



Delft University of Technology

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

Veitch, Daisy; Bochner, Melissa; Fellner, Lilian; Leigh, Christopher ; Owen, Harry

DOI

[10.1080/24735132.2018.1451454](https://doi.org/10.1080/24735132.2018.1451454)

Publication date

2018

Document Version

Final published version

Published in

Design for Health

Citation (APA)

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*, 2(1), 40-57.
<https://doi.org/10.1080/24735132.2018.1451454>

Important note

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

Copyright

Other than for strictly personal use, it is not permitted to download, forward or distribute the text or part of it, without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license such as Creative Commons.

Takedown policy

Please contact us and provide details if you believe this document breaches copyrights.
We will remove access to the work immediately and investigate your claim.

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

Daisy Veitch, Melissa Bochner, Lilian Fellner, Christopher Leigh & Harry Owen

To cite this article: Daisy Veitch, Melissa Bochner, Lilian Fellner, Christopher Leigh & Harry Owen (2018) Design, development and validation of more realistic models for teaching breast examination, Design for Health, 2:1, 40-57, DOI: [10.1080/24735132.2018.1451454](https://doi.org/10.1080/24735132.2018.1451454)

To link to this article: <https://doi.org/10.1080/24735132.2018.1451454>



© 2018 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group.



[View supplementary material](#)



Published online: 04 May 2018.



[Submit your article to this journal](#)




Article views: 135



[View Crossmark data](#)

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

Daisy Veitch ^a, Melissa Bochner^b, Lilian Fellner^c, Christopher Leigh^d and Harry Owen ^c

^aFaculty of Industrial Design, TU Delft, Delft, The Netherlands; ^bBreast and Endocrine Unit, Royal Adelaide Hospital, Adelaide, Australia; ^cSchool of Medicine, Flinders University, Adelaide, Australia; ^dFaculty of Health and Medical Sciences, University of Adelaide, Adelaide, Australia

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 multi-layered breast models representing a range of normal human variation for durability (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 (durability 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 durability.

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.

ARTICLE HISTORY

Received 4 February 2018
Accepted 7 March 2018



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).

CONTACT Daisy Veitch  daisy.veitch@gmail.com

 Supplemental material for this article can be accessed at  <https://doi.org/10.1080/24735132.2018.1451454>.

© 2018 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group. This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License (<http://creativecommons.org/licenses/by-nc-nd/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited, and is not altered, transformed, or built upon in any way.

The triple test

Early detection of breast cancer saves lives and reduces mortality (Cancer Australia 2004, updated 2009; McDonald, Saslow, and Alciati 2004). 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 (process of using one's hands to examine the body to diagnose breast 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 screening and 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, mammographic screening misses 10% to 20% of clinically palpable breast cancers (Barlow et al. 2002; Cahill et al. 1981; Donegan 1992; Haakinson et al. 2010; Goodson 2010). Further, Goodson (2010) argues that CBE, despite originating as a diagnostic tool, is now a screening 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 screening 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 screening 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 et al. 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, Saslow, and Alciati (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 life-like 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 pre-prepared 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 6](#)).

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 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. During this selection process, the 5%, 15% and 20% thinner test 'pots' were deemed so

