widely appreciated but the increased prevalence of obesity also impacts on breast cancer risk and detection. Higher Body Mass Index (BMI) is correlated with an increased risk of breast cancer, and women whose BMI is ≥ 30 kilograms/m^2 face a threefold increase in breast cancer risk (Montazeri et al. 2008). Also an inverse relationship between CBE sensitivity and increased body weight has been reported (Oestreicher et al. 2002). Health professionals need specific help to develop their palpation skills to detect lumps in obese patients (Silk and McTigue 2011), and with obesity in children now common (Magarey, Daniels, and Boulton 2001), this will be a continuing training need. Another consequence of overweight and obesity is that these women are less likely to present to their doctor for intimate examinations, including CBE (Fontaine and Bartlett 2002), so health professionals will need to offer confident and competent CBE as CBE in obese women takes longer. Poor confidence in CBE skills is a barrier to this (Iannotti et al. 2002) and is compounded when the patient is obese (Ferrante et al. 2010).

There are several reports of health professionals perceiving the need for more training in CBE generally (Pennypacker et al. 1999) and of perceived

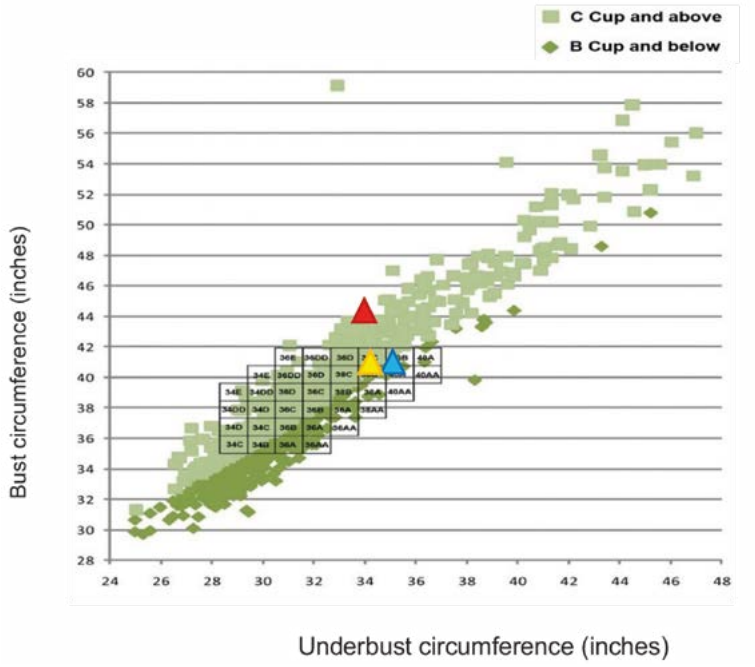
inadequacies in performing CBE on obese patients(Ferrante et al. 2010). Good initial training must include adapting the examination to patients with large breasts, obesity or morbid obesity and this needs to be followed up by programs focussing on skill maintenance (Chalabian et al. 1996).

Precise measurements of breast size can be derived from three-dimensional (3D) body scans and manually collected one-dimensional (1D) data. There is no Australian database for the 3D measurements, but there are height and weight mean averages: Australian data for women has the population mean weight at 67.7 kilograms (kg) (Australian Bureau of Statistics 2004-5) and mean height at 1,639 millimetres (mm) (Australian Bureau of Statistics 1995). This population data was matched to an analysis of a raw data subset from the Civilian American and European Surface Anthropometry Resource (CAESAR®) (World Engineering Anthropometry Resource 2013) (n=939). The subset analysed were female, aged 18 to 65 years, civilian, white women living in the United States (US), mean weight 68.7 kg and mean height at 1,651 mm, which is comparable to the Australian means. The US subset matched to Australian data revealed that 52% have a breast cup size classification of C or above (see the pale squares in Graph 3.1). The bra sizing classification chosen for this analysis is the "International" sizing in which the women categorized as C cup and above are those with a difference of 6 inches and greater in their bust and under bust measurement (Wright 2002). Although millimetres are the international standard for measurement, the international bra sizing is quoted in inches, so inches are used for ease of analysis here.

It should be noted that 174 women (nearly 20%) were too large for any standard size bra in this prediction chart, having a bust circumference > 42 inches or an under bust of > 36.5 inches and almost all of these have breast size of C cup or greater.

According to a recent report from a major lingerie manufacturer, bra cup size in Australia has tripled over the last 50 years (Woods 2010). The average cup size was 10B in 1960, 12B in 2000 and 14C in 2010, which might mean women who are not overweight may be developing larger breasts, or it might indicate an allometric phenomenon. Huxley and Teissier (1936) define allometry as, "the growth of a part of a body at a different rate from that of a body as a whole…". Allometry for bust and underbust circumference (Graph 3.1, Figure 2.1 and Table 3.1) shows that women of larger circumferences usually have a larger cup size. Thus, increased obesity in the population results in an increased proportion

of women with large cup size. We draw this conclusion from the assumption that increased circumferences are linked to increased weight. The pale squares in Graph 4.1 indicate individuals who have a C-cup or above and the dark diamonds represent B-cup or below. The division line is skewed. This shows that breast cup size C and above is much more frequent in large circumference women. Therefore, as the population circumference mean increases more bras of cup size C and above will be sold.



Graph 3.1. *Distribution of cup sizes with overlay of International bra sizing prediction chart.*

According to a recent report from a major lingerie manufacturer, bra cup size in Australia has tripled over the last 50 years (Woods 2010). The average cup size was 10B in 1960, 12B in 2000 and 14C in 2010, which might mean women who are not overweight may be developing larger breasts, or it might indicate an allometric phenomenon. Huxley and Teissier (1936) define allometry as, "the growth of a part of a body at a different rate from that of a body as a whole…". Allometry for bust and underbust circumference (Graph 3.1, Figure 2.1 and

Table 3.1) shows that women of larger circumferences usually have a larger cup size. Thus, increased obesity in the population results in an increased proportion of women with large cup size. We draw this conclusion from the assumption that increased circumferences are linked to increased weight. The pale squares in Graph 4.1 indicate individuals who have a C-cup or above and the dark diamonds represent B-cup or below. The division line is skewed. This shows that breast cup size C and above is much more frequent in large circumference women. Therefore, as the population circumference mean increases more bras of cup size C and above will be sold.

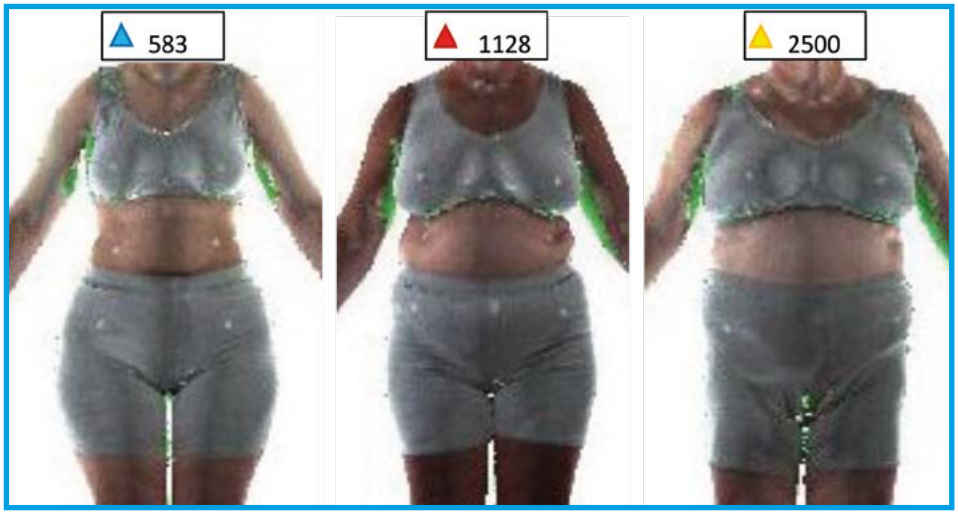


Figure 3.1 *Scanned data from three figures of similar height and weight but with different circumferences, hence body shape, are shown with measurements and means of the subset (n=100). Circumferences are in millimetres and weight in kilograms.*

Locations of the three body shape variations illustrated in Figure 3.1 are plotted on Graph 3.1 and 3.2 using body measurements listed in Table 3.1. Body scan of Subject 583 has a blue triangle, Subject 1128 has a red triangle and Subject 2500 a yellow with orange bordered triangle.

Subject	HT (mm)	WT (kg)	Bust	Underbust	Waist	Hip	Thigh	C7-waist*
583	1,649	83	1,034 (40.7)	902 (35.5)	811	1,236	729	402
1128	1,629	80	1,111 (43.7)	879 (34.6)	942	1,145	650	386
2500	1,640	86	1,175 (46.3)	968 (38.1)	1,055	1,071	618	402
Mean (n=100)	1,637	79	1,040 (40.9)	855 (33.7)	873	1,126	656	397

*C7– waist is a commonly used clothing vertical measurement of seventh cervical vertebra to waist

Table 3.1 *Body measurements of women showed in Figure 3.1 in millimeters converted to inches in brackets.*

Approach

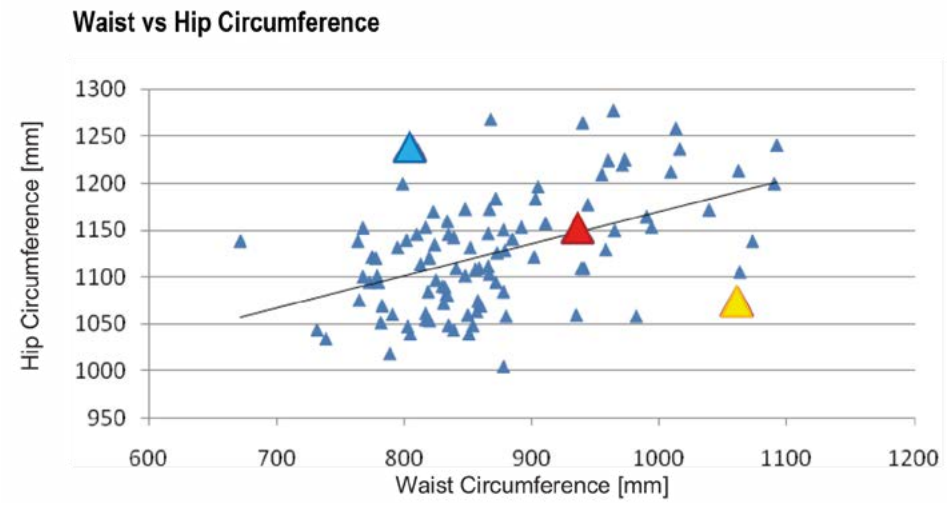
The statistical method for this project was developed by the United States Air Force Computerized Anthropometric Research and Design Laboratory (USAF CARD Lab) with Surface Human Anatomy Replication of People (SHARP) Dummies Pty Ltd. SHARP Dummies is a private research company that specializes in anthropometric research applied to design such as manikins. This method produced SHARP's first biofidelic manikin for the apparel industry. The current project to develop the breast cancer large manikin shape was based on a second apparel collaboration with US-based companies. It uses body scan data from a representative sub-population of large-size women to create more realistic models. Using CAESAR® data we applied the following measuring and manufacturing materials and methodology.

Body selection

Using 1D data, such as height and weight, is not sufficient to define body shape. This is because women of the same weight and height can vary significantly in the distribution of adipose tissue and thus circumferences (Figure 3.1 and Table 3.1). Therefore more detailed measurements, such as bust, underbust, waist and hip circumference, are required to define shape (Table 3.1). Bivariate plots have been used to select the most commonly occurring body shapes (Graph 3.1). Each blue dot in the plot represents an individual's measurements. For the simulator we selected an individual of weight 82 kg and height 1,639 mm

who was in the centre of the waist versus hip scatter plot (and also underbust versus bust). These 1D measurements have been used in conjunction with other factors, such as symmetry, assessed visually using the images of 3D scans.

Analysis of individual data shows subjects are within 3kg of each other and 20mm in height. However, the waist minus hip shows subject 583 is a "curvy" subject, 1128's shape is "most common" (on the line of best fit) and subject 2500 is "straight" (Robinette 2005). For this study, we selected an individual from the centre of the distribution.



Graph 3.2 *Bivariate plot of waist vs. hip circumference of 100 North American civilian women who weigh between 70-95 kg and whose height is from 1,620 to 1,650 mm.*

Results

SHARP Dummies and the University of Adelaide undertook a National Size and Shape Survey of 1,250 adult women in 2002 (Henneberg and Veitch 2003). The population mean for height and weight results of this survey, along with those of the Australian Bureau of Statistics (Australian Bureau of Statistics 2004-4, Australian Bureau of Statistics 1995), were matched with CAESAR®

height and weight data. This comparison of Australian versus North American data shows that these populations were very similar, so we made the decision to apply North American data to the Australian population. The high quality, usability and access to 3D scans provided by the North American CAESAR® data enabled the detailed analysis in this project. Only a subset of these data were used: large-size females of weight range 70-95kg of average height 1,620-1,650mm tall. There were 100 women in this category. This subset enabled us to create a manikin representative of a large-size real world patient.

Once we selected a representative individual, we cleaned their 3D data using computer-aided design (CAD) and checked the measurements (Graph 3.2). The selected shape was made 'watertight' for rapid prototyping because any 'holes' or gaps in the 3D data cause milling errors. We then made fiberglass moulds or negatives of the master shape or positive, so multiple copies of the manikin could be produced.

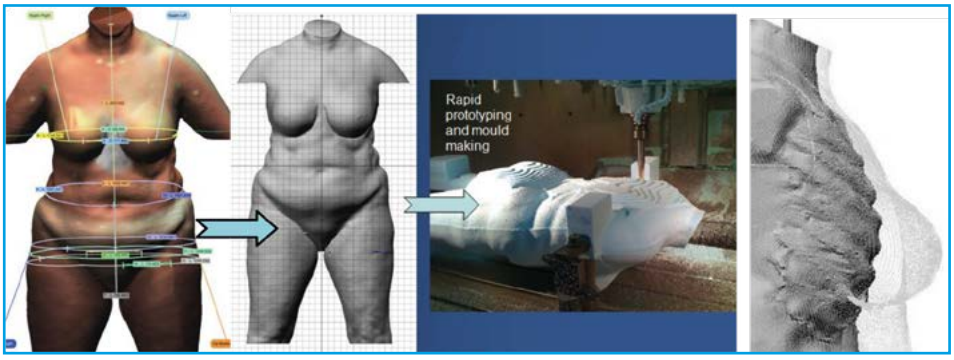


Figure 3.2 *Left side shows body scan data collected using Cyberware laser scanner being prepared for Computer-aided design (CAD) in Polyworks. The middle right picture shows rapid prototyping by milling of the CAD skin from 3D body scan data. The right picture shows CAD images during the development of the lifelike breast model lateral view of the rib cage overlaid with adipose tissue shape.*

We added underlying anatomical features, such as the skeleton, with CAD (See Figure 3.2 above). Both the skeleton and surface anatomy were rapidly prototyped using a 5-axis milling machine. These features were manufactured separately from molds and assembled later. Extensive testing of materials for feel, dimensional stability and durability were conducted for skin, adipose

tissue, rib, cartilage, lungs and tumors. Materials were then selected that mimic the lifelike feel of the torso (skeleton and muscles) and breasts (normal breast tissue, tumours and lymph nodes). The manikin was constructed from multiple layers of the materials to resemble a real body with optimal results in look, colour, texture and feel. Six clinicians (including two practising breast surgeons) reviewed the model and reported the breast and tumours felt lifelike. The breast changes throughout life and two clinicians commented that the simulator had characteristics of a postmenopausal breast.

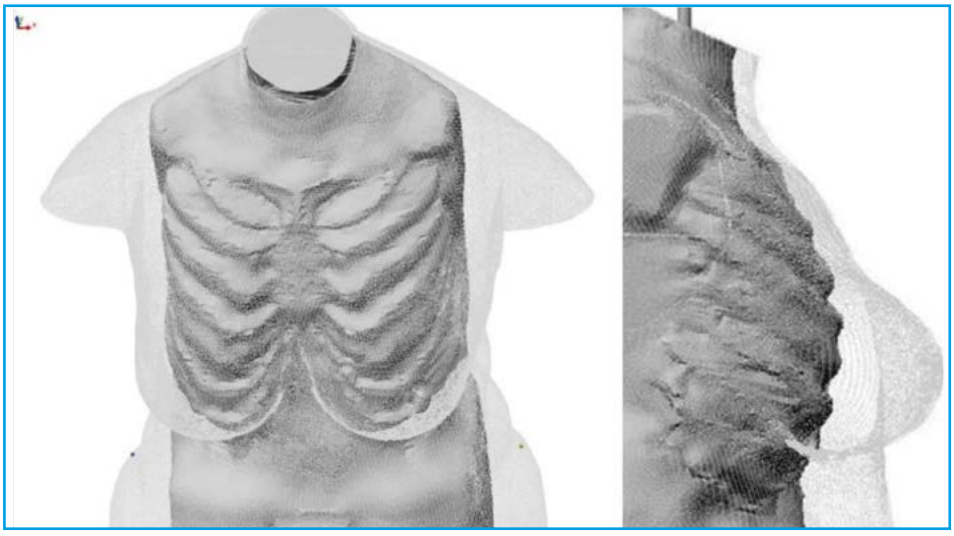


Figure 3.3 *CAD image of ribs overlaid with 'skin'.*

This multilayering of the biofidelic model enables the trainee to feel the complexity of the underlying anatomical structure. The fingers are thereby trained to detect both normal anatomy and any lesions, such as tumors, under a large breast, making the learning experience more representative of a complex real patient breast examination.

Fourteen tumors have been inserted in a variety of locations, including the axillae and high on the chest wall near the clavicle, which could occur in real-life, but would be outside the range of a mammogram, making CBE an essential skill for early detection. Tumors also have been inserted deep in the breast where they cannot be detected using CBE, giving the trainee, as one of the training outcomes, some degree of uncertainty as to whether a lesion is present or not.

The correct action then would be referral of the patient for a mammogram. This combination of tumors in the manikin is designed to create a sense in the trainee of the need for further detective work to achieve a reliable outcome. Training should be complex enough to reinforce the three pillars of the 'triple test': imaging (including mammography), biopsy, and CBE, which, when fully executed, will detect a breast cancer with 99.6% sensitivity (Irwig, Macaskill, and Houssami 2002). In addition, it should highlight the need to take extra care and time in examining large-breasted patients, because of the higher degree of difficulty with these patients. Specialist training should be provided, as there is some evidence physicians may be reluctant to perform CBE on large women, perceiving such examinations to be more difficult; large patient simulators provide the opportunity for this training (Silk & McTigue, 2011).

Discussion and conclusion

Obese patients are more likely to develop breast cancer, but are less likely to present with breast symptoms and, if they do, breast lumps are more difficult to detect, because they are harder to feel. Some studies using silicone models suggest that, with training, lumps as small as 3mm can be palpated, but not reliably, and at the cost of reduced specificity (Fletcher et al. 1989). Studies of health professionals reveal many have little recent experience of CBE, and this lack of confidence impairs their performance (Wiecha and Gann 1989). In many areas of medicine, lack of confidence is most often ascribed to the small numbers of cases encountered during training.

The time taken to examine a large breast will be longer than a small breast. Silk and McTigue (2011) have suggested more than 3 minutes per breast is required, but following the now recommended technique using small circular movements of the first three fingers and a vertical strip pattern, it requires 3 to 4 minutes for an average breast examination (McDonald, Saslow, and Alciati 2004). This is much longer than what may be happening in clinical practice. Practising palpation on large breast simulators will help trainees become comfortable in taking what seems like a long time for a thorough examination. They should also rehearse the explanation they give about the procedure and be prepared for the extra time needed to reposition the obese patient to facilitate the examination (Barton, Harris, and Fletcher 1999).

Small size reduces the cost of making and transporting the models and space required for storage, but it also makes them less useful for training and assessment. Large breasted patient simulators are needed to provide a more realistic representation of the current population and so improve CBE teaching. A chest wall and ribs allow realistic feeling, so that one can practice determining the pressure required for deep palpation, and the clavicles and axillae are required for thorough palpation. Some health professionals worry about hurting the patient and so will not apply enough pressure to detect abnormalities in deeper tissues (Steiner, Austin, and Prouser 2008). A realistic skin feel and texture allows for practising palpation technique with the pads of three fingers.

We were disturbed to discover that some students thought mammography was an alternative to CBE, and this is not an isolated finding. Apparently some general practitioners (GPs) do not place value on the skill of CBE, and are willing to rely on mammograms for the detection of lesions (Thistlewaite 2007). Mammography screening misses some of clinically palpable breast cancers – exact values vary depending on the definition of a positive mammographic examination, mammography done with older technology and/or larger screening intervals (Barlow et al. 2002, Cahill et al. 1981, Donegan 1992, Haakinson 2010, Irwig 2002*)*. This highlights the need to emphasize the continuing importance of CBE in early breast cancer detection to medical students, and the need for more training opportunities for both students and graduates.

There are currently gaps in the availability of resources to teach the skills required for the investigation of a new breast symptom, and this is not helped by a lack of standardisation in teaching practice. An increasingly obese population with increased risk of breast cancer intensifies the need for awareness of this issue and for the skills required to effectively investigate a new breast symptom, particularly in large breasts. Thorough training in CBE at medical school is necessary for all students, but more experienced health professionals may also need opportunities to practise CBE, particularly on a larger model.

Sensitivity of lesion detection can be improved using basic silicone models (McDermott et al. 1996), but a realistic model of at least the upper half of the body is required for the systematic teaching of breast palpation technique. Acquiring competence requires authentic simulators, providing a range of sizes that includes the very large. Teaching inspection and palpation of the breast help trainees become comfortable with intimate examinations, but this rarely

happens with large patients. Obese volunteers need to be deliberately included in medical training (Silk & McTigue, 2011).

The development of the large-size biofidelic simulator described here attempts to fill this training gap in the attention given to large-size patients. It provides a representative model based on the population who need it; they have an increased cancer rate and are becoming increasingly common in the population, but they have been previously avoided. Reproducible multiple copies create the essential base for the standardised model upon which a standardised CBE training module can be developed.

Acknowledgements

Design and manufacture of the breast models were funded through the Flinders University Collaborative Research Grants Scheme. Dr S Kirubakaran, Dr A Vnuk and Dr M Bochner provided CBE training and advice on using breast models in clinical skills training.

Chapter 4 — Development of realistic model for teaching breast examination

Daisy Veitch, Christopher Leigh and Melissa Bochner

Extended abstract

Status: Published Aug 2014 – The Breast, Volume 23, Issue 4, pages S2-S3 DOI:10
Veitch, D., Leigh, C., and Bochner, M. (2014). Development of a Realistic Model for Teaching Breast Examination

Background and purpose: Breast cancer mortality can be significantly reduced by early detection, however many medical students and doctors report that they feel they could improve their skills in clinical breast examination (CBE). There are more medical students and fewer opportunities for them to practice on patients. Realistic simulation models can help address this need. Training programs including silicone breast simulators can improve the rate of detection of lumps in patients. (Saslow et al. 2004) Despite this, medical students and trainees typically have low performance scores for breast examination. This indicates that current simulation models are not sufficient to provide the training required for CBE. Most patient simulators lack complexity, are not shaped and do not feel like real people. In this paper we show the process for developing realistic breast examination simulators.

Method: This paper shows the development of a complex, multilayered breast model. Through the testing of various materials it shows the systematic building of a lifelike look and feel model, including the realistic, anatomically correct layering of ribs, soft adipose tissue, nodularity and complex placement of tumors.

Design, development and validation of realistic breast models for teaching breast examination

Veitch, D., Bochner, M., Fellner, L., Leigh, C., and Owen, H.
Status: Published April 2018 – http://explore.tandfonline.com/page/ah/design-for-health (Design for Health)

Rationale is explained for an authentic range of breast simulation models. A range of materials are tested and the effects of their multilayering are explored in relation to feel. A range of realistic simulation models are created. The models are compared to real patients by breast surgeons for durity and nodularity. The models are graphed with real patient data. N=78

Abstract

Our objective was to design, develop and validate better clinical breast examination (CBE) models addressing the deficiencies of previous models. Detailed research and a methodological design approach led to the development of a new technique for creating lifelike models for teaching CBE. Six multilayered breast models representing a range of normal human variation for durity (hardness/softness), nodularity (fibro-glandular tissue) and adiposity (fatty tissue) were developed and validated. Various construction materials, MRI scans, traditional casting and three-dimensional (3D) printing were used to build models with lifelike look and feel (biofidelic). The models realistic in anthropometry (size and shape), feel (durity and nodularity) and appearance (skin feel and colouring) – visual biofidelity enhances perception of feel – incorporate anatomically correct layering of ribs, soft adipose tissue, nodularity and additional signs of breast disease, both benign and pathological.

These were validated by four breast surgeons who compared their feel alongside a sample of breast patients (N=78). Models were rated as 'undecided', 'similar' or 'very similar' to 81% of patients for nodularity and 82% for durity.

These are the first models to incorporate normal human variability and be validated with real patients. These novel biofidelic models provide a standardized way of teaching health professionals normal from abnormal.