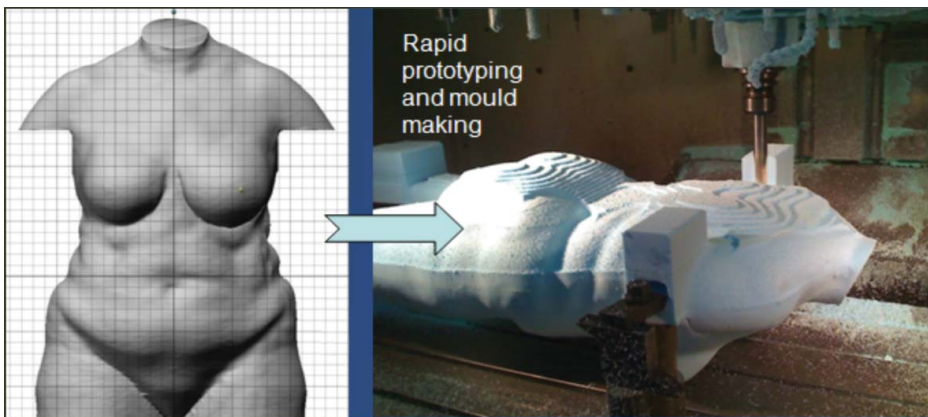


Figure 1. CAD data (left) ready for rapid prototyping using a CNC milling machine (right) prior to mould-making.

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 was realistic feeling.

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 durability. 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 7).

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 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 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 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. We copied the breast movement effect illustrated in



Figure 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).

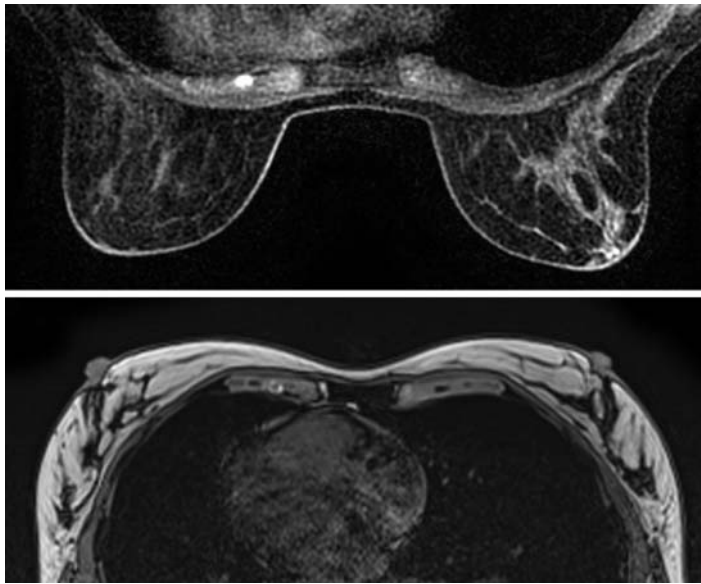


Figure 3. Two MRI transverse slices of the same 50-year old patient taken at the same transverse height from different scans in two different postures, one lying prone (above) and one supine (below), showing a significant amount of breast tissue movement occurring during postural change.

Figure 3 and subsequently flattened our simulation models accordingly – see Table 1.

Ribs

Ribs were scanned and aligned with the breast model in CAD (see Figure 4). 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.

Table 1. Breast descriptors.

| 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 |



Figure 4. CAD image of ribs overlaid with 'skin'.

Lesions

Lesions were developed that mimicked the feeling of cancer, cysts and fibroadenoma (see [Figure 5](#)). 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 multi-layered model and thereby constructed a model with biofidelic feel



Figure 5. A simulated silicone cancer shown on the left and cysts of two sizes shown on the right.



Figure 6. 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.

(see [Figure 6](#)). This model became Breast 3 (see [Figure 7](#)). Assessment of the match between the patient and the model was subjective.

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 1](#)) is distinct and useful for teaching. There are five categories for durability and three categories for nodularity because Breasts 4 and 1 were equally smooth; Breasts 3, 2-Thinner and 2-Fatter were all similarly



Figure 7. Prototype breast simulation model.

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 durability 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 durability 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. See Supplementary material for the completed questionnaire.

Results

Six biofidelic models have been developed that differ in feel, especially two physical characteristics of feel durability and nodularity, but with some adiposity variation (see [Figure 8](#)). 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 is summarized in [Table 2](#).

Twenty-four per cent of patients had an A or B cup, 73% were C cup and above and 3% had no data recorded. Forty-six per cent of patients examined were post-menopausal, 26% unsure or peri-menopausal and 31% pre-menopausal.

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 durability (see [Table 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. For durability, Breast 3 was the most common

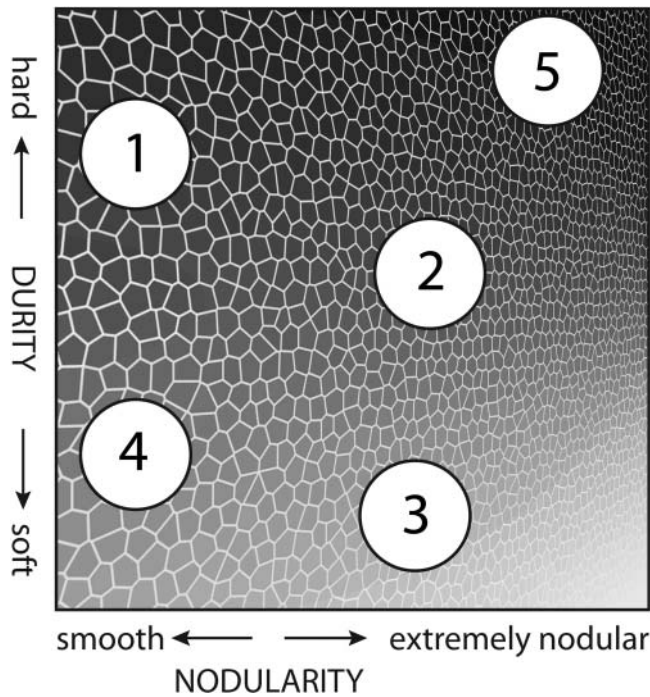


Figure 8. Showing the location of breast models differing in feel arranged in a bi-variate format where the axes represent the range of normal for durity (y) and nodularity (x).

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'.

Table 2. Mean, median, minimum and maximum summary statistics for the 78 patients for age, weight and body mass index (BMI).

| | | 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 3. Showing 18% of patients were rated not similar to the models and 82% of patient examinations rated undecided or better for durity. Showing 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 tissue? | 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% |

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 multi-layered 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 multi-layered into the simulation models (see Figure 6).

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 and screening. 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, multi-layered, 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 ($N = 78$) and confirm they 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 multi-layered 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.

Acknowledgments

The authors would like to thank Jeff Hudson for the CAD images (Figures 1 and 4), 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 2 (left) and the staff at the Royal Adelaide Hospital Women's Health Centre who generously gave their time for the collection of data.

Disclosure statement

No potential conflict of interest was reported by the authors.

Notes on contributors

Daisy Veitch is a PhD degree candidate at TU Delft, Industrial Design Engineering. She trained in fashion design and worked as an apparel pattern-maker before making realistic full-body manikins for testing clothing fit and other model-making. She is also a criterion anthropometrist and an expert in body scanning. She conducted an Australian National Size and Shape Survey in 2002. She has won a number of awards including Australian Wool Corporation Young Designer award in 1987. Her published work includes technical reports related to applied design. Her current interests include work in not-for-profits that share high quality scientific anthropometric data applied to design.

Melissa Bochner trained in breast and thyroid surgery at the Royal Adelaide Hospital in 1998 and the Edinburgh Breast Unit in 1999. She attained a Master of Surgery degree by research from the University of Sydney in 2001. Her current positions are staff specialist surgeon, Royal Adelaide Hospital Breast and Endocrine Unit, and visiting surgeon, Women's 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 has interests in oncoplastic surgery, teaching and research.

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

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.

Harry Owen is a retired professor of Anaesthesia and Pain Medicine at Flinders University and director of the School of Medicine Clinical Skills and Simulation Unit. Professor Owen established the first simulation facility in Australia in 1999 specifically for entry-level medical education. He 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.