KEYWORDS

Medical simulation; clinical breast examination; design process; biofidelic manikin; medical teaching

INTRODUCTION

'Breast cancer is the most common cause of cancer death in women worldwide, estimated to be responsible for around 458,500 female deaths in 2008 or nearly one in seven (around 14%) of all cancer deaths in women.' (Cancer Research UK 2013)

Early detection of breast cancer saves lives and reduces mortality (Cancer Australia 2004, updated 2009; McDonald, Saslow, and Alciati 2004). Western countries facilitate early detection with screening programs, usually mass screening mammography of asymptomatic women. In Australia symptomatic women present to a GP for a CBE. When CBE is used in this context it is part-diagnostic. Further tests are ordered if required then the symptomatic patient is referred for specialist investigation. (BreastScreen October 2017) Thus competency skill in CBE is important for GPs in Australia.

The triple test

The best practice for detecting breast cancer is the 'triple test' with above 99% sensitivity where any of the three components is positive (Ahmed et al. 2007; Irwig, Macaskill, and Houssami 2002). The triple test includes Clinical Breast Examination (CBE) involving an oral history, visual scrutiny and palpation (the process of using one's hands to examine the body and diagnose breast health or disease). The other two components are radiological imaging and biopsy. However, the triple test is not always practised (Goodson 2010). For example, remote areas or underdeveloped countries may have no access to medical imaging and so breast cancer detection and diagnosis in these places are heavily reliant on clinical findings (CBE) (U.S. Preventive Services Task Force 2014). CBE does not require expensive equipment or specialist input and is therefore affordable by most communities (Albert and Schulz 2003). Thus, CBE remains an important tool in the diagnosis of breast disease.

The role of CBE

In more affluent countries, primary healthcare providers may rely on mammography and may not perform CBE (U.S. Preventive Services Task Force 2012). However, mammography screening misses some of clinically palpable breast cancers – exact values vary depending on the definition of a positive mammographic examination, mammography done with older technology and/or larger screening intervals (Barlow et al. 2002; Cahill et al. 1981; Donegan 1992; Haakinson et al. 2010; Irwig 2002, Goodson 2010). Further, Goodson (2010) argues that CBE, despite originating as a diagnostic tool, is now a part-diagnostic tool and so remains relevant, for it can detect interval cancers (cancers found between image-based screening appointments). The loss of CBE skills, combined with an attendant lack of confidence in CBE, constitutes a 'major reason for physician-caused delay in the diagnosis of breast cancer' (Goodson 2010, 83). Confidence in determining normal variation in the feel of breast tissue during part-diagnostic examinations may reduce unnecessary referrals for imaging or expert opinion, thus reducing the opportunity cost associated with obviously healthy women accessing scarce specialist resources. Thus, CBE can be used for both part-diagnostic and diagnostic purposes and is a useful tool for directing women towards the additional resources of the triple test.

The need for simulation models

The principal problem of CBE is that training healthcare providers in confident use of the technique is difficult and time-consuming. Over recent years, the number of medical students has increased to meet anticipated workforce deficiencies, and patients are increasingly being managed in outpatient or private clinics, leading to increased demand for student access to patients in public hospitals, but a correspondingly decreased number of patients suitable for student learning. Therefore, students and trainees need to access alternatives to real patients for their training. Good-quality medical simulation models combined with standardized training could provide this (Simpson 2014). Additionally, training programmes that include silicone breast simulators are reported to improve the rate of lump-detection in patients (Saslow et al. 2004; McDonald, Saslow, and Alciati 2004).

The need for realistic (biofidelic) simulation models

There are existing breast simulation models on the market e.g. Erler Zimmer, Laerdal, Limbs and Things, Mammacare. Students trained on silicone breast simulators were more likely to detect lumps in the models and benign lumps in patients, although the overall skills remained low (McDonald, Saslow, and Alciati 2004).

One study by Brydges et al. (2010) compared 850 students taught using different levels of fidelity models to teach the insertion of intravenous catheters. The study showed that students trained only on a low-fidelity simulator performed lower on a measure of technical skill than students trained on either high-fidelity or a mixture of high and low. One reason for this may be that the more inexperienced the student, the more accurate or realistic the simulation needs to be. So, while an expert can accurately conceptualize the gap in feel between a real breast and a simulation, when a less-experienced student imagines a gap, their imagining is unlikely to be true to life.

In addition, cross-modal studies in selective attention show extensive links between modalities; for example, looking at an object while touching it can help focus and improve information-processing from that area (Spence 2002), so it is helpful if the simulator looks like an actual breast while the student is examining it.

One reason overall CBE skills might be deficient is that existing models are too simplistic. Although there are many skills that can be taught using these simulators (such as documentation and CBE process), low-fidelity simulators do not provide the varied scenarios needed for clinical success (Brydges et al. 2010). Other people have tried to fill this deficiency by modifying existing models. For example, some papers discuss modifying existing manikins to make them more realistic by either 1) simulating a wider range of anatomical variation (Mehta et al. 2014), which implies existing models lack this; 2) by adding virtual reality (Semeraro et al. 2009) or 3) by replacing an existing function with a more realistic one for a specific purpose (Atamanyuk et al. 2014; Auerbach, Kessler, and Foltin 2011). McDonald et al. (2004) indicated present models can be useful but more realistic models may produce better outcomes in students.

The range of normal – how many models do we need?

The feeling of breasts defined by nodularity (lumpiness) and durity (softness) (Goodson and Moore 2002) like many other biological values, such as height and weight, is continuously variable. The range of normal variation is quite broad, yet human variation in normal breast durity and nodularity is not reflected in existing breast-simulation models. A single model with a single feel to teach palpation does not communicate normal human variation to the student; however, it is impractical to create a full range of models to represent the feeling of all women's breasts as too many models would be needed. From a practical perspective, a range of five to nine models would be desirable and the distribution of these models on the range of normal human variation would seek to cover the most important variations for teaching.

Each individual varies in durity and nodularity, and these variations can cause breast lesions to be missed through CBE; these are important factors in delayed diagnosis of breast cancer (Goodson 2010) and they need to be taught. This indicates that a range of normal models representing different cases, each varying in durity and nodularity, is essential to facilitate the discussion of risk factors such as very dense nodularity. Existing models (particularly when only one is used in teaching) are too simplistic to allow consideration of the feel of normal breast texture variation versus abnormal lesions. One of the difficulties in developing realistic breast models is the extreme variation in the palpation characteristics of the normal breast. Breast characteristics vary between women, and for the same woman at different times, depending on factors such as age, parity (number of children previously borne), adiposity (fatness), menopausal status, stage of menstrual cycle and body variations. Most of the existing patient simulators lack complexity and are neither shaped nor feel like real people (Goodson 2010).

So, what is needed are sufficiently authentic, validated breast simulation models fit for the purpose of training in CBE (Chalabian and Dunnington 1998). The models described in this paper illustrate how an iterative design process can successfully make a range of biofidelic breast-simulation models by introducing normal human variation and realistic anatomy.

Existing models have not been validated against patient-outcomes (Simpson 2014). Our simulation models have been assessed in a clinical setting by breast surgeons to determine whether they are representative of the range of normal human variation or if we need more.

Standardizing CBE teaching

Currently, the teaching of CBE is not standardized, even though standardization has been reported to improve sensitivity (Day 2008; Campbell et al. 1994; Saslow et al. 2004). Standardized training using authentic breast simulation models could provide, like cardiopulmonary resuscitation, a path for basic accreditation in CBE and a continuing professional development for general practitioners (GPs) who act as a gateway for breast specialists in the diagnosis of breast disease.

Aims of the research

There are two main aims: to develop a range of more realistic, varied and complex breast-palpation simulators useful for teaching, and to validate their biofidelity (lifelike feel) by having experts (breast surgeons) compare them to patients in a clinical setting.

Methods

Method Part 1 – We developed six different breast models with normal anatomy. These were validated repeatedly during the design process and development by a breast surgeon (N=1). Materials were also individually tested for feel by a GP (N=1).

Method Part 2 – Once completed, the breast simulators were tested by breast surgeons (N=4) during clinical encounters in a breast clinic and rated for similarity to patients' real breast tissue for softness and nodularity (N=78).

Ethics approval

Ethics approval was obtained from Southern Adelaide Clinical Human Research Ethics Committee number 34.13.

Method part 1 – model design

We tested different approaches and found the most effective method to be an iterative design approach: a breast surgeon repeatedly establishes the most lifelike feel by directly comparing the feel of real breasts to that of a range of different simulation materials (Veitch and Bochner 2014).

The key biological features that the breast surgeon was feeling for were surface anthropometry (size and shape), adipose tissue, skin, colour, nodularity and other internal structures such as ribs.

Model materials were explored. A description of the development and testing of each of these features will be expanded in what follows. Individual preprepared biofidelic feeling components were taken into a theatre where a mastectomy was being performed. The removed breast was immediately available for inspection and comparison with each of the simulation materials – separately and combined. These configurations were rapidly tested in different arrangements to mimic the feeling of the patient's removed breast (see Figure 4.5).

Body selection – surface anthropometry

The process of torso selection for the external breast size and shape involved choosing one woman's torso from the anthropometric data of 1265 Australian and 937 North American women (the latter including three-dimensional (3D) body scans) and has previously been described. The scanned torso was developed as a Computer Aided Design (CAD) model prior to making a rapid prototype (see Figure 3.2, 3.3 and 4.1).

Model materials

A range of both non-rigid and rigid model-making materials were selected as initial candidates for the breast model. All materials were commercially available from retail outlets. The materials included urethanes, silicones and vinyls. An initial screening based on material data safety sheets was conducted and all materials with warnings of significant toxicity from unprotected exposure were excluded to protect the safety of the researchers. Silicones required the least safety equipment for safe-handling and felt the most biofidelic.

Adipose tissue

Several silicones were selected and made into small samples. A GP with more than 30 years' experience in General Practice, which included breast examination, rated the samples for lifelike breast feel. The softest silicone was selected as the most lifelike of the original options. This silicone had an optional addition of thinner, which made it feel softer. Testing revealed the maximum dilution before the material failed to set was 30%.

Sample 'pots' of each dilution of silicone were made. The 'pots' were selected so an expert, a GP, could, when using touch alone, easily discern the difference between their firmnesses and arrange them in ascending order.

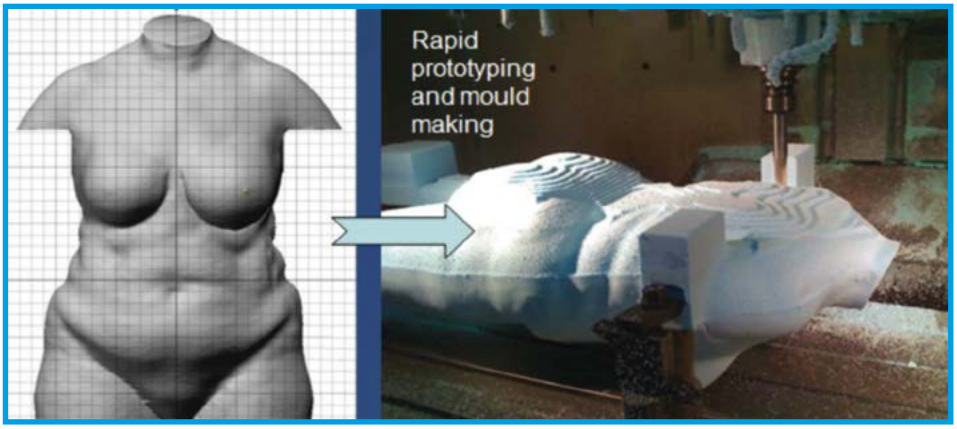


Figure 4.1 *CAD data (left) ready for rapid prototyping using a Computer Numerical Control (CNC) milling machine (right) prior to mould-making. Body scan was taken using a laser Cyberware WBX and data processed in Polyworks.*

During this selection process the 5%, 15% and 20% thinner test 'pots' were deemed so similar to other 'pots' that they were considered redundant. Four of the original seven of the 'pots' were selected this way and considered during the next phase of the test.

It is likely that all the choices would have been a similarly good starting point to simulate the adiposity (fat) of the breast. However, we chose the 0% dilution. If our starting point was a silicone that was too hard, it would have been a critical fail for the design, but all tested silicones passed our softness criteria. Therefore, all the silicones we tested were a pass. All adiposity used for future development was silicone with no thinner. The feeling of this silicone was checked later many times during the iterative development by the breast surgeon who thought it had realistic feel.

Skin

A range of silicone 'skins' of varying thickness and elasticity is added to the adipose tissue base previously selected and the testing of firmness was repeated.

The 'skin' was made thicker than real skin for longevity of the model. This caused increased durity. Sometimes, this was useful as some of the models needed a firmer feel but when it was undesirable, we reduced the surface tension by detaching the skin and in one case created a skin gusset.

Colour

The look of the skin was a consideration in the making of the model because the perception of feel is enhanced when the model also looks real. This improvement is due to cross-modal agreement (Spence 2002). A range of skin colours were explored using standardized photographs from 11 breast patients and 1 breast model.

We collected a sample spread of the skin colour of these patients, photographed as part of a routine breast clinic. The location for each colour swatch was in the upper inner quadrant of the breast, just above the nipple, and the location was standardized for each patient. This location was chosen as there was no shadow from the lights and very little sun damage to the skin. The silicone breast model varied from the real skin colours. Ten of the patients were Caucasian and one patient was of African descent. Our model was a neutral mid-tone between them.

Further investigation of skin tones showed that each individual is made up of a series of tones. Each patient's skin tones can be analysed into a vast array of colours. The lead author hand-painted our models using silicone paints in 15 different layers and multiple colours to realistically simulate the look of skin (see Figure 0.1)

Nodularity

The location, shape, size and consistency of nodularity caused by fibro-glandular tissue were explored in a subject with a normal breast. Breast parenchymal shapes were developed based on images from this subject obtained from ultrasound, prone and supine MRI, palpation and 3D body-scanning using a laser scanner.

The ultrasound and MRI images demonstrated the complex structures that contribute to findings in breast palpation – skin, adipose tissue, Cooper's ligaments, glandular nodularity and ribs. Imaging with MRI in both prone and supine positions shows the amount of movement the breast experiences when the patient shifts position (see Figure 4.3). The goal was to make the breast

nodularity of the model from the MRI data in the supine position and have it flexible enough to move, thus to also accurately represent the structure in a prone position. Data was extracted in two ways for comparison: (1) by hand, layer by layer and (2) using *Mimics* software. *Mimics* software was used to create the 3D image by stacking of two-dimensional (2D) images from the MRI data. Two subjects were modelled, one middle-aged and one adolescent. The CAD-extracted structure was then milled in soft material (see Figure 4.2 (left)). A mixture of the two techniques was used to construct the internal structures. The lead author made moulds for each 5 mm layer in the coronal plane extracted from the MRI scan and these were used to cast very soft silicone. Thus, 35 individual moulds were made and later stacked by hand to make the nodularity. These structures create the complexity of the feel and make it difficult for the novice to determine the difference between normal anatomy and pathology, and this complexity clearly contributes to the challenges of creating a realistic model.

Figure 4.3 emphasizes how much the posture variation affects the breast shape and internal nodularity structure. The CBE experts repositioned the patient during palpation to minimize the thickness of tissue, so the patient is usually supine, sometimes on a slight angle with gravity flattening the breast to facilitate the physical examination.

Figure 4.2 *Internal shapes of normal breast mass/nodularity built from slices of MRI data: left-side built using a 3D printer in soft material (TU Delft) and right built by hand-layering data in the coronal plane (frontal plane).*

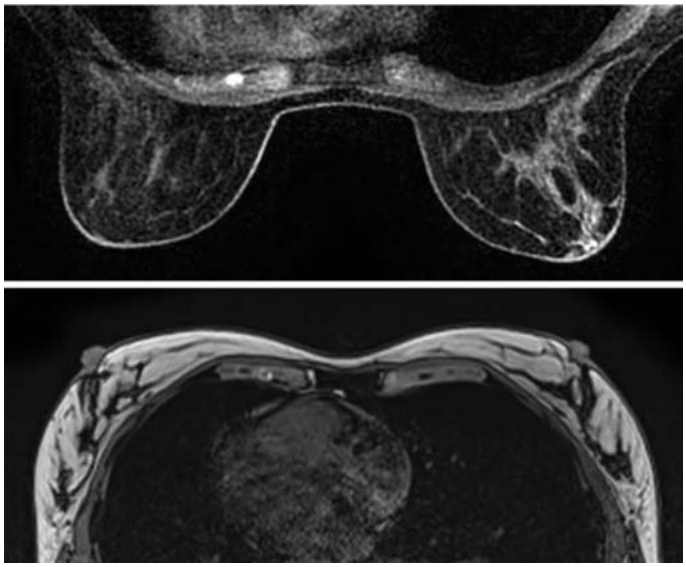


Figure 4.3 *Two MRI transverse slices of the same 50-year old patient taken at the same transverse height from different scans in two different postures, one lying prone (above) and one supine (below), showing a significant amount of breast tissue movement occurring during postural change.*

We copied the breast movement effect illustrated in Figure 4.3 and subsequently flattened our simulation models accordingly – see Table 4.1

Ribs

Ribs were scanned and aligned with the breast model in CAD (see Figure 3.3). As with the external shape, the ribs were milled using a CNC machine. A mould was made and materials were again tested repeatedly by feel to mimic real ribs when palpated.

Different tissue types, including skin, fat and nodularity were reproduced using silicones, each matched for tactile properties and overlaid on different materials, including plastic, plaster and wood to test for the feel of ribs. The rib shape, developed using scanned data, was eventually reproduced in semi-rigid vacuum-moulded plastic.

Name	Nodularity	Durity	Size (grams)	Shape (supine)	Colour skin tone	Comment age
1	Smooth	Hard	1100	Mound	Mid	Younger
2 Thinner	Medium	Medium	680	Ptotic	Mid	Middle
2 Fatter	Medium	Medium	1000	Ptotic	Mid	Middle
3	Medium	Soft	1400	Ptotic	Mid	Middle
4	Smooth	Softish	1050	Ptotic	Mid	Post-menopausal
5	Nodular	Hard	700	Ptotic	Mid	Anatomical variation – any age

Table 4.1 *Breast descriptors describing differences in nodularity, durity, size, shape, colour and likely patient presentation.*

Lesions

Lesions were developed that mimicked the feeling of cancer, cysts and fibroadenoma (see Figure 4.4). The cancer was made from non-rigid silicone and the cysts were made from silicone skins and injected with silicone gel. Again, these were tested for feel in various models. They are removable and can be placed randomly in any location in the normal breasts. This has two advantages; first, different configurations can be created, and second, this avoids a wear pattern developing in the skin over a lesion.

Building the first model

A breast cancer patient having surgery allowed her excised breast to be assessed for palpation characteristics during the operation. The model-maker compared the different structures of the real tissue with the different components and then of the multilayered model and thereby constructed a model with biofidelic feel (see Figure 4.5). This model became Breast 3 (see Figure 0.1). Assessment of the match between the patient and the model was subjective.

Figure 4.4 *A simulated silicone cancer shown on the left and cysts of two sizes shown on the right.*

Figure 4.5 *Materials previously prepared laid out ready to build a breast simulator in theatre. Layers had different tactile properties. The nodular layer was much firmer glandular tissue.*

Building subsequent models

The remaining breast models were constructed according to data obtained from imaging and palpation and guided by subjective assessment from a breast specialist. All the models included variations on the key features described previously. The features that varied most were the amount of adiposity, skin tightness and the quantity, location and firmness of nodularity.

Each of the examples (see Table 4.1) is distinct and useful for teaching. There are five categories for durity and three categories for nodularity because

Breasts 4 and 1 were equally smooth; Breasts 3, 2-Thinner and 2-Fatter were all similarly nodular, but the latter two were of different fatness; Breast 5 was extremely nodular.

Method part 2 – model validation

Four surgeons examined 78 patients without cancer during routine appointments in a Women's Health Clinic in 2016. The patients were selected if they were attending the clinic on a data collection day and they were booked in to see one of the breast surgeons participating in the trial. Patient data was collected anonymously. The breast surgeons were asked to fill in questionnaires collecting demographics relevant to breast feel and specific data about durity and nodularity. Patient demographics included age, weight, height, bra cup-size and hormonal status. The surgeons were asked to rate each patient's breasts using feel for durity in five categories from soft to hard. They were given the six breast simulation models. The surgeons were then asked to rate how similar the breast models were to each patient's real breast tissue. The categories were 'not at all similar', 'not similar', 'undecided', 'similar' and 'very similar'. They were asked which breast model was most similar to the patient and the code was recorded. They were also asked for a description of feel, and asked to rate their confidence in their categorization. These questions were repeated for nodularity. The five categories for nodularity were 'smooth', 'between smooth and nodular', 'nodular', 'between nodular and extremely nodular' and 'extremely nodular'. A trial of the questionnaire was run with a single breast surgeon before implementation.

Results

Six biofidelic models have been developed that differ in feel, especially two physical characteristics of feel: durity and nodularity, but with some adiposity variation (see Table 4.1 and Figure 4.6). Each one represents a variation of a normal case. Each of the six cases was selected because they were distinct, relevant and important for teaching.

Demographic data are summarized in Table 4.2.

24% of patients had an A or B cup, 73% were C cup and above and 3% had no data recorded. 43% of patients examined were post-menopausal, 26% unsure or peri-menopausal and 31% premenopausal.

Validation testing used a five-point scale for responses. Due to central tendency bias, 'undecided' was grouped with 'similar' and 'very similar' in data analysis. Models were rated as 'undecided' or better for 81% of patients for nodularity and 82% for durity (see Table 4.3).

For nodularity, Breast 4 was the most commonly matched breast model at 36%, followed by Breasts 2 and 3, each 24%. Breasts 1 and 5 were the least common with 4% and 8%, respectively.

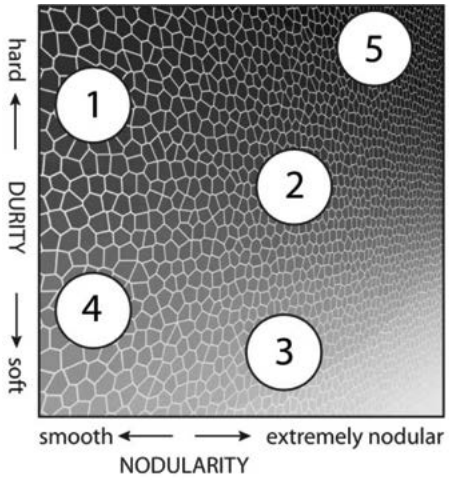


Figure 4.6 *Showing the location of breast models differing in feel arranged in a bi-variate format where the axes represent the range of normal for durity (y) and nodularity (x).*

For durity, Breast 3 was the most common match (36% of patients), followed by Breast 4 (28%) and Breast 2 (25%). Breasts 5 and 1 were the least common with 5% and 1%, respectively. Where the category was 'no similarity at all', the breast surgeon chose 'not applicable'. Although Breast 1 was not common, this was to be expected as the age demographic presenting to the breast specialists for the triple test were older women. Breast 5 is a very important teaching model as increased nodularity and breast density can be associated with delayed diagnosis.

The questionnaire included a comment section. Comments by the surgeons were included; four of the women's breasts were rated 'not similar' because the patient felt softer than the softest model; one very glandular breast rated as 'not similar at all' belonged to a breast-feeding patient; and a 'not similar' rating was given to a woman with a breast implant; the surgeon described the feeling of this person as 'bouncy'. There was one person described by the surgeon as 'harder than the firmest model' but the rating was 'similar'.

		Mean	Median	Max	Min
Age (years)	N=78	53	55	100	17
Weight (kilograms)	N=75	72	68	145	45
BMI	N=75	27	26	51	17

***Table 4.2** Mean, median, minimum and maximum summary statistics for the 78 patients for age, weight and body mass index (BMI).*

Table 4.3 shows 18% of patients were rated not similar to the models and 82% of patient examinations rated undecided or better for durity. 3% of patients were rated not similar at all, 16% not similar, 81% of patient examinations rated undecided or better to the models for nodularity.

How similar are the breast models to the real breast tissues?	Nodularity %	Durity %
Very similar	1	0
Similar	66	67
Cannot decide	14	15
Not similar	16	18
Not similar at all	3	0
Total	100%	100%

***Table 4.3** How similar are the breast models to the real breast tissue?*

Conclusion

This is the first time a range of biofidelic breast simulation models representing a range of normal human variation have been developed. Each model has been validated with real patients by experts. This is important because it provides a new tool that educators in CBE can use to develop student proficiency.

CBE is an important clinical skill but is difficult to teach. It is a complex physical skill and requires deliberate, multisensory practice. Recent research reveals that many healthcare professionals do not feel confident in CBE and would welcome further training (Saslow et al. 2004; Chalabian and Dunnington 1998). This means it is important that medical students learn the skill well during medical school, as good initial training is required for students to take advantage of the opportunities for skill development that will arise in clinical practice.

A standardized training system incorporating life-size, anatomically correct models that look and feel authentic and encourage specific learning outcomes, greatly facilitates teaching breast palpation, and thus helps enormously to develop competence in coping with the anatomical complexity and range of normal found in the breast and with diverse pathology.

This study has demonstrated that a lifelike look and feel can be achieved by creating an anatomically correct torso with a multilayered breast construction and a palpable rib cage. The successful method involved input from a multidisciplinary team with expertise in both the design and medical fields. Each individual component was tested for look and feel and then multilayered into the simulation models (see Figure 4.2).

Existing models are too simplistic to allow consideration of the feel of normal variation versus abnormal. So, sufficiently authentic, validated breast simulation models fit for the purpose of training in CBE are needed (Chalabian and Dunnington 1998).

We have achieved a range of six novel complex models and yet have still been able to encompass much of the range of normal diversity of human breast anatomy within these models. Validation testing conducted by breast specialists on 78 patients shows that the tactile properties of the developed breast models fall within the range of normal tactility of women's breast tissue in the aspects of

durity and nodularity. This verification of biofidelity sets our models apart from other simulators.

To know what is abnormal, you must first teach what is normal, as with the concept of normal in haematology. The range here has been validated as encompassing much of the normal variation, but cannot represent everyone. Nevertheless, these are important teaching cases that give students a good idea of the possible range of normal and will facilitate better diagnosis. We acknowledge they could be refined, in particular by the addition of a seventh, even softer normal model. The addition of forms of pathological complexity (i.e. cysts, cancerous growths and fibroadenoma) has been developed and they can be inserted randomly to introduce the feeling of different types of lesions.

The models create a realistic simulation tool that educators can use to educate students in a range of different tactile experiences, each incorporating complex, multilayered, lifelike features that represent normal and diverse range of human variation in the way normal breasts feel. These realistic feeling simulation models create an additional teaching tool allowing the educator to focus on teaching the identification and discrimination of breast masses by touch, an essential goal of CBE, as early identification of suspicious lumps saves lives. This might be particularly valuable for health professionals who work in remote areas or underdeveloped countries with no access to imaging equipment, or for the detection of interval cancers that only become noticeable between imaging appointments or are mammographically occult (Haakinson et al. 2010).

The multidisciplinary team combining design and medical expertise was essential for such a detailed level of research into the design, development and testing required to create these novel models. This new simulation tool provides extended additional capacity to improve the effectiveness and efficiency of CBE teaching and as such represents the practical application of a new technique. In addition, breast surgeons directly compared the feel of the models' durity and nodularity to that of patient's real breast tissue, validating their feel mostly as 'undecided', 'similar' or 'very similar'. The experts (N=4) rate the breast simulators by feel on a bi-variate scale (durity and nodularity), directly comparing how the simulators feel in relation to the range of human variation in the feel of real women's breasts (N=78); they confirm these simulators reflect the spectrum in more than 80% of cases.

In conclusion, we have developed models realistic in appearance and texture that breast experts confirm reflect the spectrum of normal breast variability. This is important to develop and test for student proficiency in CBE.

Design lessons learnt

While constructing each model, the different tissue types felt different when they were tested individually or multilayered in the silicone breast. Layering introduces complexity that reproduces the feel of the palpated breast. Different layering and components created different results and this process was guided with iterative feedback from a breast surgeon. A subject expert was crucial to the success of the design.

Compromise: we had to balance some biofidelic aspects with durability. For example, the thinnest skin felt the most realistic but damaged too easily, so we compromised by making it a little thicker.

Technologies used: the soft material printed by the most modern 3D printer was still too hard to realistically represent the feel of nodularity, so we had to use a mixture of the latest imaging (MRI) and traditional artisan casting techniques to make the nodularity. Any techniques that get results should be allowed no matter how traditional.

Disclosure statement

No potential conflict of interest was reported by the authors.

Acknowledgments

The authors would like to thank Jeff Hudson for the CAD images, David Summerhayes for assistance in preparation of the other images and Henry Fellner for input in the initial material selection process, Martin McAvoy for editing, Griselda Raisa Susanto for research support, Randell Brown for organizing and interpreting the MRI, staff at TU Delft for the preparation and milling of the CAD model shown in Figure 4.2 (left), and the staff at the Royal Adelaide Hospital Women's Health Centre who generously gave their time for the collection of data.

Chapter 5 — The development and pilot study of a "Tactile Landscape" as a standardized testing tool

Daisy Veitch, Johan Molenbroek, Richard Goosens, Harry Owen and Melissa Bochner

The range of most commonly occurring pathological features are simulated including breast cancer, fibroadenoma, cysts and others for insertion at varying depths in a test object – a tactile landscape. The objects are entirely hidden. This landscape will be validated by a series of breast specialists. The goal is to develop a test to determine if students can discriminate by touch alone masses that might be pathological vs normal. This can be used as a student test after training in CBE. N=5 experts and N=20 students

Status: Published June 2019 – Volume 14 – Issue 3 – p 201–207 https://journals.lww.com/simulationinhealthcare/Fulltext/2019/06000/Breast_Cancer_Detection_The_Development_and_Pilot.11.aspx
(Simulation in Healthcare)

Abstract

Introduction: There is still a need for competent breast lump detection palpation skills, especially in developing countries. Our goal is to design, develop, and establish a test to determine whether students can, by touch alone, identify and discriminate between a range of different simulated lesions at different adiposity levels.

Methods: Common lesions, breast cancers, and cysts were physically simulated and hidden in a test object referred to as the "tactile landscape" (TL). Ribs, intercostal muscle, and nodularity – normal anatomical features – increased their realistic complexity. Varying depths of features simulated varying degrees of adiposity. A testing protocol was created to determine the testee's ability to *identify* and *discriminate* different commonly occurring *breast masses* using palpation (IDBM). Five experts (four breast surgeons and one general practitioner) and 20 inexperienced medical students were recruited and tested. Results were compared.

Results: The TL has been based on previously verified breast models and has softness similar to 53% of women's breasts and nodularity similar to 60% as assessed in a breast clinic by breast surgeons. The five experts indicated that the simulated lesions felt like those they might encounter in clinical practice and all of them identified the lesions and non-lesions hidden in the TL 100% correctly, thus indicating the value of the model. In contrast, only one student was able to identify all the lesions. One student identified none of them. The remaining students mean score was 65%.

Conclusions: All students but one performed poorly in comparison to the experts. This indicates that the test could be useful to test students' ability to identify and discriminate of breast masses. If successful, it will add previously missing capability to the mix of assessment instruments already used, thus potentially improving clinical breast examination training and assessment.

Key Words: Simulation, clinical breast examination, testing, training, breast cancer

Introduction

"To ignore lump detection as part of our construct of breast examination is as remiss as leaving out reading comprehension from a test of reading ability (Chalabian and Dunnington 1998)."

"Breast cancer was the most common cancer in women worldwide, contributing 25.4% of the total number of new cases diagnosed in 2018 (World Cancer Research Fund)."

The gold standard for screening for breast cancer is mammography in asymptomatic women. The "criterion standard" for diagnosis of breast cancer in symptomatic women is the Triple Test which is clinical breast examination (CBE), imaging, and biopsy, which combined have a 99.4% accuracy for detecting malignancy (Irwig, Macaskill, and Houssami 2002). The accuracy is so high because each of the components of the Triple Test can detect cancers missed by the others. A proportion of breast cancers (9.8%) are not revealed through mammography with 6.8% of these cancers being found through CBE (Irwig, Macaskill, and Houssami 2002, Haakinson et al. 2010). This underrecognized fact, combined with loss of CBE skills, is a major reason for physician-caused delay in the diagnosis of breast cancer (Goodson 2010); therefore, CBE is still relevant and important. The identification and discrimination of breast masses (IDBM) through CBE make it a core clinical skill for many medical practitioners.

Standardization of CBE has been reported to improve sensitivity in lump detection (Day 2008, Campbell et al. 1994, Saslow et al. 2004) and an evidence-based recommended technique has been published by Goodson (2010). However, there has been no agreement on standardization of CBE and trainees are exposed to differing techniques (Laufer et al. 2015). In addition to IDBM through CBE, the learner should demonstrate that their technique can be modified to accommodate variation such as large breasts and normal variation in nodularity in breasts. However, current testing for IDBM proficiency does not test for these skills. As with other clinical skills, simulation can be a valuable tool for teaching and assessing CBE. Dilaveri et al. (2013) in a systematic review and meta-analysis of simulation training for breast and pelvic physical examination identifies core skills as obtaining the clinical history (simulated), performing the examination on a model, including inspection and palpation, and identifying and describing lesions. Proficiency in breast examination is

defined as performing a complete examination, identifying all existing lesions, and describing the location and character of each lesion without error (Naylor et al. 2009). There are two main problems with the current system. Firstly, "Skills were typically tested with the same simulator model used for training," Dilaveri et al. 2013 meaning that students can learn for the specific assessment, instead of acquiring the IDBM CBE skills required for clinical success. Secondly, current simulator models such as Mammacare are anatomically simplistic, lacking ribs, nodularity, and human variation and simulate a small-breasted patient, making the identification of masses easier and less complex on a model than a real patient.

We have developed and validated more realistic models for teaching breast examination; this has previously been described (Veitch et al. 2018). We wished to test our simulation models against other models and teaching techniques, including low and high fidelity models, to determine whether students would have more efficient and effective learning in the specific skill of IDBM in a way that simulated some of the findings they might encounter in a clinical situation. However, given that students trained on a specific model would have an advantage when tested if they were examined using the same model they trained on, we needed a stand-alone physical test to test IDBM as a stand-alone physical skill. This would allow the fairer testing of different teaching styles.

These gaps led us to develop a simulation model we have called the tactile landscape (TL), which incorporates the feel of normal anatomical structures as well as various breast lesions. The use of the TL would improve the consistency of assessment of CBE, improve the realism of skills required for IDBM during CBE, highlight effective teaching methods, and identify those students and trainees who need greater support to gain proficiency in the skill of IDBM in CBE.

Aim

Our goal is to design, develop, and establish a test to determine whether students can, by touch alone, identify and discriminate between a range of different simulated lesions at different adiposity levels. In this article, our aim is specifically to determine whether a test can be developed that can effectively distinguish between skill levels for IDBM during CBE testing and remediation.

Methods

Ethics Approval

Ethics approval was obtained from Southern Adelaide Clinical Human Research Ethics Committee Number 34.13.

Development of the TL — A New Breast Simulator

What Is the TL?

A wooden tray containing strata of silicone layered upon a sloping wooden ribbed base designed to reconstruct the topography of the natural range of breast anatomy and adiposity above a base representing the ribcage.

Materials: The materials chosen were selected after rigorous testing, as described by Veitch et al. (2018). They were predominately plywood, MDF, and silicones of differing shore values: all TL components are itemized with some specifications in Table 6.1.

TL Assembly

Assembly was as follows: the tray base was constructed, the ribs cut and nailed, the intercostal material poured and allowed to set, 200 mL of "fat" was poured in the deep end to elevate the components, the components of fibroglandular tissue, cysts and cancers were placed on the base and glued, the tray photographed to record location of components, remaining fat poured and allowed to set, skin poured and allowed to set, and skin painted, dried, and then powdered.

Design Rationale

Why did we flatten the breast? This minimizes its thickness and thereby allows us to more easily and more accurately examine it. The TL appears flat but is only relatively flattened, i.e., displaced superiorly and laterally to represent breast movement from the upright position to the supine. This is in keeping with the real breast where the subject is supine and their breast is displaced this way during CBE. The large amount of breast movement is shown in a MRI of the same patient prone and supine in Veitch et al. (2018). The breast moves both superiorly and laterally during the torso movement from upright to supine – see Figure 4.3 (Veitch et al. 2018, Reece et al. 2015).

Why did we slope the internal rib cage? Each breast although relatively flattened still has thickness variations. In addition, different cup sizes (A through to E and above) have different amounts of tissue. Variations in adiposity change the feel of the breast. We have sloped the contour of the ribcage to allow the student to experience the changed feeling caused by different amounts of adiposity. The shallow end labeled "A" represents ribs to skin difference of 25 mm and the deep end labeled "F" creates a 55 mm difference.

The TL was developed using an iterative design process. Prototypes were examined by a breast surgeon for tactility, look, and feel, and the feedback received was used to make increasingly realistic TLs. The design method used here is similar to that described by Veitch et al. (2018) and parts of the TL are exactly the same as those used to make the realistic breast models. In particular, the selection of materials, the development of the layering, and the components, lessons learned were all directly applicable and used in the building of the TL. The lead author is a model-maker (20 years) and made the TL herself, the second author is a breast surgeon with 22 years experience, and the last author is an expert in medical simulation (32 years), so the design team was very experienced.

The TL frame is marked with the numbers 1 to 5 along the short edge and A to F along the long edge, with A being at the shallow end and F the deep end, to simulate breast cup-sizes. This allows a unique grid location code for each object to be created that facilitates identifying the precise locations of lesions during the testing process.

The TL has the following three varying features: 1) breast lesions, 2) normal anatomical features, and 3) attention to body mass index. The lesions incorporated were three types of commonly occurring pathology: 1) cancers; see Figure 5.1 Middle: see AQ10 F1 coordinates (A,1), (A,2), (B,1), (B,2), (C,4), and (E,3); 2) cysts; see Figure 5.1 Middle: (B,4), (B,5), (E,1), and (F,5); and 3) a calibration object (A,3) to orient the student.

Anatomical Feature	Material Used for Simulation	Shape or Position	Hardness	Size
Tray base	Wood	Rectilinear – 12 mm plywood	NA-rigid	305 x 475 x 75 mm
Ribs	Wood	MDF medium density fiberboard of a flat quad profile placed diagonally 45 degrees	NA-rigid	25 mm strips spaced 25 mm apart
Intercostal	Silicone	Liquid poured to just below the maximum height of the rib protuberance	Shore 10A	200 mL
Fibroglandular tissue	Silicone	Shape created from magnetic resonance imaging data	Shore 00-10	Various
Cancers	Silicone	From a mold	Shore 00-10	10 mL
Cysts	Two types of silicone	Shell created around various diameter beads, 25 mm and set then injected with the fat silicone	Surround shore 10A filled with silicone shore value < 00	10 g surround then filled using a syringe
Calibration object	Glass	Hemisphere	NA – rigid	10 mm diameter base
Fat	Silicone gel	Liquid	NA – softer than Shore 00	3500 m
Skin	Silicone	Liquid	Shore 00-10	100 mL plus 6 g of silicone oil (thinner)
Paint	Platinum silicone paint	Creates the look of skin		
Surround	Plastic 90 degree angle edging with mitered corners	Grid reference to provide coordinates (1,2,3,4 and 5 on short edge and A,B,C,D,E and F on the long edge)		
Powder	Creating silky skin feel	Any type of face powder or makeup finish Applied with a makeup brush		
Warmth		TL warmed with a hot water bottle before use		

Table 5.1 *Tactile landscape component descriptors.*

Before commencing, we used a 10 mm diameter glass marble halved with the dome face up to make sure that they can feel this object at (A,3). The normal anatomical features were ribs (Figure 5.1 Middle: white 45 degree diagonal lines), intercostal muscle (Figure 5.1 Middle: flesh-tone 45 degree diagonal lines), and breast nodularity (Figure 5.1 Middle: (C,1), (C,2), (C,3), (D,1), (D,2), (D,3)). These features increased the complexity and realism of the TL. Varying degrees of adiposity were simulated by varying the depths of the lesions and anatomical features using a tray with a sloped base that went from shallow to deep as shown on the lower portion of Figure 5.1.

All objects were visually hidden in a test object, covered by simulated fat and a layer of skin that was then painted with veins, etc. for visual realism (see the upper section of Figure 5.1). In addition, the TL was warmed with hot water bottles and lightly powdered to create a dry silky feel similar to skin, before the examinations. This detail enhances the cross-modal links in attention between touch and vision (Spence 2002), making the experience more realistic.

Assessment of the TL

A testing and marking protocol was developed to determine the degree of skill the testee has in the IDBM by touch alone (see document, Supplementary Digital Content 1, https://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/SIH/A/SIH_2019_01_29_VEITCH_SIH-D-17-00299_SDC1.pdf, TL assessment tool). Both experts and students followed the same testing protocol.

Students' Background

Twenty students in their final undergraduate year volunteered before admission into a 4-year postgraduate Doctor of Medicine degree; thus, they had no clinical experience. They were chosen because they were novices without experience, and thus, we avoided other possibly confounding factors such as previous training and experience. This was confirmed by an entry questionnaire asking specifically about previous breast examination experience. There were also time and space constraints: the students were proctored by breast nurses who normally work in a breast clinic, and in the time available, we could only test 20 students. They were 10 female and 10 male students whose average age was 20.75 years.

Training

The students received 30 minutes of training in CBE before being tested with TL. This is the same training usually given to 2nd-year postgraduate medical students who have some clinical examination experience. The students were trained in two groups simultaneously by two expert clinicians, both breast surgeons from Royal Adelaide Hospital, each with 22 years of clinical experience. The 30 minutes of teaching involved a short theory introduction outlining the examination and symptoms of disease, followed by a practical session of 20 minutes where there was a demonstration on a standardized patient and each student had hands-on practice.

Experts' Background (n=5)

There were five medical experts recruited and given the TL test. Of these, four were breast surgeons, two having practiced 22 years, one 20 years (10 years as a general practitioner, 10 as a breast surgeon), and one a trainee breast surgeon. There was also a general practitioner with 37 years of experience in general practice.

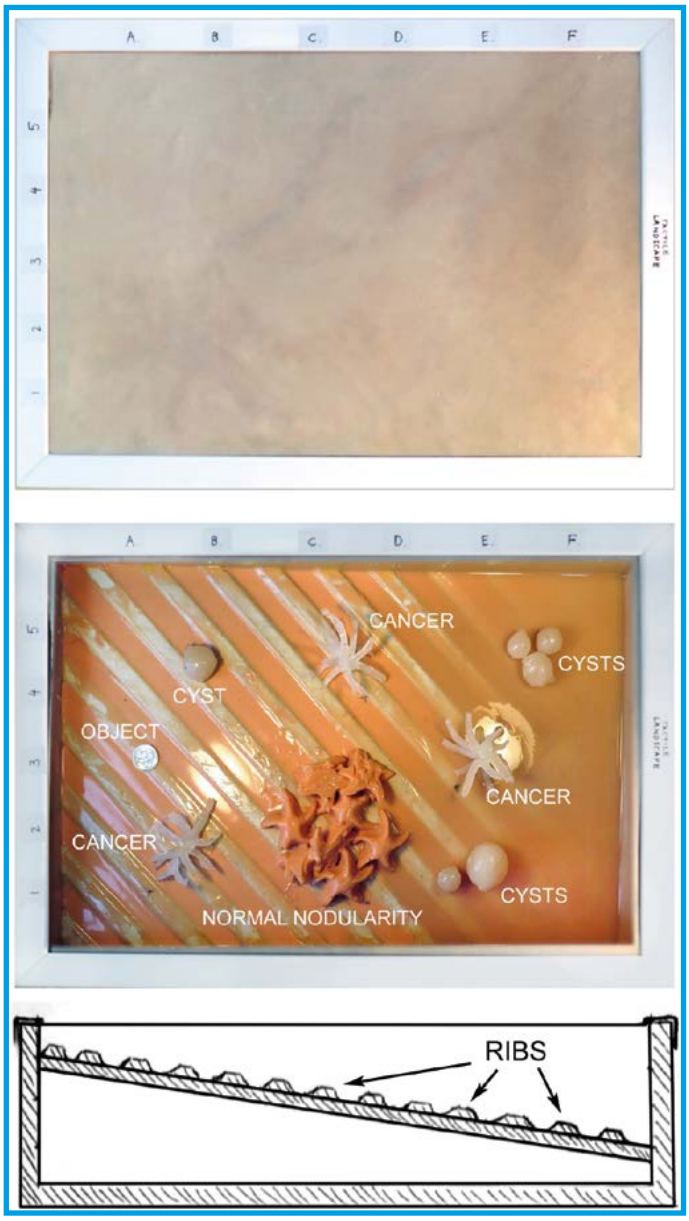


Figure 5.1 *Upper 5.1, Tactile landscape presented as a test object with all objects hidden. The skin has been painted to look like skin. Middle 5.1, Tactile landscape with objects positioned ready to be covered by silicone simulating fat and skin. Lower 5.1, cross-sectional diagram showing deep and shallow ends to simulate large and small breasts.*

Testing

The experts were not time-restrained, but the time they took to complete the task was recorded, and students were then allocated more time than the slowest expert (7-9 minutes). The novice medical student participants were given 30 minutes of CBE training and then given 11 minutes to examine the TL, starting with being guided to the calibration object in sector (A,3). They were asked to thoroughly examine the TL and sketch the location of any breast masses on a diagram marked with a corresponding grid to the TL (see Supplementary Digital Content 1). They were asked to describe each mass they found and record whether they found the mass suspicious and, if so, what action would they take?

There were two identical TLs, and we ran two assessments simultaneously. Each student was proctored by an experienced breast nurse. The two breast nurses both have more than 10 years experience working in a women's health clinic in a major teaching hospital in South Australia. Nurses were coached by the breast surgeon to standardize the proctoring. The nurse introduced the student to the TL and explained the task of identifying and discriminating any "breast masses," which the student was required to record along with their location coordinates. The student was guided to the calibration object. The nurse then observed the student for 11 minutes using the same marking criteria for all students. The nurse noted whether the student examined all areas of the TL and appeared to use appropriate hand technique and appropriate pressure, marking them on a six-point scale with 0 indicating "not at all" and 5 indicating "always." The breast nurses could also write additional comments like "The student carried out the examination with a pen in their hand."

The answer sheets were marked and the testee was given a score of 6 for the six possible lesions they could have found. Any identified lesions are true positives, missed lesions are false negatives, and any "ghost" lesions are false positives.

Results

The TL

The TL was extensively tested for lifelike feel during development – the TL uses the same materials and construction as the breast models described in a previous article (Veitch et al. 2018). Each breast model described in Veitch et al. (2018)

differs in feel from the other models, and together, they represent a range of normal comparable to real patients. Thus, each breast model is similar only to a subgroup in the range of normal. The TL feels most similar to breast models 2 and 4 from the developed set. Upon examination of 78 breast patients (n=78) in a regular breast clinic, breast models 4 and 2 were found to be similar to 60% of the patients for nodularity and 53% of patients for durity.[12] Thus, the TL, though not representing everyone, is similar to more than 50% of patients. The TL is in the middle of the distribution of normal variation for breast hardness (durity), and there are parts that are smooth and parts nodular, encompassing the range of variation in nodularity one might encounter in clinical practice.

Experts

Through palpation alone, all five experts located all six lesions presented in the TL breast simulator. Time taken varied from 7 to 9 minutes. They agreed that the lesions felt like those they would come across in clinical practice and referred all lesions for follow-up. One of the experts said that object 4 (cyst (E,1)) did not need a mammogram follow-up. However, apart from this single difference, all other experts agreed about the follow-up for all lesions.

Interestingly, the experts also correctly identified and discriminated the normal nodularity (location (C,1), (C,2), (D,1), (D,2) in Figure Middle 5.1), but all of them failed to note it on the answer sheet, despite being instructed to note all "masses." When asked afterward, they said that they had felt the "thickening" or "change of texture" but considered it normal so they had passed over it. Similarly, no expert noted simulated ribs or intercostal muscle as lesions.

The language used by the five experts to describe the feel of the lesions in the TL included the following:

characteristics: "hard," "firm," "smooth," and "rubbery"

shape: "irregular" for the cancers and "regular" for the shallower cysts, and the deeper lesions were described as "unsure of shape"

size: "large" for the cysts

location: "deep" and the grid location coordinates specific to this test

The double lesion (E,1) was correctly identified but the triple lesion was not (E-F,5). The language used to describe the lesions became less precise because their location became deeper (so rather than using a measurement like 2 cm

diameter the description became "large"), although they were still correctly identified as "suspicious."

One of the experts commented that they had to press "too hard" and their hand got tired during the exercise and they had to swap hands, especially at the deeper end.

Students

Only one student was able to locate all the lesions, one student was not able to identify any lesion, and the rest correctly identified between 50% and 80% (Figure 5.2) with the mean of correctly identified true positive being 65% (Table 5.2). In addition, In addition, the one student who did not identify any lesions also misidentified the ribs as lesions, which gave a result of 10 false positives (ghosts) (Table 5.3). Fifteen percent of students noted the normal nodularity, although of these, 5% incorrectly said that it should be referred to a specialist as potentially abnormal.

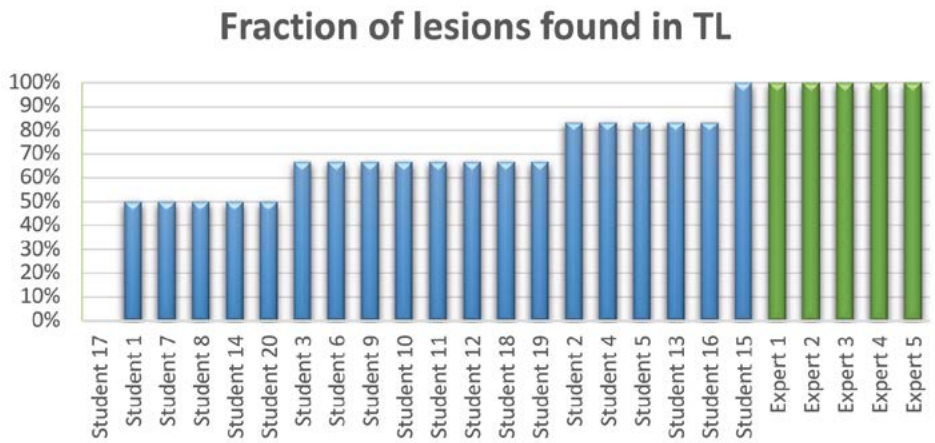


Figure 5.2 *Student scores on left vs. expert scores on right, showing the percentage of lesions correctly identified in the TL (true positives).*

The 95% confidence interval for the students' scores for detection of true positives of between 44% and 86% confirms that the students perform significantly worse than the experts who scored 100% (Table 5.2).

Object identification varied in difficulty (Table 5.4). Thus, 90% percent of students correctly identified object 1 as a lesion (A-cup depth), but only 15% correctly identified object 5, which, although it was structurally the same object as object 1, it was embedded much deeper (E-cup depth) and nearer to an area of normal nodularity.

The nurses evaluated the students who were examining the TL. None of the students in any of the questions received a rating of zero. All students were ranked as 2 or higher for examining all areas of the TL. 90% of students were ranked 2 or higher for using appropriate hand position, only 5% having a low score. Only 30% of students always used appropriate pressure, whereas 90% were ranked 2 and higher (Table 5.5). The major comments by examiners were "methodical" or "haphazard"; "did the examination with pen in hand"; "long nails"; "used fingertips"; "very strong"; "inappropriate pressure"; "too deep"; "too gentle"; "good examination"; and "appropriate". All the students passed under this method of assessment.

Discussion

In this beginner student cohort, 95% of the students missed at least one lesion, with the majority missing two to three lesions; thus, the teaching they had received was insufficient for them to be considered proficient in IDBM. Proficiency here is defined as generated zero false positives and false negatives in the TL, which all experts tested here achieved. The breast surgeons conducting the training felt that 30 minutes was insufficient time for adequate training, although that is the standard time slot they are allocated to teach CBE. If we ignore the one student who did as well as the breast surgeons as an outlier, the results support this hypothesis and indicate that the present training was insufficient for students to acquire proficiency in breast lump detection. The individual variation in this student cohort in tactile skills and subsequent comprehension of the feel of normal versus abnormal structures in the breast highlighted by this TL test suggests that some methods for testing these skills (IDBM) are needed.

The TL test results allow calculation of false positives and false negatives, both of which have very different implications.

Statistic	Result, %
Mean	65
Standard error of the mean (SEx)	10.66
95% confidence interval, 1.960 SEx	44.1 – 85.9
n	20

Table 5.2 *Percentage of lesions detected correctly by the students: mean, standard deviation, and 95% confidence interval.*

No. False Positives	Percentage of Students	Percentage of Experts
0	75	100
1	20	0
10	5	0

Table 5.3 *Percentage of false positives reported.*

False negatives are a major worry in a clinical setting, because these might involve a physician-delayed diagnosis for breast cancer, especially in the setting of a normal mammogram, because some physicians do not know that mammography can miss 9.8% of palpable cancers (Irwig, Macaskill, and Houssami 2002, Haakinson et al. 2010, Goodson 2010). False positives in a clinical setting might produce unnecessary referrals, creating anxiety for the patient (Keyzer-Dekker 2012) and increased workload for the specialists (Kollias et al. 2001). The lack of comprehension which breast lump was normal and which abnormal indicates assessment of CBE tactility skills is needed.

The varying depth of objects in the TL allows the student to experience lesions in varying adiposity, because they vary in real life; this will help test skills in IDBM in patients with, for example, very large or dense breasts. The TL showed that although 95% of students missed at least one lesion, they missed different ones for different reasons. The objects varied in difficulty in their identification by palpation mainly because of the depth, but one object, object 5 [(E,3) and (E,4)] was deep and near an area of non-pathological normal nodularity that confused the students. Understanding which object each student missed and why can help inform remediation. This indicates that this TL can determine not only which students may need remediation but also where they may need it.

Examiner comments focused on the appropriate coverage, hand technique, and pressure applied. Corrections noted incapacity due to pen in hand and fingernails too long and included many pressure comments, the students either pressing too firmly or too gently. These are valuable observations, but if these were the only criteria against which the students were judged, they would be insufficient to determine whether the student could accurately find and correctly identify a breast mass. In addition, all students passed under this assessment criteria, often being given "benefit of the doubt" despite a wide variation in performance for IDBM skill. This method of assessment then cannot distinguish an actual IDBM skill from going through the correct motions of the procedure.

The TL can be used after training in CBE to test tactile identification and the correct discrimination of different concealed breast masses, which is the goal of CBE.

Object Number	Type of Lesion	Percentage of Students Correctly Identifying the Lesion
Object 1 (A-B, 1-2)	Cancer	90
Object 2 (B, 4-5)	Cyst	80
Object 3 (C, 4-5)	Cancer	60
Object 4 (E,1)	Two cysts	20
Object 5 (E,3-4)	Cancer	15
Object 6 (F,4-5)	Three cysts	65

Table 5.4 *Breakdown of the percentage of students who correctly identified each individual object.*

Rating	Did student examine all areas of the tray?	Did student use appropriate hand position?	Did student use appropriate pressure?
5 – always	70%	45%	30%
4	20%	20%	30%
3 – mostly	5%	15%	20%
2 – mostly	5%	10%	10%
1	0%	5%	10%
0 – not at all	0%	0%	0%
Blank	0%	5%	0%

Table 5.5 *Expert rating (Proctored Result) of the students by visual assessment.*

This provides, for the first time, a standardized effective and efficient method to test students' tactile sensing and comprehension ability to both identify and correctly discriminate between various types of breast masses (normal vs. abnormal) by touch alone.

This testing tool could facilitate a path for basic accreditation in CBE, in the same way that other important skills such as cardiopulmonary resuscitation are accredited, and provide a continuing personal development for general practitioners, who act as a gateway for breast specialists when it comes to part-diagnosis and diagnosis of breast disease.

Conclusions

Proctoring resulted in all students passing, which indicates that this method of assessing does not test specifically for IDBM skills. A separate test developed specifically to test IDBM is needed.

The TL breast simulator has had a preliminary validation by experts with all experts who examined it correctly locating all the lesions. Results from a previous validation study (Veitch et al. 2018) indicate that it does mimic the tactility of 1) 60% of women's breasts in nodularity, 2) 53% for durity, and 3) anecdotally the most common lesions that could be encountered in clinical practice. It could thus have a useful role in adding the capacity to test

students for the skill of identification and discrimination of different breast masses (IDBM), including testing for true positives, false positives, and false negatives. These detailed results might inform the type of remediation required for each testee. This capacity adds a missing capability to the mix of assessment instruments already used, thus potentially improving CBE training and assessment.

The TL seems to be a useful tool for assessing IDBM CBE. It could also be useful indirectly for teaching CBE in that if the testing were extended to include the middle-of-novice to expert levels, this would allow more precise mapping of the learning curve for this procedure, which could inform teaching styles, interventions, and student remediation, helping educators become more efficient and effective.

Lesson learned

We should have specified the identification (or noting) of only abnormal masses in the assessment instructions because the experts did this implicitly and the students needed explicit instructions to do this. The teaching time for CBE needs to be longer than 30 minutes. Lastly, description of the rating scales used needs to be clearly defined.

Limitations and future directions

The study was limited by several factors. First, the number of students (N=20) tested were small and the test was only done in one location and at one time. It is recommended that this be repeated with additional students and multiple locations.

Second, these were novice students new to clinical settings and we did not control the teaching but allowed the breast surgeons to conduct their usual training. It is recommended that this testing be extended to include the middle-of-novice to expert continuum to allow more precise mapping of the learning curve for this procedure. Further testing might even reveal where in the progression proficiency is achieved.

In the future, this prototype would need to be brought to manufacturing readiness by including, as with any product development, good quality control and durability testing, as well as a variety of different TLs for repeated testing to show student improvement. The utility of the TL will depend on the ease of manufacture, which in part will be determined by economies of scale.

Chapter 6 — Evaluation of conventional training in clinical Breast Examination (CBE)

Daisy Veitch[a,*], **Richard Goossens**[a], **Harry Owen**[b], **James Veitch**[c], **Johan Molenbroek**[a] and **Melissa Bochner**[d]

[a] *Medisign, Delft University of Technology (TU Delft), Delft, The Netherlands*

[b] *Clinical Skills and Simulation Unit, School of Medicine, Flinders University, Adelaide, SA, Australia*

[c] *Thermofisher Scientific Inc, CA, USA*

[d] *Breast Endocrine and Surgical Oncology Unit, Royal Adelaide Hospital, Port Road, Adelaide, SA, Australia*

Status: March 2019 - WORK: A Journal of Prevention, Assessment & Rehabilitation 62 (4)

Work. 2019;62(4):647-656. doi: 10.3233/WOR-192899.

Summary: This study aims to evaluate how well novice students, after training, identify and discriminate breast masses (IDBM) on actual patients. Students (S) are tested in a simulated clinical setting with patients (Examinations – E) and also a previously developed test object – the tactile landscape (TL). Student performances are evaluated in three ways. Clinical findings, visually by a supervising breast specialist and tactilely by the patient. N(S)=20, N(E)=100, N(TL)=20. This paper will have a message by observation, i.e. how do students perform in clinical setting with real patients? The main conclusion is that novice students do not seem to be able to accurately detect breast masses in a clinical setting even after training. On the basis of these results, we believe that a comprehension component directly related to IDBM in the current CBE testing is needed in addition to the current methods of testing.

Abstract

Background: Clinical Breast Examination (CBE) is the examination of a women's breasts by a healthcare professional, such as a breast surgeon, family physician or breast-care nurse who is trained to recognise many different types of abnormalities and warning signs in the breast (National Breast Cancer Foundation Inc 2018). CBE is particularly important in rural areas and developing countries who have limited access to technology such as mammography. CBE needs to be taught to health professionals like any other clinical skill used by medical professionals in the workplace. CBE in part involves palpation of the breast, that is, determining by touch which breast lumps are normal and which feel suspicious. The gold standard for assessing tactile skills in CBE is seeing whether students can accurately identify and discriminate between different breast lumps (also known as masses)(IDBM) on actual patients in a clinical setting. However, this is not practical in a medical education setting. Usually the testing methods 'go through the motions' of feeling the breast as part of CBE. So the students' technique is examined either using unrealistic simulation models or using an intimate examination associate (IEA), an actor/volunteer who permits students to examine their intimate body parts, such as breasts or genitals, for teaching purposes. These volunteers do not have any abnormalities so this teaching does not include the actual detection of suspicious lumps. We undertook a study of clinical skill with 10 medical students to examine different methods of assessing novice student clinical skills after a brief training in CBE.

Objectives: This study aims to evaluate the effectiveness of current training and assessment of novice students in CBE and their capacity to identify and discriminate breast masses (IDBM) on actual patients.

Methods: We assessed each student's IDBM ability in an actual clinical situation, a breast clinic with a mixture of eight IEAs and one real patient with a large, easily palpable, putative breast cancer. We recruited 10 clinically inexperienced medical students, who were trained for 30 minutes by two breast surgeons using an IEA. Students were tested in a simulated clinical setting, a breast clinic where each examined 4 IEAs and one patient. The students were blind to who was the real patient and who was an IEA. Patients were examined by a breast surgeon in private prior to the commencement of the study. The breast surgeon recorded any clinical finding on the patients during the initial

examination. The surgeon coached each patient on how to mark the students and showed the patient their results so the patients had a benchmark. After each examination was finished the students had four different assessments: 1) patients marked each student, 2) students were independently proctored – that is, marked by an expert, 3) students recorded their clinical findings and 4) students recorded how confident they were that they had the correct findings. Results from different kinds of student assessments were compared.

Results: A chi-square test for independence between true positive or negative masses versus student-assessed positive or negative masses was not significant at alpha=.05. This means that there was no statistical association in the indication of positive or negative presence of masses versus whether such masses were actually present or absent. By comparison, experts (breast surgeons) were able to detect normal and abnormal breast masses by palpation alone 100% of the time and rate their confidence level as 'certain'. Unlike the experts, student self-reported confidence was unrelated to their competence score (CS). Proctoring was inversely related to the students' CS.

Conclusions: The main conclusion is that novice students do not seem to be able to accurately detect breast masses in a clinical setting even after training. On the basis of these results, we believe that a comprehension component in the current CBE testing is needed in addition to the current methods of testing.

Keywords: Medical training, medical education, simulation training, student testing, palpation, Medisign

List of abbreviations

BCS/MD	Bachelor of Clinical Sciences/Doctor of Medicine
CBE	Clinical Breast Examination
CS	Competence Score
IDBM	Identification and Discrimination of Breast Masses
IEA	Intimate Examination Associate

Introduction

Breast cancer is still the most prevalent cancer in women, and the second most common cancer diagnosed worldwide (World Cancer Research Fund).

The gold standard for breast cancer diagnosis is the triple test with more than 99% sensitivity (Ahmed et al. 2007, Irwig, Macaskill, and Houssami 2002). As suggested by the name, the triple test has three different parts: Clinical Breast Examination (CBE), imaging and biopsy: each of which can detect breast cancer in different ways. Each part of the triple test uses different equipment and needs a different skill set to administer. Clinical Breast Examination (CBE) is defined as the examination of a woman's breasts by a healthcare professional, such as a breast surgeon, family physician or breast-care nurse who is trained to recognise many different types of abnormalities and warning signs in the breast (National Breast Cancer Foundation Inc 2018). Out of these three tests, CBE is the first line in symptomatic women, and requires clinician training but not specialist equipment such as mammography. CBE is important as a tool for rural and remote communities with limited access to expensive technological resources. Even in first-world countries with all available imaging techniques, CBE remains important for detecting interval cancers (those that become apparent between image-based appointments) and those that that are mammographically occult (negative on a mammogram but palpable) (Irwig, Macaskill, and Houssami 2002, Haakinson et al. 2010). In addition, lost CBE skills among health professionals at work are an issue in 50% of physician-delayed diagnosis (where the clinician falsely reassured the patient that the lump being palpated was benign), while delayed diagnosis after a mass has been palpated is the leading cause of malpractice litigation related to breast cancer (Goodson 2010, Goodson and Moore 2002a).

CBE requires taking a patient history and completing a physical examination. The physical examination requires breast palpation. Breast palpation skills are taught and assessed in medical school. The gold standard for assessing tactile skills and CBE is determining whether a student can accurately identify and discriminate between different breast lumps on actual patients in a clinical setting. However, this is not practical in a medical education setting. Student in medical school assessment conditions are usually assessed on IEA actors who do not have putative cancer thus IDBM findings are always normal. Alternatively, students can be assessed on simulation models where there are always positive

IDBM findings. Thus, in the absence of real patients with cancer and those without, students cannot be assessed on IDBM in a realistic way. Instead students are usually tested on their technique alone. One recent analysis of testing techniques compare 4 different tests: 1) technical skills using checklists and global rating scales, 2) assessment by a trained actor, sometimes called a teaching associate or intimate examination associate (IEA), whose breast is normal, 3) student questionnaire and self-assessment, and 4) questionnaire on the frequency of performing intimate examinations skills during internship (Hendrickx et al. 2009). Sometimes student testing involves proctoring where a breast nurse observes the student and assesses them for physical manoeuvres, asking 'did the student examine all areas of the breast?', 'did they use appropriate pressure?', 'did the student introduce themselves?' etc.

These skills are important and testing for them is necessary; however, we are not aware of any routine tests in medical school that involve detecting and discriminating breast lumps in a simulated clinical environment with real patients. In addition, we are not aware of any objective, standardised physical testing for students in identifying and discriminating between different breast masses (IDBM) as part of medical student training. Given the importance of CBE in the diagnosis of breast cancer, this seems to be a significant lack in medical training.

Chalabian and Dunnington (1998) argue that "to certify competence in clinical breast evaluation or any physical examination skills, we must remind ourselves that demonstration of a physical examination manoeuvre does not equate with ability to detect physical examination findings. To ignore lump detection as part of our construct of breast examination is as remiss as leaving out reading comprehension from a test of reading ability".

Up to 85% of medical students report that they feel they need further training in detecting breast masses (Chalabian et al. 1998, Saslow et al. 2004). This indicates that while CBE is a core part of the curriculum, what is taught is not sufficient to produce competency in a large percentage of students. By competency we mean the accurate identification and discrimination of breast masses (IDBM), which is not only the essential goal of CBE, but also of the triple test (CBE, imaging, and biopsy) and all combinations of the various technologies and series of manoeuvres developed to detect breast cancer.

Methods

This paper explores test results of 10 novice students (year 2 of a 6 year medical degree) after a 30-minute training in CBE. The training was conducted by two breast surgeons using IEAs or teaching associates (real women as training subjects) and students were given an opportunity to practise.

All students were given a code according to the order they enrolled in the study. None of the students had prior experience in breast examination although one had received informal training from a parent. There were five males and five females.

This paper will compare existing conventional methods of assessing student's skill in CBE with results of testing students in a clinical setting with a mixture of patients and actors. The tests were administered after a 30 minute training session in clinical breast examination (CBE). The methods are 1) student self-confidence assessment, 2) proctoring, and 3) patient feedback, compared to the gold standard of examining a breast patient in a clinical setting.

The trial was conducted in the Women's Health Clinic which is attached to the Royal Adelaide Hospital for four hours on a single afternoon, during normal breast clinic times. The trial was supervised by the regular clinic staff composing of four breast surgeons and two breast nurses. These staff acted as the proctors and marked the students. Students believed that all the patients were real patients and were not told that all but one were actors. The real patient was recruited in a GP clinic the day before the trial and was on her way to have an MRI breast scan to investigate a large suspicious putative cancer that was easily palpable. The patient also had bilateral breast implants and inframammary scars that were potential clinical findings. The actors were examined by the breast specialists and found to be normal prior to the commencement of the trial. Medical students (NS=10) who were novice (pre-clinical) were recruited from Flinders Medical Centre. Students (S) were tested in a clinical setting with a blinded mixture of patients (P) (NP=1) and actors (NA=8) making the examinations – (E). Each student conducted five examinations in a random order. There was a total of 50 examinations (NE=50).

Student performances in CBE were evaluated in four ways. Clinical findings recorded were recorded by the student after each physical examination on a questionnaire where they also rated how confident they were that they had the clinically correct finding. While the student was filling in their questionnaire the

supervising breast specialist recorded a proctored score for each student, rating them for coverage, pressure and appropriate hand technique. The patient also ranked each student's performance.

Student performance was compared in the clinical setting with real patients so a correct diagnosis (absolute truth), as determined privately by a breast surgeon, that is, palpable putative breast cancer 'present' or 'not present', was known for each patient. The four assessment methods were students; 1) conducting a CBE and recording clinical findings of putative cancer or not, 2) proctored by breast surgeons, 3) as self-assessed by themselves (confidence), and 4) as assessed by the patient. We wanted to assess the relationship between confidence and competency and devised a Competence Score as described next:

Students conducting a CBE and recording clinical findings of putative cancer or not

The students had a possibility of four combinations of answers in the clinical setting, see Table 6.1.

	Diagnosis no lump (0)	Diagnosis with lump (1)
Actor (0) Truth = absent	Truth (0,0)	False (0,1)
Patient (1) Truth = present	False (1,0)	Truth (1,1)

***Table 6.1** Matrix to describe possible competency scores.*

We calculated a difference score (DS) for each student ($n=s_1, s_2, s_3, \ldots, s_{10}$):

$$DS(n) = \left(\frac{n_{0,0}}{4} - 1\right)^2 + \left(\frac{n_{0,1}}{4}\right)^2 + \left(\frac{n_{1,0}}{4}\right)^2 + \left(\frac{n_{1,1}}{4} - 1\right)^2$$

We divided by 4 so that we could equally weight the penalty for being wrong with a real lump versus no real lumps. This was arbitrary and in real life we might want to weight it differently according to a cost-benefit analysis, but we went for simplicity here.

To make a Competence Score (CS) we looked at deviation from the truth where the truth was defined as the diagnosis made when the breast surgeon examined

the patient. The worst possible DS score was 4. So the CS was calculated by subtracting the student's DS from 4.

$$CS_n = 4 - DS_n$$

Table 6.2 shows the range of scores. Lines 3,4 and 5 show the scores from 3 possible scenarios, 2 of directed guesses and the last line shows the scores if there was a random guess, which is theoretical as it is of course impossible to divide a patient result into .5 where results are binary.

	Truth (0,0) no lump	False (0,1) positive	False (1,0) negative	Truth (1,1) lump	DS	CS
Best possible score	4*	0	0	1*	0	4
Worst possible score	0	4	1	0	4	0
Directed guess everyone has a lump	0	4	0	1	2	2
Directed guess no one has a lump	4	0	1	0	2	2
Random guess	2	2	.5	.5	1	3

*actual number of patients

Table 6.2 *Range of scores including the best and the worst possible score.*

Student assessment by an expert – 'Proctoring'

Proctoring for this trial was one usually used in medical schools (Hendrickx et al. 2009). Students were each supervised by an expert (1 of 5 breast surgeons) who assessed them during each clinical examination. They were assessed for appropriate hand positioning, whether they examined all areas of the breast and used appropriate pressure. They were assessed on a 6-point scale where 0 was 'not at all' and 5 was 'always'. The proctors also scored them on a pass/fail scale as part of their coursework. All of these students passed.

Student self-assessment – Confidence

Students completed a questionnaire (Q1) prior to the start of the study, after training, before the clinical trial (Q2), and also an exit questionnaire (Q8). Students were asked the following questions three times and asked to rate themselves on a six-point scale from 0=false to 5=true:

A "Knowledge perspective (I feel I have a good grounding in theory of CBE)"

B "Practical perspective (I feel comfortable conducting a physical examination on a patient)"

C "Practical perspective (I feel I can competently apply the theory of CBE in practice)"

The results presented here averages the self-reported confidence scores of each student (Q8) recorded after each of the five patients were examined.

Student assessment by each patient

Students were assessed by each patient they examined at the completion of each examination. Patients had previously been examined by a breast surgeon and had been coached in technique and how to rate or assess the student. Patients were asked, "Do you think they (the student) carried out the physical examination competently?". Patients recorded the student's mark on a 6-point scale where 0 was 'not at all' and 5 was 'always'.

We used a Pearson's chi-square statistic to test the relationship between the different types of student test.

Results

Clinical assessment CBE CS versus student assessment by an expert – 'Proctoring'

The specialist results

The eight actors and one real patient were each examined by a breast surgeon prior to the start of the study. The breast surgeon filled out the student answer sheet (Q3) and this became the marking sheet. As expected none of the eight actors had any suspicious breast lumps. The real patient however had bilateral breast implants, inframammary scars, nodularity periareolar and a large suspicious lump on top of one of her implants that was clearly palpable and diagnosed the day before. She participated in our trial and then went immediately to her specialist appointment as it was a putative cancer. Two of the actors had inverted nipples but no other signs. All of the specialists marked

their confidence as 5 ("I'm absolutely certain"), i.e., that they gave the right recommendations.

The student results

	Descriptive Statistics				
	N	Minimum	Maximum	Mean	Std. Deviation
Competence Score (CS)	10	.0	3.5	1.800	1.0750
Confidence (self-reported)	10	1.4	4.0	2.960	.7412
Proctor (educator's view)	10	2.0	4.1	2.990	.5953
Patient's view of student competence	10	1.8	4.4	2.880	.8702
Valid N (listwise)	10				

Table 6.3 *Descriptive statistics for the student's scores.*

Of the 50 student examinations, 33 were incorrect (66%) and 17 were correct (34%). The students found a breast mass that they thought needed to be referred in 31 (62%). However, there were only four student referrals of the true positives (8%). The actual incidence of suspicious breast masses in this study was exactly 20%. They found no suspicious breast masses in 19 (38%). However, the actual incidence of negative findings in the study was 80%.

Real Patient – false negatives

There were 10 examinations of the real patient and 4 students correctly identified the putative cancer, although only one of these students noted the scar and none noted the breast implant. So there were 6 false negatives, which in clinical practice would directly relate to 'physician delayed diagnosis' (Goodson 2010, Goodson and Moore 2002a).

Actors – false positives

There were 40 examinations in total of the actors. Of these 13 (32.5%) were correctly identified as negative. However, 27 (67.5%) examinations were false positives also known as 'ghosts'. The students largely referred the false positive patients for specialist follow-up, so in practice this would result in specialist resources being occupied with normal patients.

Table 6.4 shows the results. Where the answers are correct, the box is shaded green.

Breast Lump	True Positive	True Negative	Total
Indicated Positive	4	27	31
Indicated Negative	6	13	19
Total	10	40	50

***Table 6.4** Student scores.*

The Chi-square test of relationship between truth and indicated anomalies (breast lesions) was done. Chi-square=2.5679 with a p value of 0.109052. This is not significant at alpha=.05. There does not appear to be a relationship between the true state and the student-assessed state. The student assessment appears to be arbitrary. If we look at the marginals, student indication of positive when true positive is 40%, and student indication of positive when true negative is 67.5%. Any potential relationship between student indication and truth would be an inverse relationship. This is in contrast to the breast surgeons who achieved 100% accuracy.

Student scores are shown in descending order by CS score in Table 6.5. The proctors' view of their ability is also shown, along with the patient's assessment of student competence.

Number of patients shaded grey	Truth (0,0) no lump	False (0,1) positive	False (1,0) negative	Truth (1,1) lump	CS	Confidence (self-reported)	Proctor (educator's view)	Patients' assessment of student competence
Maximum score					**4**	**5**	**5**	**5**
Student 5	0	4	1	0	0.0	4	2	1.8
Student 8	1	3	1	0	0.9	2.8	4.1	3.4
Student 1	1	3	1	0	0.9	3.8	3.3	3.4
Student 2	2	2	1	0	1.5	1.4	2.9	1.8
Student 3	2	2	1	0	1.5	2.2	3.7	4.4
Student 4	3	1	1	0	1.9	3.2	2.6	3
Student 9	0	4	0	1	2.0	3	2.7	2.6
Student 7	1	3	0	1	2.9	3	3.1	3.8
Student 10	1	3	0	1	2.9	3.2	2.8	2.4
Student 6	2	2	0	1	3.5	3	2.7	2.2

Table 6.5 *Student competency scores (CS) are arranged from worst to best out of a possible maximum of 4. Student self-reported confidence, the proctor's score and patient's assessment are in the remaining columns.*

Student 5 scored zero, i.e., of the five 'patients' examined, all four actors were referred for unnecessary follow-up and the actual patient was considered normal. However, Student 5 was confident enough to self-report a score of 4 out of 5 that the right recommendations had been made. Interestingly the proctor score for this student was the lowest although this was still a pass (all the students passed when assessed for CBE physical manoeuvres). The five patients rated this student at an average of 1.8 out of a possible 5.

The lowest Proctor Score was 2 and highest was 4.1. This is not a very broad range out of 5, possibly due to central tendency bias.

Pearson Correlations					
		Competence Score (CS)	Confidence (self-reported)	Proctor (educator's view)	Patient's view of student competence
Competence Score (CS)	Pearson Correlation	1	-.192	-.063	.019
	Sig. (2-tailed)		.594	.864	.958
	N	10	10	10	10
Confidence (self-reported)	Pearson Correlation	-.192	1	-.379	-.057
	Sig. (2-tailed)	.594		.280	.877
	N	10	10	10	10
Proctor (educator's view)	Pearson Correlation	-.063	-.379	1	.731*
	Sig. (2-tailed)	.864	.280		.016
	N	10	10	10	10
Patient's view of student competence	Pearson Correlation	.019	-.057	.731*	1
	Sig. (2-tailed)	.958	.877	.016	
	N	10	10	10	10

* Correlation is significant at the 0.05 level (2-tailed).

Table 6.6 *Pearson Correlations.*

The proctor's competency rating was compared to the CS, see Table 6.6. The correlation (r=-0.063) was not significant indicating that the score on the competency exam is not indicative of actual competency. However, examination of the two variables in a plot revealed a possible outlier. See Figure 6.1 below.

Student proctored marks ranged from 2 to just above 4, however Subject 5 seems to be an outlier. The correlation was recalculated without Subject 5 (r=-0.619) and was significant at α=.10. This indicates a potential inverse relationship between competency evaluation and actual competency. In other words, a good score on the competency exam (physical maneuverers) would indicate a poor score in actual competency.

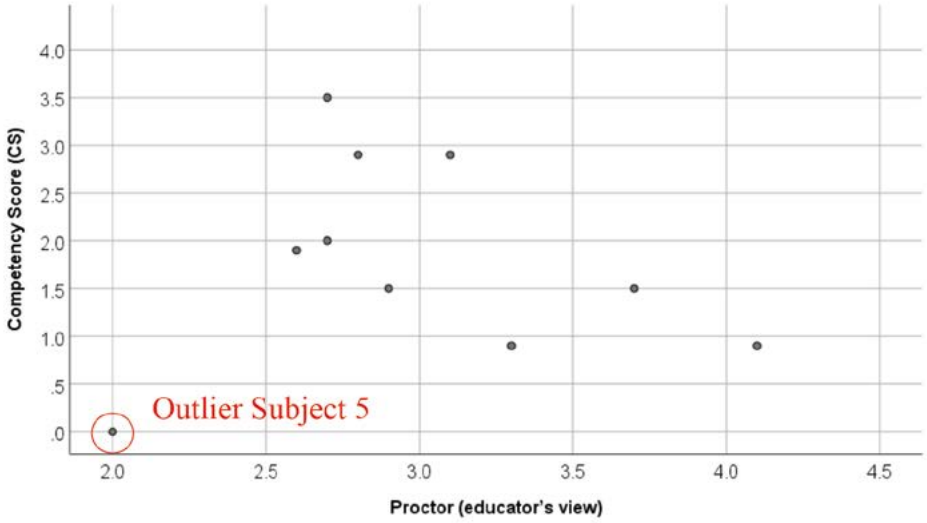


Figure 6.1 *Proctored marks given by breast surgeons on the y-axis and Competence scores (CS) on the x-axis.*

Clinical assessment CBE CS versus student self-assessment – Confidence

Scores from the final self-reported confidence questionnaire were compared to competence scores (CS). The Pearson Correlation between student self-reported confidence in their competence and their actual competence (r=-0.192) was not significant. See Table 6.6.

Clinical assessment CBE CS versus student assessment by the patient

A comparison was done of the patients' view of student competence and their CS. The correlation was not significant indicating the patient assessment of competence was not related to actual competence.

Patient assessment versus proctor assessment

The strongest correlation was between patient assessment of student competency and proctor assessment (r=.731) which was significant at α=.05. This indicates that the competency assessment examination may be testing student interpersonal skills plus CBE physical manoeuvres rather than actual competency in IDBM.

Discussion

The students did no better than chance in the clinical setting for IDBM with a Chi-square score of 2.5679 and p value of 0.109052. This was in contrast to the expert who achieved 100% accuracy. The students were correct in their clinical findings 34% of the time and incorrect in 66% of their clinical examinations in the four possible combinations of answers: true-positive, false-positive, true-negative and false-negative. The actual incidence of true-positive in the study was 20%. Although the students reported positive findings 62% of the time, the actual incidence of the students reporting a true-positive finding was only 8%. The data suggest that the students were prone to over-diagnose, thus there was a high incidence of false-positives. However, even with this bias it was not enough to prevent the all-important false-negatives that, if they occurred in practice would result in physician-delayed diagnosis. The incidence of false-negatives in this study was very large at 12%.

There was no correlation or relationship between proctor (=-0.063), student (=-0.192) and patient (=0.019) assessment scores and CS. However, there was a strong correlation between proctor and patient assessment scores (=0.731). This seems to indicate two things: 1) current education is not demonstrating competency at actual IDBM and 2) the existing test is only evaluating how comfortable the students are during CBE. The proctor marked the student on a 6-point scale for appropriate positioning, examining all areas of the breast including the axilla, using appropriate hand positioning and pressure with '0' being not at all and '5' always. That is, the proctor was marking the student on physical examination manoeuvres. The clinical findings are the same as the CBE physical examination findings which equates to CS. This paper supports results of previous studies that demonstration of physical examination manoeuvres do not equate with the ability to detect physical examination findings for CBE (Chalabian & Dunnington, 1998). The proctor and the patient were both assessing the student on these manoeuvres hence the strong correlation.

The borderline negative correlation (when subject 5 is omitted) between proctors' mark and actual competence might potentially have been caused by student inexperience combined with an effort to look professional. A novice student may have 1) taken longer, 2) expressed uncertainty and 3) conducted parts of the examination repeatedly, all of which might have appeared to look unprofessional. Thus, students who showed uncertainty (because they were

uncertain) were potentially being penalised by the proctor marking which encourages the student to ignore the clinical findings in favour of 'looking professional'. So current assessment for CBE novice students appears to encourage them to go through the motions of CBE at the expense of the clinical findings. The proctor marking in this research passed all the students probably due to the educator giving the student the benefit of the doubt. Potentially it is difficult to fail a student if the fail criteria is missing a putative cancer when there are no abnormal patients, thus no putative cancers to identify in the test. This type of test may be beneficial for becoming comfortable examining patients, but not for demonstrating ability in IDBM.

Conclusion

Current training for CBE based in medical schools appears to be inadequate and actual training of IDBM is needed. Despite the best efforts of the breast surgeons teaching the students, the tests do not indicate competency in actual anomaly (breast lesion) detection. One of the reasons may be a lack of real cancer patients for demonstration and teaching purposes. The IEAs used do not actually have any suspicious breast lumps, which limits the students' exposure to abnormalities such as those experienced by experts in clinical situations. Also, with a single teaching associate or IEA the student can't experience the range of normal for softness or lumpiness. Current simulation models do not show these problems in the complex and nuanced way required for translation of the skill into actual clinical practice.

Current CBE marking schemes favour students who appear confident and professional by going through the motions of the physical examination. This means students are potentially more focussed on interpersonal skills than clinical findings. While looking professional results in a pass mark for the student, it is not sufficient to demonstrate competence in their capacity to IDBM. Looking professional is not sufficient for patients, for whom clinical competence is the primary requirement. If the core skills of IDBM are not being tested, then there can be no assurance of competence in CBE of medical students and graduates.

Teaching and marking that only involves IEA (teaching associates) where pathology is absent, or simulated models that do not have the complex multilayered realism needed by beginner students, are not sufficient to teach and test IDBM. The IEA teaching that our novice students received in this trial

was not sufficient for them to pass a clinical test. However, using the current assessment methods all of the students would have passed, despite their lack of competence in IDBM. Existing student assessment is relevant and important and needs to remain; yet this trial suggests there needs to be an additional test for IDBM comprehension. This implies the teaching needs to be supplemented with an additional component that adds the physical skill of palpation and interpretation of what is felt as a component of the overall teaching.

The results indicate there is no comprehension component in the current CBE testing though this is clearly needed. If there was effective testing for IDBM the quality of training could be tested and immediately be improved, especially in relation to the poorest performing students.

Creation of a teaching package with simulation models and a standardized testing tool calibrated to actually test for the students' ability to identify and discriminate between breast masses (IDBM) both normal and pathological would greatly facilitate the teaching of CBE, making it more cost-effective and efficient, thereby saving lives. It is cost-effective because under the current system overworked hospital doctors and staff have to catch every inadequately trained student at intern stage and individually remediate them. It is efficient because if the hospital staff were freed up from teaching the basics to those students who missed them the first time around, they could concentrate on refining and improving the skills of all students, making the identification of breast masses more accurate. This would then save many unnecessary false-negative referrals and free up much needed resources for the true positives, thereby improving overall patient care.

This study only included 10 students and further testing is needed to verify these results and also to derive a satisfactory training process or methodology. We were extremely lucky to have recruited a real patient at all, considering the timeline between patient diagnosis with a breast lump and further testing can be as short as a day. Our patient only had 24 hours between diagnosis and her hospital follow-up. She stopped to participate in the study on her way to hospital. In addition, this can be a very emotional time for a patient with suspected (putative) breast cancer. Nonetheless, we would recommend extending any future study and recruiting more actual patients for future work.

Acknowledgments

We wish to acknowledge the input from the many people who helped to make this study a success – in particular the staff and doctors at the Breast Clinic, Womens Health Centre, Royal Adelaide Hospital who generously gave their time and allowed us to run the study during clinic hours. Special thanks to Dr Janne Bingham for teaching the students. Thank you to the many volunteers who participated as 'patients' and IEAs, to Anne Veitch, Sharlene Lynch and Verna Blewett who came along and helped organise on the day, to Dr Henry Fellner for recruiting the actual patient, many thanks to the patient who so generously stopped by between medical appointments (you know who you are!), to Lilian Fellner, who coordinated and recruited the medical students from Flinders University, and lastly thank you to the Flinders University BCS/MD(2020) students for participating in the study.

Authors' contributions

Daisy Veitch conceived and designed the analysis, organised the logistics, collected the data and wrote the paper. Melissa Bochner co-conceived the study, provided medical expertise, recruited the medical staff, provided the facilities, conducted the teaching, trained the patients and proctored the students as well as editing the paper. Harry Owen contributed the original idea and gave valuable suggestions to the design of the study. James Veitch conceived the competency score statistic and gave valuable guidance in addition to editing the paper. Richard Goossens and Johan Molenbroek supported the project and edited the final paper.

Conflict of interest

None to report.

Ethics approval

This research has ethics approval SA HREC 34.13.

Funding

The research has been self-funded by the authors.

Chapter 7 — General discussion and conclusions

The central question of this thesis was, how to design tools to improve the teaching and testing of identification and discrimination of breast masses (IDBM) through tactile examination.

We successfully developed and tested six tactile-correct realistic breast. They represent a range of normal variation for softness and texture and include various breast pathologies. We established that breast surgeons thought the models were true to life representing more than 80% of breast patients when compared side-by-side during clinical examinations (N=78). No existing breast models represent a range of normal.

Research Applicability

This research is applicable to those who need to teach and learn skills in CBE for part-diagnostic or diagnosis purposes. For the first time a range of 6 simulation models with modelled pathology necessary for teaching) and a dedicated test of tactile skills gained from their use that allows IDBM to be tested as an individual competency, have both been developed. Educators can thus test where students might be on the continuum of learning this core competency; it would allow them to observe and better understand how acquisition of palpation skills, and subsequent understanding of the difference between normal and abnormal, develops in the student. This combined increase in understanding can allow educators to study the efficiency and effectiveness of IDBM teaching as part of CBE or as a separate skill. If improved teaching and student competency is a result then these improved skills could produce a reduction of false positive and false negatives, and an increase in true positive and true negatives, leading to earlier detection of some cancers and improved patient outcomes.

Limitations

Some of the limitations we were expecting didn't eventuate; some did. In other cases we encountered limitations we were not expecting.

Expected limitations

We were expecting difficulty recruiting very busy breast surgeons; in fact we had more volunteers (17) than we could actually accept (7). Volunteer breast surgeons told us that this project is fulfilling a real need and has a high philanthropic potential.

We anticipated a limitation due to the lack of external funding. This has been offset to some extent by many people kindly offering their time and facilities (in-kind resources) pro bono.

We anticipated some difficulties in developing the design brief due to the many varied ways others had tried to solve these problems such as bio-mechanical tests and finite element analysis. We explored each of the techniques and applied a practical test of 'did it actively teach IDBM to students. If it did not directly address the students being able to more efficiently and effectively identify and discriminate breast lumps in patients by palpation then we decided not to pursue that particular avenue. This led to the design brief with the silicone models.

We anticipated technical difficulties with making the manikins. In particular there is no database describing the range of breast softness and nodularity. This was mitigated by having a breast surgeon on the development team to guide us. During testing we found we could represent more than 80% of women in both nodularity and softness using only 6 models. After testing we concluded an additional seventh model was required to represent women with extremely soft breasts. The last two breast models developed were the most challenging as we needed to create a completely different feel. This involved using Magnetic Resonance Imaging (MRI) data and sophisticated software to process the 3D digital data into a 3D printable file. In the actual development of the different-feeling breasts, we reduced the risk of failure by allowing adequate time for the iterative development and testing and also by using a range of model-making techniques, both artisan and new.

We anticipated a geographically-challenged team would present some coordination difficulties, and we were right. However, we reduced some of these difficulties by locating the ethics approval and primary research in the same location as the breast specialist.

Unexpected limitations

We were anticipating creating a formal teaching package to accompany the models but did not expect to need to create the IDBM test. We thought there would some existing way of testing student palpation skills when IDBM is the core requirement for detection of breast cancer. Without such a test for IDBM there was no way to quantify how students acquire skills and when they become competent; this meant we couldn't test our teaching package. Thus creating a test for IDBM was added as one of the foci of this dissertation rather than developing a formal teaching package.

We were anticipating being able to recruit medical students and patients with breast cancer for our clinical trial. However, we didn't anticipate how busy medical students are in their clinical years. We addressed this by recruiting medical students in their preclinical year; so all were novices with no prior clinical experience. The testing will need to be repeated with medical students at different stages of their learning journey.

It was difficult to recruit patients with breast cancer as they have an extremely short timeline between diagnosis and surgery. In addition, the most suitable patients for our trial would be presenting to a GP. We had breast surgeons recruiting for us, so we had to find a suitable GP to ask to recruit on our behalf. In the end we were very lucky to get an appropriate patient with an easily palpable suspicious lump who was willing to participate in our trial and work with actors who had no breast disease indicators.

We were anticipating difficulty in replicating the complicated geometry of the nodularity of the breast due to complex undercuts in the shapes. We thought we could bypass this by using the latest sophisticated technology to extract the CAD shape from MRI data (Mimics software) and print this shape in soft material. Printing of soft material is emerging technology. However, unexpectedly, the softest material printed using this technique was still many times too hard for our application so in the end we couldn't use this combination of technologies. Although new technology is opening doors to new rapid prototyping and visualization in the end we had to use traditional techniques to create the required lifelike feel. We learnt that any combination of hi- and low-tech methods should be allowed to create high-fidelity outcomes.

Reflecting on the gaps

We needed to fill the three identified gaps: 1) human variation in normal breast durity and nodularity is not reflected in existing simulation models; 2) variation in breast disease pathology is not reflected in existing simulation models; and 3) there is no validated testing tool for the tactile component in the teaching of CBE to test how and when students achieve proficiency in the discrimination and identification of various breast masses (IDBM) which is the essential goal of all types of breast examinations.

What are the best design criteria for making a simulated human breast that feels real?

It surely depends on what you are feeling for, and who you are, and what we understand by 'best'.

We are making physical breast models for teaching palpation to students training to detect possible breast cancers as part of CBE. The models mimic the feeling of normal and abnormal masses within real human breasts. To know what is abnormal, the student must first know what feels normal. Just like brushing hair, whether it be curly or straight, course or fine, thick or thin, the student must be able to feel the difference between normal brushing texture and tangles. The breasts must feel real enough they demonstrate to our fingers a range of different textures all of which are normal, so the student can learn to feel the 'tangle' or abnormal textures and shapes.

One serendipitous finding was the perception that a need for better breast simulation models was strong amongst the breast expert community and made their recruitment for this study straightforward. This was different to the medical students who didn't know what they didn't know. For example, Prof Dr Jenepher Martin says that 'I just accept that novice clinical students, it's nice if they come with a protocol and they know the steps, but I just accept they don't have technique so this stuff about patting the skin, they're not actually feeling the breast, they're just going through the motions.' (2016) She is further supported by Dr Melissa Bochner, who comments that if novice clinical students could come into their clinical placement with her with the basic palpation techniques in IDBM already learnt, that would be extremely helpful. The experts' concerns about student performance resulted in the first investigations in this topic and their opinions were supported by subsequent findings in the literature.

The nature and usefulness of simulation models is a crucial concept that underpins this research. George E.P Box (statistician p74) comments, "Remember that all models are wrong [i.e., "not the whole truth" about that of which they are models]; the practical question is how wrong do they have to be not to be useful.". Further Box asks "...the only question of interest is "Is the model illuminating and useful?" During this research, we have created models which we believe are both illuminating and useful in the teaching of IDBM. We hope that students who learn on these models will do more than "patting the skin" when first encountering patients, and will instead be aware of the basics of normal and abnormal structures from the beginning of their clinical experiences.

With these comments in mind we have developed a successful design brief that addresses the criteria of teaching students' proficiency in IDBM. Proficiency means making sure the students can detect and differentiate between different breast masses so they can quickly and accurately refer patients to the appropriate services. So, the student who has reached the tipping point of proficiency should be able to successfully detect signs of breast disease including a putative cancer in a patient during CBE by palpation and correctly refer them on for further investigation via the triple test or correctly reassure a patient who had no palpable symptoms and very low probability of having breast cancer.

Gap 1 in models covering the range of normal human variation: "human variation in normal breast durity and nodularity is not reflected in existing simulation models."

Gap 2 in models covering the range of abnormal human variation: "variation in breast disease pathology is not reflected in existing simulation models."

Contribution to filling Gap 1 and 2

We have developed a range of physical breast models that have all the normal anatomical structures of a human breast in all its important normal variations, and they also can be modified to contain all kinds of abnormal lumps, cysts, fibroadenoma and cancers. Testing by experts revealed that the breast models developed for this thesis feel similar to real breasts in more than 80% of female patients. Further, breast surgeons reported the breast models are realistic enough to teach essential palpation skills.

However, if the essential goal is being able to identify breast masses as effectively and efficiently as possible in real patients, then we identified that something

more than the existence of models may be needed. Other essential components in good teaching of detecting breast masses include repeated multisensory practice across our diverse range of models representing normal human variation. The language of touch or feel of the breast masses is described in Chapter 1 with physical examples to assist in a shared understanding of what words such as 'hard' or 'soft' mean in terms of breast feel.

Gap 3 in the provision of a validated test for IDBM in CBE: "there is no validated testing tool for the tactile component in the teaching of CBE to test how and when students achieve proficiency in the discrimination and identification of various breast masses (IDBM) which is the essential goal of all types of breast examinations."

Contribution to filling Gap 3

Lastly, we provide a testing regime that evaluates the student's ability to detect breast masses and mimics their future clinical practice. The TL supports the expert medical educator by providing feedback on student proficiency. The educator could then provide timely and meaningful feedback to the student as part of a standardised education package or at minimum develop better curriculums themselves. For the educator to understand the learning curve of proficiency and be able to identify not just where that student is but the point at which the student achieves proficiency could greatly assist in the development of effective and efficient teaching packages.

Contribution to filling Gap 1

Breasts vary on a continuum of durity and nodularity, but for practical purposes, a limited set of representative teaching models must be used. Additionally, the trade-off of realism versus durability and cost must be balanced. Durability was prioritised in aspects of the design such as thicker skin. This was found to be an acceptable trade-off. Keeping in mind the earlier concept that a model is only an "illuminating and useful" tool, the six breast models that were eventually produced, were found by the experts to be biofidelic enough (Chapter 4). An important finding from this study was that a seventh extremely soft model would be required to represent a missing portion of the population.

Contribution to filling Gap 1, 2 and 3

Our contribution was to explore different ideas which resulted in the successful techniques used to create and test a method for developing teaching resources that blended the outcomes required by the medical specialists and the medical educators with the iterative design process. During the process we broke down each component required like softness of adiposity, ribs, etc and colours and created final designs using a mixture of the latest of 3D imaging technology and rapid prototyping with the appropriate artisan techniques to mimic the feel of different breasts and pathology.

This resulted in individual designs to create standardised teaching models and test objects that tests lump detection and calibrate and validate this test via testing in clinical situations. Then medical educators can teach to the test because we know the test is relevant to practice.

Relevance of this research

The gold standard for screening asymptomatic women is screening mammography. But the recommended pathway for symptomatic women in Australia is CBE. The purpose of this thesis is not to add CBE to screening rather recognize that CBE is used for more than detecting breast disease - it a wholistic method that looks at a woman's health, balancing her concerns with risk factors and her breast symptoms to investigate her concerns and find suitable pathways for treatment when treatment is required. Each case will vary. The GP may encounter different scenarios. For example: the patient might be one of the 45% of women in Australia who do not participate in screening programs and who has normal breasts; or they might participate in screening but have discovered symptoms and might present with an interval putative cancer; or they may have other breast symptoms that are benign. GPs must be competent in CBE to direct each woman appropriately, however CBE is not always practised well. GPs who are competent in CBE allow the judicious use of resources for further investigation. This research addresses training and testing competency gaps of one component of CBE, IDBM, at a medical student and GP level.

There are other reasons why this research is relevant. Firstly, imaging is not available to remote communities, communities without electricity or third-world country populations, so competency in CBE is particularly important for these communities. Secondly, the amount of emotional pain caused by false

positives and the actual physical harm caused by false negatives is sufficient justification for our claim that this is an important piece of research. Lastly, any reduction in false negatives will improve clinical outcomes by improving the directing of breast cancer resources to those who need it – the true positive group of breast cancer patients.

This study aimed to evaluate how well novice students, after training, identify and discriminate breast masses (IDBM) on actual patients. Twenty students were tested in a simulated clinical setting with patients and with a previously developed test object – the tactile landscape (TL). Student performances were evaluated in three ways: their own clinical findings, then visually by a supervising breast specialist, and finally tactilely by the patient. The main conclusion was that novice students do not seem to be able to accurately detect breast masses in a clinical setting even after training. On the basis of these results, we believe that a IDBM comprehension component in the current CBE testing is currently missing and is needed in addition to the current methods of testing.

Current training for CBE based in medical schools appears to be inadequate and actual training of IDBM is needed. Despite the best efforts of the breast surgeons teaching the students, the tests do not indicate competency in actual anomaly (breast lesion) detection. One reason may be a lack of real cancer patients for demonstration and teaching purposes. The IEAs used do not actually have any suspicious breast lumps, which limits the students' exposure to abnormalities such as those experienced by experts in clinical situations. Also, with just one 'intimate teaching associate' or IEA the student can't experience the range of normal for softness or lumpiness. Current simulation models do not show these problems in the complex and nuanced way required for translation of the skill into actual clinical practice.

Current CBE marking schemes favour students who appear confident and professional when going through the motions of the physical examination. This means students are potentially more focussed on interpersonal skills rather than clinical findings. While looking professional can result in a pass mark – due to the testing regime that focusses on going through the motions rather than testing the skill – for the student, it is not sufficient to demonstrate competence in their capacity to IDBM. Looking professional may be necessary in some situations but it is not sufficient for patients, for whom clinical competence is the primary requirement. If the core skills of IDBM are not being tested,

then there can be no assurance of competence in CBE of medical students and graduates.

Teaching and marking that only involves IEA (intimate teaching associates) where pathology is absent, or with simulated models that do not have the complex multilayered realism needed by beginner students, are not sufficient to teach and test IDBM. The IEA teaching that our novice students received in this trial was not sufficient for them to pass a clinical test. However, all of the students would have passed the current assessment methods, despite their lack of competence in IDBM. Existing student assessment is relevant and important and needs to remain; yet this trial suggests there needs to be an additional test for IDBM comprehension. This implies the teaching needs to be supplemented with an additional component that adds the physical skill of palpation and interpretation of what is felt as a component of the overall teaching.

The results indicate there is no comprehension component in the current CBE testing whilst this is clearly needed. If there was effective testing for IDBM the quality of training could be tested and immediately be improved, especially in relation to the poorest performing students.

Creation of a teaching package with simulation models and a standardized testing tool calibrated to actually test for the students' ability to identify and discriminate between breast masses (IDBM) both normal and pathological would greatly facilitate the teaching of CBE, making it more cost-effective and efficient, thereby saving lives. Cost-effective because under the current system the overworked hospital doctors and staff have to catch every inadequately trained student at intern stage and individually remediate them. Efficient because if the hospital staff were freed up from teaching the basics to those students who missed them the first time around, they could concentrate on refining and improving the skills of all students, making the identification of breast masses more accurate. This would then save many unnecessary false-negative referrals and free resources for the much needed true-positives, thereby improving overall patient care.

The potential impacts on medical systems include better/more efficient use of scarce and expensive resources, social and health benefit for patients who have more reliable and speedier diagnoses, and reduced cost of false negatives and false positives.

Using this method as a case study can provide a roadmap for others wanting to design other simulation models and tests that require physical skills in palpation.

Implications for future research

This study only included 10 students, so could be treated as a pilot study as further testing is needed to verify these results and also to derive a satisfactory training process or methodology. We were extremely lucky to have recruited a real patient at all considering the timeline between patient diagnosis with a breast lump and further testing can be as short as a day. Our patient only had 24 hours between diagnosis and her hospital follow-up. She stopped to participate in the study on her way to hospital. In addition, this can be a very emotional time for a patient with suspected (putative) breast cancer. Nonetheless, we would recommend extending any future study and recruiting more real patients for future work.

In the future, this prototype would need to be brought to manufacturing readiness including, as with any product development, good quality control and durability testing, as well as a variety of different TLs for repeated testing to show student improvement. The TL's utility will depend on the ease of manufacture, which in part will be determined by economies of scale.

There is interest in the further development of a CBE curriculum specifically for health professionals working in rural and remote areas (see Appendix 1).

Summary

This dissertation presents research conducted into the design of physical breast models for teaching palpation to students training to detect possible breast disease as part of CBE; the models mimic the feel of normal and abnormal masses within real human breasts. In addition, it focusses on developing testing to a standard that determines if students have the necessary skill-level to competently engage in IDBM by touch. The contributions of this work are threefold: creating simulation models covering the range of human variation in breast durity and nodularity, creating simulated pathology attachable to normal breast models to represent breast disease, and creating a validated testing tool for tactile education in CBE. This tool can be also used to train and test health professionals in IDBM, the central goal of CBE. Moreover the method provides a roadmap for other designers tackling similar design challenges.

This dissertation is presented in a series of peer-reviewed publications, posters, extended abstracts and one short video which are summarized on the following pages.

Summary of chapter 1 — Introduction

The central question of this dissertation [thesis] is how do we design tools to improve the teaching and testing of the identification and discrimination of breast masses (IDBM) through tactile palpation in clinical breast examination (CBE). The different contexts of this question and its research solution are addressed: Firstly, the medical (and medical training) context and its target audience of medical professionals and educators, general practitioners and medical trainees. Secondly, the simulation (design) context is discussed, in particular the different approaches in the engineering and design world to assisting detection of breast cancer. The problem of replicating a breast specialist's hand skills is indicated; only one of nine approaches identified would actually train these skills, i.e., by using lifelike, biofidelic silicone models.

So the main aim of this dissertation [thesis] is to design tactile-correct (biofidelic) teaching models for training medical staff to part-diagnose the large varieties of breast condition and disease by touch (one part of CBE); and then with the Tactile Landscape (TL) to test medical staff and students for the appropriate tactile skills.

Three further research questions were formulated to fill the three identified *gaps* in present teaching models:

1) How do we reflect variation in normal human breast durity and nodularity in simulation models, *when existing models fail to do this (gap 1*)? (Chapters 2, 3, 4 of this thesis set out to address this *gap*; also chapters 4 and 5 while addressing *gap 2*, along with future work in chapter 8).
2) How do we reflect variation in human breast disease pathology in simulation models, *when existing models fail to do this (gap 2)*? (Chapters 4 and 5)
3) How do we design a validated testing tool for the tactile component in the teaching of CBE to test how and when students achieve proficiency in IDBM, *when no such tool exists at present (gap 3)*? (Chapters 5 and 6, and future work in chapter 7)

There is a brief overview of the research method in three parts, an account of the assumptions underlying the research, and a description of the structure of the thesis, showing how each chapter of the thesis and its component parts addresses the gaps identified.

Summary of chapter 2 — Size, shape and body scan data to improve biofidelity of patient simulators

Most patient simulators are not shaped like real people. This has implications for training transfer from simulated patient encounters to clinical practice. Sub-routines of clinical skills can be learnt on quite abstract models but mastering skill sets requires lifelike surface anatomy.

More than half the Australian population is overweight or obese but the current manikin shapes used as patient simulators do not reflect this. This project uses body scan data from a representative population to create more realistic models. These data were originally collected as an anthropometric base for other industries to solve design problems in products used by the general population.

The abstract and conference presentation (SimTech) and poster (HFESA) describe the background, methods, results and conclusions producing a large-size female breast-model for breast examinations training medical students to detect breast cancers.

The successful construction method used in the development of the prototype and final design of a tactile-correct teaching models is indicated and described at length in Chapter 4 and 5.

Summary of chapter 3 — The development of a lifelike breast cancer patient simulator using anthropometric data

The aim was to provide a breast-model simulator representative of the large-size female population and provide more varied scenarios for breast lump palpation. A prototype representing women with larger breast size and a relatively high body mass index (BMI) was developed. The body-scan used to base the simulator on was an individual large-size woman of approximate BMI 30, 82 kg and 165cm tall. with a large cup-size (D); by our analysis more than 50% of women are C cup or above. Our conclusions were that confident, competent breast palpation requires a lifesize model that looks and feels lifelike, yet currently available breast examination simulators don't model the size and shape of patients encountered. This impedes the development of confidence

and competence in healthcare workers who need these skills. Lifelike look and feel require an anatomically-correct, multilayered soft breast construction, incorporating palpable, anatomical underlying features, including tumors.

The development of the large-size biofidelic simulator described here attempts to fill the training gap in the attention given to large-size patients. It provides a representative model based on the population who need it; they have an increased cancer rate and are becoming increasingly common in the population, but they have been previously avoided. Reproducible multiple copies create the essential base for the standardised model upon which a standardised CBE training module can be developed.

Size, shape and body scan data were applied in making these patient simulators and used to investigate how much current manikins need to be modified to reflect the predominant shape of patients. 1265 Australian women and 937 North American women were surveyed to create a manikin representative of a real-world patient. As currently available breast simulators don't model the shape of patients encountered, medical students (and practitioners trained on such models) have generally little confidence or competence in their palpation skills. Combining one woman's body scan, computer-aided design, rapid prototype techniques, and the latest biofidelic (lifelike) silicone technology we created an anatomically-correct representation of a real-world patient. The reproduction of realistic feel, anatomically- and tactile-correct breast models of multilayered construction with detectable underlying features is an essential requirement for CBE training.

Developing a teaching package with simulation models such as these and a standardized testing tool calibrated to actually test for the students' ability to identify and discriminate between breast masses (IDBM) both normal and pathological would greatly facilitate the teaching of CBE, making it more cost-effective and efficient, thereby saving lives. A multidisciplinary team was essential for developing and implementing an effective design brief. This enables extending the design criteria to include non-quantitative skills such as the specialists' language of feel, which could well have significant application wherever the human body is involved in multisensory activity. (The application of this specialist language is discussed in detail in Chapter 1 above.) The overall design is then created and enhanced as intended, both fit-for-use and fit-for-purpose.

Summary of chapter 4 — Development and validation of realistic breast models for teaching breast examination

Following on from this single model project our next objective was to design, develop and validate more clinical breast examination (CBE) models addressing as many of the deficiencies of previous models currently identified. A multidisciplinary team of experts from the fields of medicine (clinical breast experts), education (medical educator) and design (manikin designer and maker) worked to produce direct the design questions and brief towards the desired outcome. Detailed research and a methodological design approach led to the development of a new technique for creating lifelike models for teaching CBE. Six multilayered breast models representing a range of normal human variation for durity (hardness/softness), nodularity (fibroglandular tissue) and adiposity (fatty tissue) were developed and validated. Also additional signs of breast disease, both benign and pathological, were created as realistic models to be incorporated.

These models were validated by four breast surgeons who compared their feel alongside a sample of 78 breast patients. These are the first models to incorporate normal human variability and be validated alongside real patients. As novel biofidelic models, they provide a standardized way of teaching normal and abnormal to health professionals. For the first time a range of biofidelic breast simulation models representing the range of normal human variation has been developed. Each model has been validated with real patients by experts. This is important because it provides a new tool that educators in CBE can use to develop student proficiency.

On completion there were six models that vary in softness and lumpiness, each model relating to cases that teach important instances of each of these two qualities as well as offering hands-on tactile/visual experience. The six novel models are similar to more than 80% of the population for biofidelic feel. For completeness a seventh model that varies by representing extremely soft breasts would need to be developed.

Summary of chapter 5 — The development and pilot study of a "Tactile Landscape" as a standardized testing tool

A testing tool was developed for students after training that built on the design discoveries made from the use and development of anthropometric data and biofidelic, tactile-correct teaching models.

The range of most commonly occurring pathological features was simulated, including breast cancer, fibroadenoma and cysts for insertion at varying depths in one test object – a tactile landscape (TL). The objects to identify are entirely hidden within it. This landscape was validated by five breast specialists. The goal was to develop a test to determine if students could discriminate masses that might be pathological or normal by touch alone. This can be used as a student test after training in CBE or if an accreditation path were developed for CBE.

The TL looks to be a useful tool for assessing IDBM in CBE. It could also be indirectly useful for teaching CBE if the testing were extended to include the middle range between novice and expert; this would allow more precise mapping of the learning curve for this procedure, and so inform teaching styles, interventions, and student remediation, helping educators become more efficient and effective.

In conclusion, we should have specified that only abnormal masses were to be noted in the assessment instructions – though the experts did this implicitly the students needed explicit instructions to do this. The teaching time for CBE should be longer than thirty minutes. Thirdly, the rating scales used have to be more clearly defined.

The study was limited by several factors. First, the number of students (twenty) tested was small and the test only done in one location and time. We recommend this be repeated with additional students and multiple locations.

Second, these were novice students new to clinical settings and we didn't control the teaching but allowed the breast surgeons to conduct their usual training. If as suggested the testing were extended to include the middle of novice-to-expert continuum, this would not only allow more precise mapping of the learning curve for this procedure; further testing could also reveal where in training proficiency is achieved.

In the future, this prototype would need to be brought to manufacturing readiness by including, as with any product development, good quality control and durability testing, as well as a variety of different TLs for repeated testing to show student improvement. The TL's utility will depend on the ease of manufacture, which in part will be determined by economies of scale.

Summary of chapter 6 — Evaluation of conventional training in Clinical Breast Examination (CBE)

The next study aimed to evaluate conventional training, in particular how well novice students, after training, identify and discriminate breast masses (IDBM) on actual patients. Twenty students were tested in a simulated clinical setting with patients and with a previously developed test object – the tactile landscape (TL). Student performances were evaluated in three ways: assessing their clinical findings, visually by a supervising breast specialist, and tactilely by the patient. The main conclusion was that novice students are unable to accurately detect breast masses in a clinical setting even after training. On the basis of these results, we believe a comprehension component, that is student comprehension of IDBM in the current CBE testing, is required in addition to the current methods of testing.

Current training for CBE based in medical schools appears to be insufficient and actual training of IDBM is needed. Despite the best efforts of the breast surgeons teaching the students, the tests don't indicate competency in actual anomaly (breast lesion) detection. One reason may be a lack of real cancer patients for demonstration and teaching purposes. The Intimate Examination Associates (IEAs) have no suspicious breast lumps, limiting student exposure to abnormalities experienced in clinical situations. Also, with a single associate the student can't experience the range of normal for softness or lumpiness. Current simulation models don't show these problems in the complex, nuanced way required for translation of skill into clinical practice.

This study only included ten students and further testing is needed to verify these results and also to derive a satisfactory training process or methodology. We were fortunate to have recruited a real patient, when the timeline between patient diagnosis with a breast lump and further testing can be as short as a day. Our patient only had 24 hours between diagnosis and her hospital follow-

up. She stopped to participate in the study on her way to hospital. In addition, this can be a very emotional time for a patient with suspected (putative) breast cancer. Nonetheless, we would recommend extending any future study and recruiting more real patients for future work.

Summary of chapter 7 — General discussion and conclusions

Our central task was to design tools to improve teaching and testing IDBM by tactile examination. The research successfully developed and tested six tactile-correct realistic breast-models representing a range of normal variation for softness and texture and including various breast pathologies. Breast surgeons confirmed the models to be true-to-life and representative of more than 80% of real breast patients based on a side-by-side comparisons in clinical examinations. No existing breast models cover even a range of normal. In addition, it provides a guide for developing a design brief for those who wish to develop similar tools.

Despite some limitations, this research has demonstrated its applicability to those needing to teach and learn skills in CBE for part-diagnostic or diagnosis. Educators can test for IDBM while observing and understanding how palpation skill-acquisition and subsequent discrimination of normal and abnormal develops in students and practitioners. This cumulative understanding means educators can study the efficiency and effectiveness of IDBM teaching as part of CBE or as a separate skill. If improved teaching and student competency is the educational outcome then improved applied skills should produce a reduction of false positive and negatives and an increase in true positive and negatives, leading to earlier detection of some cancers and much-improved patient outcomes.

We identified three serious gaps in present breast models and the provision of tools for teaching palpation in CBE and addressed them to create both simulation models suitable for teaching and test objects that test lump detection by palpation, and calibrate and validate this test in clinical situations. Medical educators can teach to the test now we have shown its relevance to practice.

This research is important for several reasons. CBE is the first line in symptomatic women who present to their primary health care practitioner. CBE is more than detecting breast disease - it a medical examination that looks

at a woman's health, balancing her concerns with risk factors and her breast symptoms to investigate her concerns and find suitable pathways for treatment when treatment is required. GP's must be competent in CBE to direct each woman appropriately however CBE is not always practised well. Competent CBE allows the judicious use of resources for further investigation. This research addresses training and testing competency gaps of one component of CBE, IDBM, at a medical student and GP level.

Imaging, although the gold standard in screening in the first world, is unavailable in many communities, so competency in CBE is particularly vital for them. There's interest in further development of CBE curriculum specifically for health professionals in rural and remote areas.

The confusion of false positives and physical harm caused by false negatives is sufficient justification for claiming this as an important piece of research. Any reduction in false negatives will improve clinical outcomes by improving the directing of breast cancer resources to those who need them – the true positive group of breast cancer patients.

The potential impacts on medical systems include better/more efficient use of scarce and expensive resources, social and health benefit for patients who have more reliable and speedier diagnoses, and reduced cost of false negatives and false positives.

This student study could be treated as a pilot; further testing is needed to verify these results and produce a fully satisfactory training process or methodology.

Using this method of simulation model design as a case study can provide a roadmap for others wanting to design other simulation models and tests for physical skills in palpation.

In the future, any such prototype needs to be brought to manufacturing readiness by including, as with any product development, good quality control and durability testing, using a variety of different TL tools for repeated testing to show student improvement. The tool's utility will depend on the ease of manufacture, which in part will be determined by economies of scale.

Summary in Dutch (exact translation of the English summary)

Samenvatting

Deze dissertatie beschrijft onderzoek dat nodig was voor het ontwerp van fysieke borst modellen voor het aanleren van het palperen voor medische studenten op zoek naar borst aandoeningen als deel van hun Klinisch Borst Onderzoek(KBO); deze borst modellen simuleren qua gevoel het normaal en abnormaal borstweefsel in echte vrouwen borsten. Daarnaast benadrukt dit proefschrift ook het ontwikkelen van een standaard voor een toetsmodel dat vaststelt of de student over voldoende vaardigheid beschikt om een borst tumor te ontdekken door palpatie. Inhoudelijke bestaat dit werk uit 3 delen:

- het creëren van simulatie borst modellen die de variatie bestrijken van diverse zachtheden en bobbels in gezonde borsten
- het creëren van pathologie die in veel voorkomende borst aandoeningen voorkomt
- het creëren van een gevalideerd toetsmodel ten behoeve van tactiele training in het klinisch borst onderzoek (KBO)

Dit toetsmodel kan ook gebruikt worden om KBO-professionals te trainen en te toetsen. Tenslotte dient deze methode als voorbeeld voor andere tactiele ontwerp uitdagingen.

Deze dissertatie bestaat uit een serie hoofdstukken waarvan sommige gepubliceerd zijn in internationale wetenschappelijke publicaties en enkele bijlagen, die in de volgende paragrafen kort worden samengevat

Samenvatting hoofdstuk 1 — Inleiding

De centrale vraag in deze dissertatie is hoe we design tools kunnen ontwerpen die het onderwijs en het toetsen verbeteren van de identificatie en discriminatie van borstweefsel door palpatie bij Klinisch Borst Onderzoek(KBO).

De verschillende contexten van deze vraag en de bijbehorende onderzoeks-aanpak worden beschreven: eerst de medische (en medische training) context en de bijbehorende doelgroep van medische professionals en opleiders, huisartsen en medische stagiaires. Ten tweede wordt de gesimuleerde ontwerp context besproken en in het bijzonder de verschillende benaderingen in de ingenieurswereld en de design context om te kunnen bijdragen aan het ontdekken van borst kanker. De probleemstelling is het repliceren van de handvaardigheden van de borstspecialist; slechts een van de negen benaderingen lijkt te gaan werken om deze vaardigheden te kunnen trainen en dat is door het gebruik van bijna levensechte, siliconen modellen.

Daarom is het hoofddoel van deze dissertatie om een tactiel correcte en zo levensecht mogelijke onderwijs model te ontwerpen om de medische staf te kunnen trainen, zodat zij het verschil kunnen constateren tussen de gewone variatie van borstweefsel en een mogelijk aanwezige ziekte (als deel van Klinisch Borst Onderzoek naast mammografie en punctie). Daarna dienen de vereiste vaardigheden met het in dit project vervaardigde Tactiele Landschap te toetsen te zijn.

Verder zijn 3 onderzoeksvragen geformuleerd om de bestaande leemte te kunnen identificeren:

1) Hoe geven we in een gesimuleerde omgeving de normale variatie van het borstweefsel aan met zijn onderliggende structuren en bobbels, wanneer bestaande modellen falen op dit gebied . Hoofdstuk 2,3,4 van dit proefschrift beschrijven deze leemte(Gap1) en ook ten dele in wordt dit beschreven in hoofdstuk 4 en 5.
2) Hoe geven we pathologische borstaandoeningen weer in de simulatie borstmodellen, wanneer bestaande modellen erin falen(Gap2). (Chapters 4 and 5).
3) Hoe ontwerpen we een gevalideerde toets voor het tactiele deel van het leermodel van Klinisch Borst Onderzoek, terwijl er geen vergelijkbaar model bestaat. (Gap 3)? (Hoofdstuk 5 en 6 en toekomstig werk in hoofdstuk 7).

Dit hoofdstuk beschrijft de noodzaak , de focus en de werkwijze voor onderzoek. Ook de toepassing van dit onderzoek in de praktijk wordt beschreven en tenslotte volgt de structuur van de dissertatie.

Samenvatting hoofdstuk 2 — Afmeting, vorm en 3d scan data om de levensechtheid van borst simulators te verbeteren

De meeste simulators/avatars/modellen van (delen van) mensen zijn niet vormgegeven zoals echte mensen. Dit heeft effect op de training met deze simulatoren bij de overgang naar de klinische praktijk. Subroutines kunnen geleerd worden via simulatoren maar voor het vakmanschap is een echter een bijna levensechte oppervlakte anatomie nodig.

Meer dan de helft van de Australische bevolking heeft overgewicht (BMI>25) of is obees (BMI>30), maar dat zie je niet terug in de simulatoren/modellen op de markt. Dit project gebruikt echter 3d scans van een representatieve steekproef van echte mensen om beter realistische simulatoren/modellen te maken. Deze data werden oorspronkelijk verzameld voor een antropometrische database voor ontwerpers gericht op het gebruik van consumentenproducten voor het algemene publiek.

De abstract en de conferentie paper (SIM Tech) en poster (HFESA) in de bijlagen beschrijven de achtergrond, methoden, resultaten en conclusies van de productie van een (adipositas) vrouwen-borstmodel voor borst onderzoek door medische studenten die tumoren trachten te vinden.

Dit hoofdstuk beschrijft de achtergrond, methoden, resultaten en conclusies van de productie van realistisch modellen van borsten van vrouwen ten behoeve van klinisch borstaandoeningen onderzoek voor medische studenten .

De beschrijving van het ontwerp en de constructie van het prototype van het tactiel-correct leermodel staat in hoofdstuk 4 en 5.

Samenvatting van Hoofdstuk 3 — De ontwikkeling van een realistisch borst-model tbv borstkanker onderzoek door gebruik van 3D-antropometrische data

Het doel was om modellen van vrouwen borsten te maken die representatief zijn voor een vrouwen met overgewicht en een grote borsten met een variatie aan tumor(knobbels) die palpeerbaar zijn. Dit resulteerde in een prototype representatief voor vrouwen met grote borsten en een hoge BMI. De persoon die geselecteerd is, was een vrouw met een BMI van 30, een lichaamsgewicht van 82 kg en cupmaat D; tijdens onze analyse bleek dat meer dan de helft van de vrouwen cup C of meer hadden. Onze conclusies waren dat een betrouwbare en correcte borst palpatie een borst-model op ware grootte en levensechtheid vereist. De huidige borst-modellen voldoen daar niet aan. Dit vereist ook een nieuwe training voor de medewerkers met deze anatomisch correcte maar zacht en soepel aanvoelende borst modellen inclusief palpeerbare onderliggende anatomische structuren, waaronder tumoren.

De ontwikkeling van een realistisch borstmodel met grote cupmaat, die hier beschreven wordt, tracht de leemte te vullen van de gap die bij de training naar voren kwam bij grote cupmaten. Het voorziet in een representatief borstmodel voor dat deel van de populatie, die het nodig heeft; zij hebben een grotere kans op borstkanker en komen steeds vaker voor in de maatschappij, maar zijn voorheen vaak gemeden. De basis wordt gevormd door reproduceerbare standaard borstmodellen die in serie geproduceerd beschikbaar zijn, zodat een standaard klinisch borst onderzoek (KBO) kan worden ontwikkeld voor studenten geneeskunde.

Maat, vorm en lichaams 3D scan data werden toegepast om deze borstmodellen te maken en werden gebruikt om te onderzoeken hoeveel borstmodellen variaties nodig zijn om een goede weerspiegeling te geven van de variatie in de borstvormen bij de bevolking. Totaal deden 1250 Australische vrouwen, 4000 Amerikaanse en Europese vrouwen mee in de steekproef. De huidige borstmodellen zijn echter niet representatief en wekken weinig vertrouwen bij de medische studenten en huisartsen die deze modellen gebruiken bij de huidige trainingen en ook niet bij de huidige lessen in het palperen met deze borstmodellen.

Voor een training in KBO (Klinisch borst onderzoek) is het essentieel dat er een realistisch borstmodel in serie wordt geproduceerd, dat anatomische en tactiel correct is gemaakt en voorzien is van voelbare onderliggende structuren en die bovendien representatief is voor de variatie van de echte borsten in de samenleving.

De ontwikkeling van een lespakket met borstmodellen zoals deze en een standard toetst systeem dat gekalibreerd is om de vaardigheden van studenten te toetsen op zodanige wijze dat ze het verschil kunnen palperen tussen normaal en pathologisch borstweefsel. Dat zou meer kosten-effectief zijn en daarbij levens kunnen redden.

Een multidisciplinair team was essentieel voor de ontwikkeling van de design brief. Dit maakte het mogelijk om de design criteria uit te breiden met niet kwantificeerbare vaardigheden zoals de taal van het gevoel, die significante invloed heeft zodra er een menselijk lichaam in betrokken is. Meer hierover staat in Hoofstuk 1 hierboven. Tenslotte volgt de beschrijving van de ontwikkeling van het definitieve borstmodel, dat zowel geschikt is voor de gestelde doelen.

Samenvatting van hoofdstuk 4 — Ontwikkeling en validatie van een realistisch borstmodel voor de lessen in borst onderzoek

Volgend op het voorgaande enkelvoudige borstmodel project, was het nieuwe doel de ontwikkeling en validatie van een variatie aan borst modellen die overeenkwamen met afwijkingen die momenteel bekend zijn. Door gedetailleerd onderzoek en methodisch ontwerp kwam er een nieuwe techniek naar voren die leidde tot een 6 lagig borstmodel die representatief is voor een grote range van een normale menselijke variatie in hardheid en zachtheid, borstknobbeltjes, vetweefsel en fibroglandulair weefsel.

Deze borst modellen werden gevalideerd door 4 borst chirurgen die de tactiele aspecten vergeleken met de variatie in een steekproef van 78 borstkanker patiënten. Deze nieuwe borstmodellen waren voor het eerst in staat om op een gestandaardiseerde wijze het verschil uit te leggen tussen normaal borstweefsel en abnormaal borstweefsel. Elk borstmodel is gevalideerd met echte patiënten door deze borst chirurgen. Dit is van groot belang omdat het nu voorziet in een nieuwe tool voor docenten in Klinisch Borst Onderzoek en kan ook worden

gebruikt voor de professionalisering van de medische student. Er zijn 6 borst modellen die variëren in zachtheid en hardheid in grote en kleinere borst knobbels. Elk model is gerelateerd aan een representatieve cases uit de praktijk, maar het presenteert ook een hands-on tactiele en visuele ervaring. De 6 innovatieve modellen simuleren meer dan 80% van het levensechte gevoel. Een 7e model dat extreme zachte borsten simuleert, dient nog verder ontwikkeld te worden om deze serie compleet te maken.

Samenvatting van hoofdstuk 5 — De ontwikkeling en proef studie van een 'Tactiel Landschap' als een standaard test gereedschap

Een toetsmodel is ontwikkeld voor medische studenten na een training met antropometrisch en tactiel bijna levensechte onderwijs borst modellen

De range van de meest voorkomende pathologische verschijnselen werd gesimuleerd, inclusief borsttumoren, fibroadenoma en cystes op verschillende diepten in een toets system, dat eruit ziet als een voelbaar tactiel landschap(TL). De objecten die gepalpeerd moeten worden zijn verborgen onder het landschap. Dit landschap is daarna gevalideerd door 5 borstspecialisten/chirurgen. Het doel was om de toets zo te ontwikkelen dat het duidelijk werd in hoeverre de student het verschil kon palperen tussen het normale en het pathologische borstweefsel. Deze toets kan gebruikt worden na de training in het Klinisch Borst Onderzoek ten behoeve van eventuele accreditatie.

De TL lijkt bruikbaar als een tool om de vaardigheid in het palperen te testen bij Klinisch Borst Onderzoek (KBO). De TL zou ook gebruikt kunnen worden bij het KBO-onderwijs als de toets uitgebreid zou worden met een midden-range tussen een beginnend student en een expert; dit zou een meer preciese mapping van de leercurve vergen.

Conclusie: ten eerste is er een verbeterpunt dat alleen abnormale weefsels genoteerd moesten worden, hoewel de experts dit impliciet deden en de studenten expliciete instructies hiervoor nodig hadden. De leertijd van het Klinisch Borst Onderzoek was niet meer dan 30 minuten. Maar de beoordelingschaal moet iets duidelijker worden gedefinieerd. Aanbevolen wordt om dit te herhalen met meer studenten en op meer locaties.

Ten tweede: dit waren studenten, onervaren in KBO, en nieuw in de klinische setting; het leren werd niet gemonitord (achteraf gezien was dat beter geweest) maar gefaciliteerd doordat de borst chirurgen de normale conventionele training deden. Als de toetsing ook geschikt was gemaakt voor de meer ervaren studenten, hadden we ook beter kunnen zien waar meer effectiviteit in de training te behalen was.

In de toekomst zou het ideaal zijn als dit prototype borst model in serie geproduceerd wordt en voorzien van een goede kwaliteits controle en duurzaamheids toetsen om herhaald toetsen van studenten en hun gemonitorde progressie mogelijk te maken. Door een serie productie van TL-systeem zal die hogere kwaliteit en duurzaamheid haalbaar zijn.

Samenvatting van hoofdstuk 6 — Evaluatie van conventionele training bij Klinisch Borst Onderzoek (KBO)

De volgende studie heeft als doel om de conventionele training te evalueren en in het bijzonder hoe goed studenten, die geen ervaring hebben in KBO, na een training, het verschil kunnen ontdekken tussen gezond borstweefsel en borst weefsel voorzien van een variatie in veel voorkomende aandoeningen bij echte patiënten. Twintig studenten zaten in de steekproef die deze toets deden. Ze werden vooraf getraind in het conventionele system door borst specialisten. Nu werden ze getoetst met het TL-systeem. De prestaties van deze studenten werden op drie wijzen geëvalueerd:

-een toets op hun klinische diagnose, observatie door een borst specialist en tactiel door de patiënt. De hoofd conclusie was dat de onervaren studenten niet in staat zijn om borst weefsel met een aandoening te detecteren in een klinische setting, zelfs niet na de conventionele training. Op basis van deze resultaten is de conclusie terecht dat er naast toetsen op de observatie van de routine handelingen bij KBO ook getoetst dient te worden op begrip: is er een tumor of niet?

De huidige KBO- training in medische opleidingen lijkt onvoldoende te zijn en een meer actuele training is noodzakelijk. Ondanks de inspanningen van borst specialisten die les geven aan studenten, zijn de toetsen niet in staat een tumor te differentiëren. Een reden zal vermoedelijk zijn dat er geen echte borstkanker

patiënten beschikbaar zijn voor deze onderwijs doelen. Het IEAs (Intimate Examination Associates) heeft weinig patiënten met verdachte borstknobbels, beperkte beschikking over ervaringen in abnormaliteiten in klinische situaties. Ook met de beschikbare acteur kan de student niet de variatie voelen die in het echt aanwezig is, binnen het normale een het abnormale borstweefsel en borstknobbels.

De huidige borst modellen laten de complexiteit en de nuances bij deze variaties aan verschijnselen helemaal niet zien, hetgeen eigenlijk nodig is om de vaardigheid in het deskundig palperen in de praktijk te kunnen toepassen .

Deze studie behelste slechts 10 van de 20 studenten, die het echte klinische onderzoek konden doen. Daarom is verdere testen nodig om deze resultaten te kunnen verifiëren en om een voldoende trainingsproces en methodologie te kunnen ontwikkelen.

We hadden geluk met het rekruteren van een echte patiënt met borstkanker. Onze patiënt had slechts 24 uur tussen diagnose en opname. Ze pauzeerde onderweg even om deel te nemen aan dit onderzoek. Hoewel deze periode voor een patiënt met een verdachte borst tumor, behoorlijk emotioneel is, is het toch aan te raden om in de toekomst meer van deze patiënten proberen te rekruteren omdat er zoveel van geleerd kan worden.

Samenvatting hoofdstuk 7 — Algemene discussie en conclusies

De hoofdtaak van deze promotie was het ontwerpen van tools voor het aanleren en testen van IDBM (Identificatie en differentiatie van borstweefsel) bij palperen.

In dit promotie project werd succesvol 6 anatomische borstmodellen ontwikkeld en getest. Ze representeerden de normale variatie in soepelheid en weefselstructuren inclusief enkele pathologische.

Borstchirurgen hebben bevestigd dat deze borstmodellen levensecht zijn en representatief zijn voor meer dan 80% van de echte borstkankerpatiënten. Dit is gebaseerd op een 1:1 vergelijking met klinische onderzoeken. Er bestaat nog geen borstmodel op de markt dat de normale variatie bestrijkt.

Dit betekent ook dat deze borstmodellen een richtlijn geven voor ontwerpers van vergelijkbare tools.

Ondanks enkele beperkingen heeft dit promotieonderzoek bewezen dat de uitkomsten toegepast kan worden bij het aanleren en testen van het palperen bij klinisch borstonderzoek.

Docenten kunnen de vaardigheid van IDBM toetsen, terwijl ze observeren en meer inzicht krijgen in de vaardigheden van studenten geneeskunde bij hij het differentiëren tussen normaal en abnormaal borstweefsel.

Dit cumulatief inzicht betekent dat docenten de effectiviteit en efficiency van IDBM kunnen onderwijs als een deel van het klinisch borstonderzoek of als een aparte vaardigheid.

Indien blijkt dat deze verbeterde manier van aanleren van palperen positief blijkt dan zullen er minder vals positieven en negatieven geconstateerd worden en een meer echte positieven en negatieven, waardoor vroegere ontdekking van sommige kankers en een verbeterde patiënten beleving.

Tijdens dit promotieonderzoek werden 3 serieuze tekortkomingen ontdekt in de huidige borstmodellen en in de voorzieningen voor het aanleren van palperen binnen het Klinisch Borst Onderzoek (KBO). Hierdoor werd het mogelijk betere simulatie modellen te ontwikkelen en deze te testen in klinische situatie.

Medische docenten kunnen nu de methode onderwijzen.

Dit onderzoek is van belang vanwege diverse redenen. KBO is de eerste stap bij vrouwen met borst klachten die bij een huisarts komen. KBO is meer dan alleen het constateren van een borst aandoening; het is een medisch onderzoek dat nagaat of er gezondheidsklachten zijn en gaat na wat haar bezorgdheid inhoudt om daarna een route te definiëren waar langs zij behandeld kan worden. Huisartsen moeten bekwaam zijn in KBO om elke vrouw de juiste weg te kunnen wijzen. KBO wordt echter niet altijd in praktijk gebracht omdat het een verstandig gebruik van bronnen verder onderzoek vergt. Dit promotie onderzoek vestigt de aandacht op de training en toetsingsvaardigheid van een deel van het KBO (de palpatie) bij een medische student en huisarts.

Een mammogram als een surrogaat voor KBO is gebruikelijk in de westerse wereld, terwijl dit in de derde wereld vaak niet beschikbaar is. Daarom is getrainde en getoetste palpatie vitaal voor deze doelgroepen. De ‘best practice’ is de drievoudige procedure (palperen+mammogram+punctie). Dit promotie

project onderzocht de palpatie capaciteit in de medische wereld om dit probleem te reduceren.

De verwarring over vals positieven en fysieke schade door vals negatieve uitslagen bij mogelijke borsttumoren is een voldoende reden om dit onderzoek als rechtvaardig te claimen. Elke reductie in vals negatieven zal de klinische uitslagen verbeteren in de richting van degenen die ze nodig hebben- de echte positieve groep van borstkanker patiënten.

Het potentiele impact op medische systemen houdt in dat er efficiënter en effectiever om wordt gegaan met schaarse en dure bronnen, sociale en gezondheid voordelen voor patiënten die betrouwbaarder en snellere diagnoses krijgen tegen lagere kosten van vals negatieven en vals positieven.

Dit promotie onderzoek kan als een pilot gezien worden; verder testen is noodzakelijk om de resultaten te verifiëren en om een goed bruikbaar trainingsproces te kunnen maken.

References

Access Economics. (2006). The Economic Costs of Obesity. *Diabetes Australia*.

Ahmed, I., Nazir, R., Chaudhary, M. Y., & Kundi, S. (2007). Triple assessment of breast lump. *J Coll Physicians Surg Pak, 17*(9), 535-538. doi:09.2007/jcpsp.535538

Albert, US., & Schulz, KD. (2003). Clinical Breast Examination: What Can Be Recommended for Its Use to Detect Breast Cancer in Countries with Limited Resources? *Breast Journal, 9*(Suppl. 2), S90-S93. doi:10.1046/j.1524-4741.9.s2.10.x

Atamanyuk, I., Ghez, O., Saeed, I., Lane, M., Hall, J., Jackson, T., . . . Burmester, M. (2014). Impact of an open-chest extracorporeal membrane oxygenation model for in situ simulated team training: a pilot study. *Interact Cardiovasc Thorac Surg., 18*(1), 17-20.

Auerbach, M., Kessler, D., & Foltin, J. C. (2011). Repetitive pediatric simulation resuscitation training. *Pediatr Emerg Care, 27*(1), 29-31. doi:10.1097/PEC.0b013e3182043f3b

Australian Bureau of Statistics. (1995). *How Australians Measure Up*. Retrieved from http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/CA25687100069892CA256889001F4A36/$File/43590_1995.pdf

Australian Bureau of Statistics. (2004-5). *Overweight and Obesity in Adults*. Retrieved from

Australian Institute of Health and Welfare. (2019). *BreastScreen Australia Monitoring Report 2019*. Retrieved from Canberra: https://www.aihw.gov.au/reports/cancer-screening/breastscreen-australia-monitoring-report-2019/contents/table-of-contents

Barlow, W. E., Lehman, C. D., Zheng, Y., Ballard-Barbash, R., Yankaskas, B. C., Cutter, G. R., . . . Taplin, S. H. (2002). Performance of diagnostic mammography for women with signs or symptoms of breast cancer. *Journal of the National Cancer Institute 94*(15), 1151-1159.

Barton, M., Harris, R., & Fletcher, S. (1999). Does this patient have breast cancer? *Journal of the American Medical Association, 282*(13), 1270-1280.

Boyd, N. F., Guo, H., Martin, L. J., Sun, L., Stone, J., Fishell, E., . . . Yaffe, M. J. (2007). Mammographic Density and the Risk and Detection of Breast Cancer. *The New England Journal of Medicine, 356*(3), 227-236. doi:10.1056/NEJMoa062790

BreastScreen SA. (October 2017). Keeping Abreast BreastScreen SA newsletter for general practitioners. In (Vol. 25).

Brydges, R., Carnahan, H., Rose, D., Rose, L., & Dubrowski, A. (2010). Coordinating Progressive Levels of Simulation Fidelity to Maximize Educational Benefit. *Academic Medicine, 85*(5), 806-812.

Cahill, C. J., Boulter, P. S., Gibbs, N. M., & Price, J. L. (1981). Features of mammographically negative breast tumours. *Br J Surg, 68*(12), 882-884.

Campbell, H., McBean, M., Mandin, H., & Bryant, H. (1994). Teaching medical students how to perform a clinical breast examination. *Academic Medicine., 69*(12), 993-995.

Cancer Australia. (2004, updated 2009). Early detection of breast cancer. *Cancer Australia*.

Cancer Research UK. (2013). Retrieved from http://www.cancerresearchuk.org/cancer-info/cancerstats/types/breast/mortality/uk-breast-cancer-mortality-statistics#world

Chalabian, J., & Dunnington, G. (1998). Do Our Current Assessments Assure Competency in Clinical Breast Evaluation Skills? *The American Journal of Surgery, 175*(6), 497-502. doi:http://dx.doi.org/10.1016/S0002-9610(98)00075-0

Chalabian, J., Formenti, S., Russell, C., Pearce, J., & Dunnington, G. (1998). Comprehensive needs assessment of clinical breast evaluation skills of primary care residents. *Annals of Surgical Oncology, 5*(2), 166-172. doi:10.1007/BF02303850

Chalabian, J., Garman, K., Wallace, P., & Dunnington, G. (1996). Clinical breast evaluation skills of house officers and students. *American Journal of Surgery, 62*(10), 840-845.

Day, N. (2008). The Need for Performance and Standardization of the Best Clinical Breast Exam. *The Journal for Nurse Practitioners, 4*(5), 342-349.

Dilaveri, C., Szostek, J., Wang, A., & Cook, D. (2013). Simulation training for breast and pelvic physical examination: a systematic review and meta-analysis. *120*, 1171-1182. doi:10.1111/1471-0528.12289

Donegan, W. L. (1992). Evaluation of a Palpable Breast Mass. *The New England Journal of Medicine, 327*(13), 937-942.

Ferrante, J. M., Fyffe, D. C., Vega, M. S., Piasecki, A. K., Ohman-Strickland, P. A., & Crabtree, B. F. (2010). Family Physicians' Barriers to Cancer Screening in Extremely Obese Patients. *Obesity (Silver Spring), 18*(6), 1153-1159.

Fiche, M., Lepori, D., Guntern, D., Jucker-Kupper, P., Jeanneret, W., Zaman, K., . . . Delaloye, J.-F. (2010). Improving Breast Cancer Education: The Case of an Evolving Multidisciplinary Module for Undergraduate Medical Students (Lausanne Medical School, 1993–2008). *Journal of Cancer Education, 25*(1), 101-105.

Fletcher, S., O'Malley, M., Pilgrim, C., & Gonzalez, J. (1989). How do women compare with internal medicine residents in lump detection? *Journal of General Internal Medicine, 4*, 277-283.

Fontaine, K., & Bartlett, S. (2002). Access and use of medical care among obese persons. *Obesity Research, 8*, 403-406.

Goodson, W. H. (2010). Clinical Breast Examination and Breast Self-Examination. In E. R. Sauter & M. B. Daly (Eds.), *Breast Cancer Risk Reduction and Early Detection,* . Berlin/Heidelberg, Germany: Springer Science+Business, LLC.

Goodson, W. H., & Moore, D. H. (2002a). Causes of physician delay in the diagnosis of breast cancer. *Archives of Internal Medicine, 162*(12), 1343-1348.

Goodson, W. H., & Moore, D. H. (2002b). Overall Clinical Breast Examination as a Factor in Delayed Diagnosis of Breast Cancer *Archives of Surgery, 137*, 1152-1156.

Haakinson, D. J., Stucky, C. C., Dueck, A. C., Gray, R. J., Wasif, N., Apsey, H. A., & Pockaj, B. (2010). A significant number of women present with palpable breast cancer even with a normal mammogram within 1 year. *The American Journal of Surgery, 200*(6), 712-718.

Hendrickx, K., Winter, B. D., Tjalma, W., Avonts, D., Peeraer, G., & Wyndaele, J.-J. (2009). Learning intimate examinations with simulated patients: The evaluation of medical students' performance. *Medical Teacher, 31*, e139-e147.

Henneberg, M., & Veitch, D. (2003). National Size and Shape Survey of Australian. *Kinanthreport 2003: Newsletter of the International Society for the Advancement of Kinanthropometry, 16*, 34-39.

Hennigan, T., Franks, P., Hocken, D., & Allen-Mersh, T. (1990). Rectal examination in general practice. *British Medical Journal 301*, 478-480.

Huxley, J., & Teissier, G. (1936). Terminology of relative growth. *Nature, 137*, 780-781.

Iannotti, R. J., Finney, L. J., Sander, A. A., & De Leon, J. M. (2002). Effect of clinical breast examination training on practitioner's perceived competence. *Cancer Detection, 26*, 146-148.

Irwig, L., Macaskill, P., & Houssami, N. (2002). Evidence relevant to the investigation of breast symptoms: the triple test. *The Breast, 11*, 215-220.

Kahn, K., Pattison, T., & Sherwood, S. (2011). Simulation in medical education. *Medical Teacher, 33*, 1-3.

Kandel, E. R., Schwartz, J. H., Jessell, T. M., Siegelbaum, S. A., & Hudspeth, A. J. (2000). *Principles of Neural Science* (4 ed.): McGraw-Hill Professional.

Kann, P. E., & Lane, D. S. (1998). Breast Cancer Screening Knowledge and Skills of Students upon Entering and Exiting a Medical School. *Academic Medicine, 73*(8), 904-906.

Keating, N. L., & Pace, L. E. (2015). New Guidelines for Breast Cancer Screening in US Women. *Journal of American Medicine Association, 314*(15), 1569-1571.

Keyzer-Dekker, C. M. G. (2012). *Anxiety and quality of life in (benign) breast disease.* Tilburg University, Ridderkerk. Retrieved from https://pure.uvt.nl/portal/files/1443309/Keyzer-Dekker_anxiety_05-10-2012.pdf

Kollias, J., Bochner, M. A., Gill, P. G., Malycha, P., & Coventry, B. J. (2001). Quality assurance in a multidisciplinary symptomatic breast assessment clinic. *ANZ journal of surgery, 71*(5), 271. doi:10.1046/j.1440-1622.2001.02105.x

Laufer, S., Ray, R. D., D'Angelo, A.-L. D., Jones, G. F., & Pugh, C. M. (2015). Use of simulators to explore specialty recommendation for a palpable breast mass. *The American Journal of Surgery, 210*(4), 618-623.

Magarey, A., Daniels, L., & Boulton, J. (2001). Prevalence of overweight and obesity in Australian children and adolescents: reassessment of 1985 and 1995 data against new standard international definitions. *Medical Journal of Australia, 174*(11), 561-564.

McDermott, M. M., Dolan, N., Huang, J., Reifler, D., & Rademaker, A. (1996). Lump detection is enhanced in silicone breast models simulating postmenopausal breast tissue. *J Gen Intern Med, 11*(2), 112-114. doi:10.1007/BF02599588

McDonald, S., Saslow, D., & Alciati, M. (2004). Performance and Reporting of Clinical Breast Examination: A Review of the Literature. *CA Cancer Journal for Clinicians, 54*(6), 345-361.

Mehta, N. N., Miyasaki, S. H., Hirsch, J., & Fidler, R. L. (2014). Easy-to-implement oral cavity modification to expand simulation-based training in airway management. . *Simul Healthc, 9*(4), 260-263.

Montazeri, A., Sadighi, J., Farzadi, F., Maftoon, F., Vahdaninia, M., Ansari, M., . . . Harirchi, I. (2008). Weight, Height, body mass index and risk of breast cancer in postmenopausal women: a case-control study. *BMC Cancer 8*, 278-285.

National Breast Cancer Foundation, I. (2019). National Breast Cancer Foundation, Inc. Retrieved from https://www.nationalbreastcancer.org/early-detection-of-breast-cancer/

National Breast Cancer Foundation Inc. (2018). What's The Difference Between A Breast Self-Exam And A Clinical Breast Exam? Retrieved from https://www.nationalbreastcancer.org/clinical-breast-exam

Naylor, R. A., Hollett, L. A., Valentine, R. J., Mitchell, I. C., Bowling, M. W., Ma, A. M., . . . Scott, D. J. (2009). Can medical students achieve skills proficiency through simulation training? *The American Journal of Surgery, 198*, 277–282.

NHG Nederlands Huisart Genootschap. (2016). Diagnostiek en verwijsbeleid bij klachten van de borst(en). Retrieved from https://www.nhg.org/standaarden/samenvatting/diagnostiek-van-mammacarcinoom#idp25856

Nigam, M., & Nigam, B. (2013). Triple Assessment of Breast - Gold Standard in Mass Screening for Breast Cancer Diagnosis. *IOSR Journal of Dental and Medical Sciences, 7*(3), 1-7.

Oestreicher, N., White, E., Lehman, C., Mandelson, M., Porter, P., & Taplin, S. (2002). Predictors of sensitivity of clinical breast examination (CBE). *Breast Cancer Research & Treatment, 76*(1), 73-81.

Oncoline. (2019). Klinisch borstonderzoek. Retrieved from https://www.oncoline.nl/index.php?pagina=/richtlijn/item/pagina.php&id=41160&richtlijn_id=1069

Pennypacker, H., Naylor, L., Sander, A., & Goldstein, M. (1999). Why can't we do better breast examinations? *Nurse Practice Forum, 10*(3), 122-128.

Reece, G. P., Merchant, F., Andon, J., Khatam, H., Ravi-Chandar, K., Weston, J., . . . Markey, M. K. (2015). 3D surface imaging of the human female torso in upright to supine positions. *Medical Engineering and Physics, 37*(4), 375-383. doi:10.1016/j.medengphy.2015.01.011

Robinette, K. (2005). *Body Scanner Standard Overview*. Paper presented at the ASTM D-13 55, Washington DC.

SA Health. (2019). Breast Cancer. Retrieved from https://www.sahealth.sa.gov.au/wps/wcm/connect/public%20content/sa%20health%20internet/health%20topics/health%20conditions%20prevention%20and%20treatment/cancer/types%20of%20cancers/breast%20cancer

Sala, E., Warren, R., McCann, J., Duffy, S., Day, N., & Luben, R. (1998). Mammographic parenchymal patterns and mode of detection: implications for the breast screening programme. *Journal of Medical Screening, 5*(4).

Saslow, D., Hannan, J., Osuch, J., Alciati, M., Baines, C., Barton, M., . . . Coates, R. (2004). Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting. *CA Cancer Journal for Clinicians* (54), 327-344.

Semeraro, F., Frisoli, A., Bergamasco, M., & Cerchiari, E. L. (2009). Virtual reality enhanced mannequin (VREM) that is well received by resuscitation experts. *Resuscitation, 80*(4), 489-492.

Silk, A. W., & McTigue, K. M. (2011). Re-examining the physical examination for obese patients. *Journal of the American Medical Association, 305*(2), 193-194.

Simpson, J. S. (2014). The educational utility of simulations in teaching history and physical examination skills in diagnosing breast cancer: a review of the literature. *Journal of breast cancer, 17*(2), 107. doi:10.4048/jbc.2014.17.2.107

Spence, C. (2002). Multisensory attention and tactile information-processing. *Behavioural Brain Research, 135*(1), 57-64. doi:10.1016/S0166-4328(02)00155-9

Steiner, E., Austin, D. F., & Prouser, N. C. (2008). Detection and description of small breast masses by residents trained using a standardized clinical breast exam curriculum. *Journal of General Internal Medicine, 23*(2), 129-134.

Thistlewaite, J. (2007). Clinical Breast Examination for asymptomatic women. *Australian Family Physician, 36*(3), 145-149.

U.S. Preventive Services Task Force. (2012). The Guide to Clinical Preventive Services 2012, Appendix F: Screening for Breast Cancer. *The Guide to Clinical Preventive Services.* Retrieved from http://archive.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide2012/appendix-f.html

U.S. Preventive Services Task Force. (2014). Final Recommendation Statement: Breast Cancer: Screening. Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening#clinical-considerations

Veitch, D., & Bochner, M. (2014). Development of a Realistic Model for Teaching Breast Examination

The Breast, 23(4), S2-S3.

Veitch, D., Bochner, M., Fellner, L., Leigh, C., & Owen, H. (2018). Design, development and validation of more realistic models for teaching breast examination. *Design for Health*.

Veitch, D., Dawson, R., Owen, H., & Leigh, C. (2011). The Development of a Biofidelic Breast Cancer Large Size Female Patient Simulator using 1D and 3D Anthropometric Data. *Ergonomics Australia, Special Edition*.

Whitehead, J., Carlile, T., Kopecky, K. J., Thompson, D. J., Gilbert, F. I., Present, A. J., . . . Hadaway, E. (1985). Wolfe mammographic parenchymal patterns. A study of the masking hypothesis of Egan and Mosteller. *Cancer, 56*(6), 1280-1286. doi:10.1002/1097-0142(19850915)56:6<1280::AID-CNCR2820560610>3.0.CO;2-8

Wiecha, J., & Gann, P. (1989). Provider confidence in breast examination. *Journal of General Internal Medicine, 4*, 277-283.

Woods, E. (2010). Boom & bust. *Sunday Life*. Retrieved from www.smh.com.au/lifestyle/lifematters/boom--bust-20100719-10gx9.html

World Cancer Research Fund. (2019) Worldwide data. Retrieved from http://www.wcrf.org/int/cancer-facts-figures/worldwide-data

World Engineering Anthropometry Resource. (2013). WEAR Data Network. Retrieved from https://wear.istdayton.com/WearHome/

Wright, M. C. M. (2002). Graphical analysis of bra size calculation procedures. *International Journal of Clothing Science and Technology, 14*(1), 41-45.

Appendix 1 — Realistic breast models: can they be used for rural clinician training and accreditation?

Daisy Veitch, Lilian Fellner, Melissa Bochner

This PeArLs* seeks to gauge interest in further development of a CBE curriculum specifically for health professionals working in rural and remote areas. Clinical breast examination (CBE) is a useful part-diagnostic and diagnostic tool for the early detection of breast pathologies. CBE is part of the triple test: imaging, CBE, then biopsy. Out of these three tests, CBE is the first line, and requires clinician training but not specialist equipment such as mammography. This makes CBE important for rural and remote communities with limited access to resources, as a part-diagnostic and diagnostic tool. Realistic breast models have been developed as a teaching tool to increase clinician accuracy and confidence in performing CBE. There are six breast models representing a range of normal variation for softness and texture. They also include various breast pathologies. These models have been developed and tested in an urban context. However, we see an opportunity for the models to be particularly useful in rural and remote Australia, Canada or in third world countries, if an appropriate training program is developed.

Status: Abstract presented at 'The Muster' (Medical Education Conference), Mount Gambier, South Australia, 15-18 October 2018

Summary – Realistic breast models: can they be used for rural clinician training and accreditation?

The Muster is the sixth in a series of biannual conferences that bring together an international audience to explore and discuss community engaged medical education and research, Aboriginal health, longitudinal learning and social accountability in healthcare training (Muster website 2019).

With regard to realistic, tactile-correct breast models, we asked if they could be especially useful for rural clinician training and accreditation. This study sought to gauge interest in further development of a CBE curriculum specifically for health professionals working in rural and remote areas. CBE is a useful part-diagnostic and diagnostic tool for early detection of breast pathologies. It is one part of the triple test: imaging, CBE then biopsy. Out of these three tests, CBE is the first line, and requires clinician training but no specialist equipment such as mammography. This makes CBE important as a part-diagnostic and diagnostic tool for rural and remote communities with limited access to resources. The six tactile-correct realistic breast models were developed as a teaching tool to increase clinician accuracy and confidence in performing CBE. They represent a range of normal variation for softness and texture, and include various breast pathologies. Though these models have been developed and tested in an urban context, it's clear they could be particularly useful in rural and remote Australia, Canada or in third-world countries, if an appropriate training program is developed. Feedback indicated that the models and test would be useful in a rural context but need an appropriate teaching package.

* Personally Arranged Learning Session (PeArLs) at the Global Community Engaged Medical Education Muster Conference (Muster 2018)

http://www.muster2018.com

Appendix 2 — Ethic approval Australia

This is a placeholder for the three documents – all titled 34.13, one for initial ethics approval, then second an extension of location to add Royal Adelaide Hospital then third a time extension.

Southern Adelaide Clinical Human Research Ethics Committee

Government of South Australia
Southern Adelaide Health Service

Ethics application approval

08 April 2013

Dear Professor Owens

This is a formal correspondence from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188). This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." No hard copy correspondence will be issued.

Application Number: 34.13

Title: The Development of a Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff in Clinical Breast Examination to Improve the Early Diagnosis of Breast Cancer

Chief investigator: Professor Harry Owen

The Issue: The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) have reviewed and approved the above application. The approval extends to the following documents/changes:

- Cover letter dated 18 January 2013
- Flinders University indemnity approval from Linda Humphrys, Acting Insurance Officer dated 18 January 2013
- Letter of support from Professor Harry Owen, Director Clinical Skills and Simulation Medicine dated 17 January 2013
- Letter of support from Dr Melissa Bochner, Breast Endocrine and Surgical Oncology
- SA Health confirmation that the indemnity and insurance being provided by Flinders University is acceptable from John Markic, Insurance Services dated 18 January 2013

Your response to committee concerns received via email on 13 March 2013 containing the following:

- Cover letter dated 13 March 2013
- SAC HREC general research application form
- Participant information sheet and consent form part 2 dated 08 April 2013
- Participant information sheet and consent form part 3 dated 08 April 2013
- Recruitment letter to Private Breast Clinicians
- Letter of support from Professor Gossens, Faculty of Industrial Design, Delft University of Technology dated 12 March 2013.

Approval Period: 08 April 2013 to 08 April 2016

Please retain a copy of this approval for your records.

Flinders Medical Centre

The Flats G5 – Rooms 3 and 4

Flinders Drive, Bedford Park SA 5042

T: 08 8204 6453

F: 08 8204 4586

E:Research.ethics @health.sa.gov.au

TERMS AND CONDITIONS OF ETHICAL APPROVAL
Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions.

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below.

Researchers have a significant responsibility to comply with the *National Statement 5.5.* in providing the SAC HREC with the required information and reporting as detailed below:

1. **Compliance** with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
2. To **immediately report to SAC HREC** anything that may change the ethical or scientific integrity of the project.
3. **Report Significant Adverse events (SAE's)** as per SAE requirements available at our website.
4. **Submit an annual report on each anniversary of the date of final approval** and in the correct template from the SAC HREC website.
5. **Confidentiality** of research participants MUST be maintained at all times.
6. A copy of the **signed consent form** must be given to the participant unless the project is an audit.
7. Any **reports or publications derived from the research** should be submitted to the Committee at the completion of the project.
8. All requests for **access to medical records** at any SAHS site must be accompanied by this approval email.
9. To **regularly review the SAC HREC website** and comply with all submission requirements, as they change from time to time.
10. The researchers agree to use **electronic format** for all correspondence with this department.

Kind Regards

Petrina Kasperski
Executive Officer
SAC HREC

Government of South Australia
SA Health

Central Adelaide Local Health Network
ROYAL ADELAIDE HOSPITAL
North Terrace
Adelaide SA 5000
Tel: +61 8 8222 4000
Fax: +61 8 8222 5999
ABN 80 230 154 545
www.rah.sa.gov.au

Research Ethics Committee
Level 3, Hanson Institute
Tel: (08) 8222 4139
Fax: (08) 8222 3035
Email: rah.ethics@health.sa.gov.au

<REF: HREC/13/SAC/21>

2 May 2013

Ms Daisy Veitch
PhD Candidate
Delft University of Technology (TU Delft)
Faculty of Industrial Design Engineering
C/- 102 Gloucester Avenue
BELAIR SA 5052

Dear Ms Veitch,

Project title: **The Development of a Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff in Clinical Breast Examination to Improve the Early Diagnosis of Breast Cancer.**

Re: **Ethics Application Approval – RAH Site: Ethics Application number 34.13, approved 10/4/13 by Southern Adelaide CHREC.**

I am pleased to advise that Royal Adelaide Hospital Research Ethics Committee APPROVAL is granted to the following reviewed document in relation to the above project, for RAH purposes:

- **Flinders University Participant Information Sheet (Part 1)**

This approval is conditional to the appropriate approval from Governance for your initial application.

Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Human Research 2007.

RAH GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol changeor notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study,
  (d) a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.

Yours sincerely,

Dr A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE

Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Extension request to ethics approval approved

19 September 2016

Dear Ms Veitch

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this extension which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Your extension request form dated 09 December 2015 clearly requested a 12 month extension request in the submission.

Application number: OFR # 34.13

Study title: The Development of a Tactile Correct (Biofidelic) Teaching Model for Training Medical Staff in Clinical Breast Examination to Improve the Early Diagnosis of Breast Cancer

Chief Investigator: Daisy Veitch

Ethics approval period: 08 April 2016 – 08 April 2017

Public health sites approved under this application: Southern Adelaide Local Health Network

The below document/s have been reviewed and noted:

- SAC HREC Extension Request and Annual Review form dated 09 December 2015
- Article: A cardiac sparing technique for breast cancer radiation treatment
- RAH HREC approval letter dated 02 May 2013

TERMS AND CONDITIONS OF ETHICAL APPROVAL

As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.
2. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
3. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
4. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
5. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
6. Confidentiality of research participants MUST be maintained at all times.
7. A copy of the signed consent form must be given to the participant unless the project is an audit.
8. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
9. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
10. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
11. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

Kind regards

Petrina Kasperski
Ethics Officer (QA), Office for Research

Appendix 3 — Refining the language of touch/feel in developing evidence-based simulation manikins to teach Clinical Breast Examination (CBE)

Daisy Veitch, Richard Goossens, Johan Molenbroek, Harry Owen, Melissa Bochner

Teaching CBE could potentially be standardised by using simulation models that realistically represent the palpation characteristics important to a breast specialist when feeling for breast disease. The models need to provide complex and varied experiences, and so exhibit a range of normal breasts and lesions that provide examples of what an expert means by words such as 'smooth' or 'nodular'; thereby consistent definitions of these words are created for use in breast examination as accurate descriptions of breast texture in the language of feel.

Status: August 2018 – 22th World Congress on Ergonomics – International Ergonomics Association (IEA), Florence, Italy – video abstract
https://www.youtube.com/watch?v=kAC1XJmqWAc

Appendix 4 — The team

Daisy Veitch – CEO and Manikin Designer, SHARP Dummies Pty Ltd and PhD Student, Delft University of Technology – Department of Industrial Design Engineering, The Netherlands.

Melissa Bochner – Staff Specialist Surgeon, Royal Adelaide Hospital Breast Endocrine and Surgical Oncology Unit, Australia – a medical specialist in breast development.

Richard Goossens – Professor, Delft University of Technology – Department of Industrial Design Engineering, The Netherlands – promoter.

Johan Molenbroek – Associate Professor, Delft University of Technology – Department of Industrial Design Engineering, The Netherlands – co-promoter.

Harry Owen – Professor in the College of Medicine and Public Health, formerly of Anaesthesia and Pain Medicine, at Flinders University and now Director of the School of Medicine Clinical Skills and Simulation Unit Australia – a specialist in medical education.

Christopher Leigh – Research officer at the Faculty of Health and Medical Sciences, University of Adelaide, Adelaide, Australia – material specialist.

Lilian Fellner – School of Medicine, Flinders University, Adelaide, Australia – medical student and artist.

James Veitch – Staff Scientist, Thermofisher Scientific Inc, California, USA – statistical advisor.

Rachel Dawson – School of Medicine, Flinders University, Adelaide, Australia – medical student.

Appendix 5 —The team biographies

Daisy is a PhD candidate at Delft University of Technology in the faculty of Industrial Design Engineering. She trained in fashion design and worked as an apparel pattern-maker before designing and manufacturing realistic full-body manikins for testing clothing fit, later developing biofidelic models for medical applications. She is an experienced anthropometrist and has conducted an Australian National Anthropometric Survey of Body Size and Shape in 2002; she is also a criterion anthropometrist and an expert in body scanning. Her work experience is diverse, she has won a number of awards including the Australian Wool Corporation Young Designer award in 1987. Her published work extends to technical reports related to applied design. She is presently focussed on design consultancy promoting anthropometric design. Her additional interests involve engagement in not-for-profit professional affiliations that share high-quality scientific anthropometric data applicable to engineering anthropometry. She may be reached at **daisy.veitch@gmail.com**

ORCID
Daisy Veitch – *http://orcid.org/0000-0002-6634-5154*

Melissa Bochner trained in breast and thyroid surgery at the Royal Adelaide Hospital in 1998 and the Edinburgh Breast Unit in 1999. Her current positions are Staff Specialist Surgeon, Royal Adelaide Hospital Breast Endocrine and Surgical Oncology Unit, and Visiting Surgeon at the Womens and Children Hospital, and St Andrews Private Hospital, Adelaide. She is a clinical senior lecturer at the University of Adelaide and supervisor of clinical medical students at St Andrews Hospital. She is a member of the Breast and Endocrine sections of the Royal Australasian College of Surgeons, and has interests in oncoplastic surgery, teaching and research.
She may be reached at **melissa.bochner@health.sa.gov.au**

Richard Goossens is a full professor of Physical Ergonomics at the faculty of Industrial Design Engineering within the section of Applied Ergonomics and Design at the Delft University of Technology, where he is Head of the Industrial Design department. He is also a part-time professor of Physical Ergonomics at the Erasmus University Medical Center department of Neuroscience and an Honorary Lecturer at the University of Salford. He coordinates education of Medisign students, supervising them in design projects for medical specialists and companies.
He may be reached at Landbergstraat 15, 2628 CE Delft, Netherlands, **R.H.M.Goossens@tudelft.nl**

Johan Molenbroek, Dr, is an associate professor in the Applied Ergonomics and Design section of the faculty of Industrial Design Engineering at Delft University of Technology. He is a specialist in inclusive design, anthropometry, product safety and design for special populations like children, students, the elderly and those with physical and mental disabilities.
He may be reached at Landbergstraat 15, 2628 CE Delft, Netherlands, **j.f.m.molenbroek@tudelft.nl**

Harry Owen has been working in the area of medical simulation and teaching for over two decades. He established the first simulation facility in Australia in 1999 specifically for entry-level medical education. He is a Professor in the College of Medicine and Public Health, formerly of Anaesthesia and Pain Medicine, at Flinders University and now Director of the School of Medicine Clinical Skills and Simulation Unit Australia – a recognised specialist in medical education. Professor Owen is widely published in both clinical and education journals and has received national and international prizes and awards for research and teaching. He has a wealth of knowledge to contribute to the development of a medical simulation model for teaching CBE. Professor Owen was a recipient of the Ray Page Lifetime Simulation Achievement Award in 2015. He may be reached at **harry.owen@flinders.edu.au**

ORCID
Harry Owen – *http://orcid.org/0000-0002-5488-3377*

Chris Leigh has worked in the Faculty of Health and Medical Sciences, University of Adelaide for over 40 years, holding many research and professional positions within the Medical School. He has co-authored 64 peer-reviewed research publications and 61 conference abstracts mostly in the disciplines of medical and comparative anatomical studies. In addition to research, he manages many of the teaching laboratories in the Faculty, including a newly established Museum/Learning Hub which contains the anatomy and pathology potted specimens and other anatomical teaching material. He has a long history of preparing biological and anatomically accurate artificial material for the Faculty, and is presently one of its research officers.
He may be reached at **chris.leigh@adelaide.edu.au**

Lilian Fellner is a medical student enrolled in the Doctor of Medicine course at Flinders University, Adelaide, South Australia. She holds an undergraduate degree of Bachelor of Clinical Science. She is also an accomplished artist and sculptor and has brought those skills combined with her knowledge of anatomy into the project.

James Veitch has a PhD in Statistics from University of California, Berkeley. Currently he has the position of Staff Scientist at Thermofisher Scientific Inc, California, USA and is working in Next Generation Sequencing for their Clinical Services Division.

Rachel Dawson is a medical student at the School of Medicine, Flinders University, Adelaide, Australia.

Appendix 6 — List of Daisy Veitch's Publications (other than for this PhD)

International refereed journals

S Heraganahally, C Sprick, **D Veitch**, D Sajkov, H Falhammar, S Mehra, and S Morton (00:00-00, 2019), "A new cost-effective pleural procedure training-mannequin-based model to increase the confidence and competency in trainee-medical-officers", Postgraduate Medical Journal (in press)

T Crittenden, **DE Veitch**, M Henneberg, K Burford, P van Essen, K Deut, K Zeitouneh, E Lomax, P Griffin, NR Dean (2018), "Measuring breast volume in hypertrophy: laser scanning or water displacement?", Australasian Journal of Plastic Surgery 1(2):33-40.

K Robinette, **D Veitch** (2016), "Sustainable Sizing", Human Factors 58 (3): 1-8

JM Yip, N Mouratova, RM Jeffrey, **DE Veitch**, RJ Woodman, NR Dean, (2011), "Accurate Assessment of Breast Volume: A study Comparing the Volumetric Gold Standard (Direct Water Displacement Measurement of Mastectomy Specimen) with a 3D Laser Scanning Technique." Annals of Plastic Surgery, 2011 May 16. [Epub ahead of print]

D Veitch, K Burford, P Dench, N Dean and P Griffin (2012), "Measurement of breast volume using body scan technology (computer-aided anthropometry)", WORK: A Journal of Prevention, Assessment & Rehabilitation, Volume 41 Supplement 1/2012,available online at iospress.metapress.com/content/j175ltk0772n8497/fulltext.pdf

D Veitch, (2012) "Where is the human waist? Definitions, manual compared to scanner measurements", WORK: A Journal of Prevention, Assessment & Rehabilitation, Volume 41 Supplement 1/2012, available online at http://iospress.metapress.com/content/q63t64372qtr2514/fulltext.pdf

D Veitch, V Blewett and D Caple, (2012) "Sizing up Australia: Towards a national sizing survey", WORK: A Journal of Prevention, Assessment & Rehabilitation, Volume 41 Supplement 1/2012

D Veitch, L Veitch and M Henneberg (2007) "Sizing for the Clothing Industry Using Principal Component Analysis – An Australian Example", Journal of ASTM International, 4(3): Paper ID JAI100824, available online at www.astm.org.

M Henneberg and **D Veitch** (2005) "Is Obesity as Measured by Body Mass Index and Waist Circumference in Adult Australian Women 2002 Just a Result of Lifestyle?" Human Ecology Special Issue Volume (13):85-89.

Reports

D Veitch, C Fitzgerald, S Ward, C Shu, K Robinette and V Blewett, (2013) "Sizing Up Australia – The Next Step", Chapter 1: Report Summary, Safe Work Australia, Canberra

D Veitch, C Fitzgerald, V Blewett, S Ward, C Shu and K Robinette (2013) "Sizing Up Australia – The Next Step", Chapter 2: Literature Review, Safe Work Australia, Canberra

D Veitch, C Fitzgerald, V Blewett, S Ward, C Shu and K Robinette (2013) "Sizing Up Australia – The Next Step", Chapter 3: Survey Scope and Method, Safe Work Australia, Canberra

D Veitch, V Blewett and D Caple, (2009), "Sizing up Australia – How contemporary is the anthropometric data Australian designers use?" available online at www.ascc.gov.au/ asccAboutUsPublications ResearchReportsSizingUp AustraliaHowcontemporaryistheanthropometricdataAustraliandesignersuse.htm

Conference proceeding

D Veitch, L Fellner, M Bochner, (2018) "Realistic breast models: can they be used for rural clinician training and accreditation?" PeARLs, The Muster 2018, Mount Gambier, South Australia.

D Veitch, R Goossens, J Molenbroek, H Owen, M Bochner, (2018) "Refining the language of touch/feel in developing evidence-based simulation manikins to teach Clinical Breast Examination (CBE)", video abstract and poster, 22th World Congress on Ergonomics – International Ergonomics Association (IEA), Florence, Italy

D Veitch, C Leigh, M Bochner, (2014), "Development of realistic model for teaching breast examination", Presentation and extended abstract, Australiasian Society for Breast Disease, Gold Coast, Queensland, Australia.

C Fitzgerald, **D Veitch** and V Blewett, (2012) "Sizing up Australia: What are we waiting for?" HFESA, Canberra Australia.

S Ward and **D Veitch**, (2012), "DIY anthropometric data collection", HFESA, Canberra Australia.

D Veitch, R Dawson, H Owen and C Leigh, (2012), "Using 1D and 3D Anthropometric Data to Develop a Biofidelic Breast Cancer Patient Simulator", Asian Workshop on 3D Body Scanning Technologies, Tokyo Japan.

D Veitch, K Burford, P Dench, N Dean and P Griffin, (2012), "Using Body Scan Technology (Computer-Aided Anthropometry) to Measure Breast Volume", Asian Workshop on 3D Body Scanning Technologies, Tokyo Japan.

D Veitch, (2012), "Waist Measurements Compared: Definitions (ISO vs CAESAR) and Instruments (Manual vs 3D Scanned Data)", Asian Workshop on 3D Body Scanning Technologies, Tokyo Japan.

D Veitch, (2012), "Where is the human waist? Definitions, manual compared to scanner measurements", 20th World Congress on Ergonomics – International Ergonomics Association (IEA) Recife Brazil

D Veitch, K Burford, P Dench, N Dean and P Griffin, (2012), "Measurement of breast volume using body scan technology (computer-aided anthropometry)", 20th World Congress on Ergonomics – International Ergonomics Association (IEA) Recife Brazil

D Veitch, V Blewett and D Caple, (2012), "Sizing up Australia: Toward a national sizing survey", 20th World Congress on Ergonomics – International Ergonomics Association (IEA) Recife Brazil

D Veitch, H Owen and C Leigh, 2010, "Size, Shape And Body Scan Data To Improve Biofidelity Of Patient Simulator", SimTecHealth 2010 Simulation Conference, Melbourne Australia. Outstanding Abstract, International Society for Simulation in Healthcare (SSH)

D Veitch and B Davis, (2010), "Use of 3D Body Scan Data for Apparel Product Development", TTCP Defence Human Systems Symposium 17-19 May 2010, Sydney Australia.

D Veitch and B Davis, (2010) WEAR Valencia, "Application of Anthropometric Data to Garment Sizing and Design via Innovative Product Development Tools", presented at World Engineering Anthropometry Resource (WEAR) Conference, Valencia, Spain

D Veitch and B Davis, (2010) WEAR NZ "Use of 3D Body Scan Data for Apparel Product Development", presented at World Engineering Anthropometry Resource (WEAR) Conference, Auckland, New Zealand.

D Veitch (2009), "Anthropometry in design" presented at the Human Factors and Ergonomics Society of Australia Annual Conference – Melbourne.

D Veitch, V Blewett and D Caple (2009), "Can Australian designers use anthropometry to design-in safety" presented at the Human Factors and Ergonomics Society of Australia Annual Conference – Melbourne 2009.

D Veitch and M Henneberg (2009), "Where is the human waist?" presented at the Human Factors and Ergonomics Society of Australia Annual Conference – Melbourne 2009.

D Veitch and B Davis (2009), "Practical application of 3D data for apparel industry use" presented at the 17th World Congress on Ergonomics – International Ergonomics Association (IEA) – Beijing 2009.

D Veitch, V Blewett and D Caple,(2009) "Sizing up Australia: What use have designers made of anthropometric data?" presented at the 17th World Congress on Ergonomics – International Ergonomics Association (IEA)- Beijing 2009.

D Veitch and K Robinette (2006) "World Engineering Anthropometry Resource (WEAR): A Review", presented at Human Factors & Ergonomics Society of Australia Inc, National Conference, Sydney Australia.

D Veitch and K Robinette (2006) "BioFidelic Apparel Manikins from CAESAR 3D Anthropometric Data", presented at The International Ergonomics Association Congress, Maastricht, The Netherlands.

D Veitch, L G Veitch and M Henneberg (2005) "Size and Shape Specification for the Apparel Industry", presented at World Engineering Anthropometry Resource (WEAR) Conference, Pretoria, South Africa.

D Veitch & M Henneberg (2004) "National 'Sizing up Australia'", presented at World Engineering Anthropometry Resource (WEAR) Conference, Dayton, Ohio, USA.

M Henneberg & **D Veitch** (2002) "National Size and Shape Survey of Australia: A Work in Progress", presented at 16th Annual Scientific Meeting, Australasian Society for Human Biology, Perth, Australia.

Invited Speaker

Workshop for professionals in anthropometry conducted for the Industrial Engineering Department – Parahyangan Catholic University (UNPAR) (Bandung-Indonesia, 22 October 2013)

International Guest Judge for Asia Pacific Design Challenge (APDeC) http://www.apdec.net/ (Bandung-Indonesia, 23-25 October 2013)

Korean Agency for Technology and Standards (KATS) Keynote speaker – topic – "Standards, Case Studies and Fit Mapping" (Korea, 6 November 2013)

Appendix 7 — Indurometer

We conducted a number of biomechanical tests to investigate the properties of the breast (see Figure 1), but ultimately these data were not used so are not included in this thesis.

We borrowed an indurometer from Professor Neil Pillar, Flinders Medical Centre, South Australia and used it on a prosthetic breast to see if we could get pressure readings to measure softness. It couldn't differentiate between hardness that had different causes, such as tight skin, vs proximity to ribs, vs a breast lump, all of which the researchers were able to do with ease via palpation and all are essential in training. The resulting metrics were too crude to add value in this context.

Appendix 8 — Receptor types active in somatic sensation

Receptor type	Modality
Cutaneous and subcutaneous mechanoreceptors	Touch
Meissner's corpuscle	Stroking, fluttering
Merkel disk receptor	Pressure, texture
Pacinian corpuscle[1]	Vibration
Ruffini ending	Skin stretch
Hair-tylotrich, hair-guard	Stroking, fluttering
Hair-down	Light stroking
Field	Skin stretch
Thermal receptors	Temperature
Cool receptors	Skin Cooling (25 C)
Warm receptors	Skin warming (41 C)
Heat nociceptors	Hot temperature (..)
Cold nociceptors	Cold temperature (..)
Nociceptors	Pain
Mechanical	Sharp, pricking pain
Thermal-mechanical	Burning pain
Thermal-mechanical	Freezing pain
Polymodal	Slow, burning pain
Muscle and skeletal mechanoreceptors	Limb proprioception
Muscle spindle primary	Muscle length and ….
Muscle spindle secondary	Muscle stretch
Golgi tendon organ	Muscle contraction
Joint capsule mechanoreceptors	Join angle
Stretch-sensitive free endings	Excess stretch or force

Table showing Receptor Types Active in Somatic Sensation source:

Principles of Neural Science. (2000). (E. R. Kandel, J. H. Schwartz, T. M. Jessell, S. A. Siegelbaum, & A. J. Hudspeth Eds. 4 ed.): McGraw-Hill Professional.

[1] Pacinian corpuscles are also located in the mesentery, between layers of muscle, and on interosseous membrances

The hand has 20 different types of receptors that work together in a finely nuanced way to convey complex information that the trained observer can interpret with 100% accuracy as a normal or abnormal breast lump by touch alone. The observer can easily tell the difference between hardness caused by tight skin versus an underlying hard structure such as ribs. Mechanical tests struggle with these nuances.