ORCID

Daisy Veitch  <http://orcid.org/0000-0002-6634-5154>

Harry Owen  <http://orcid.org/0000-0002-5488-3377>

References

- Ahmed, I., R. Nazir, M. Y. Chaudhary, and S. Kundi. 2007. "Triple Assessment of Breast Lump." *Journal of the College of Physicians and Surgeons Pakistan* 17 (9): 535–538. doi:09.2007/jcsp.535538.
- Albert, Ute—Susann, and Klaus—Dieter Schulz. 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–S53. doi: 10.1046/j.1524-4741.9.s2.10.x.
- Atamanyuk, Iryna, Olivier Ghez, Imran Saeed, Mary Lane, Judith Hall, Tim Jackson, Ajay Desai, and Margarita Burmester. 2014. "Impact of an Open-Chest Extracorporeal Membrane Oxygenation Model for in situ Simulated Team Training: A Pilot Study." *Interact Cardiovascular Thoracic Surgery* 18 (1): 17–20.
- Auerbach, M., D. Kessler, and J. C. Foltin. 2011. "Repetitive Pediatric Simulation Resuscitation Training." *Pediatric Emergency Care* 27 (1): 29–31. doi: 10.1097/PEC.0b013e3182043f3b.
- Barlow, W. E., C. D. Lehman, Y. Zheng, R. Ballard-Barbash, B. C. Yankaskas, G. R. Cutter, and P. A. Carney, et al. 2002. "Performance of Diagnostic Mammography for Women with Signs or Symptoms of Breast Cancer." *Journal of the National Cancer Institute* 94 (15): 1151–1159.
- Brydges, Ryan, Heather Carnahan, Don Rose, Louise Rose, and Adam Dubrowski. 2010. "Coordinating Progressive Levels of Simulation Fidelity to Maximize Educational Benefit." *Academic Medicine* 85 (5): 806–812.
- Cahill, C. J., P. S. Boulter, N. M. Gibbs, and J. L. Price. 1981. "Features of Mammographically Negative Breast Tumours." *British Journal of Surgery* 68 (12): 882–884.
- Campbell, H. S., M. McBean, H. Mandin, and H. Bryant. 1994. "Teaching Medical Students How to Perform a Clinical Breast Examination." *Academic Medicine* 69 (12): 993–995.
- Cancer Australia. 2004, revised and updated 2009, 2015. "Early Detection of Breast Cancer." Accessed 4 April 2018. <https://canceraustralia.gov.au/publications-and-resources/position-statements/early-detection-breast-cancer>.

- Cancer Research UK. 2013. "Breast Cancer Mortality Statistics." Accessed 9 October 2013. <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/mortality#world>.
- Chalabian, Jeanine, and Gary Dunnington. 1998. "Do Our Current Assessments Assure Competency in Clinical Breast Evaluation Skills?" *The American Journal of Surgery* 175 (6): 497–502. doi: 10.1016/S0002-9610(98)00075-0.
- Day, N. B. 2008. "The Need for Performance and Standardization of the Best Clinical Breast Exam." *The Journal for Nurse Practitioners* 4 (5): 342–349.
- Donegan, William L. 1992. "Evaluation of a Palpable Breast Mass." *The New England Journal of Medicine* 327 (13): 937–942.
- Goodson, William H. 2010. "Clinical Breast Examination and Breast Self-Examination." In *Breast Cancer Risk Reduction and Early Detection*, edited by E. R. Sauter and M. B. Daly, 81–115. Boston, MA: Springer.
- Goodson, William H., and Dan H. Moore. 2002. "Overall Clinical Breast Examination as a Factor in Delayed Diagnosis of Breast Cancer." *Archives of Surgery* 137: 1152–1156.
- Haakinson, D. J., C. C. Stucky, A. C. Dueck, R. J. Gray, N. Wasif, H. A. Apsey, and B. Pockaj. 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.
- Irwig, L., P. Macaskill, and N. Houssami. 2002. "Evidence Relevant to the Investigation of Breast Symptoms: The Triple Test." *The Breast* 11: 215–220.
- McDonald, S., D. Saslow, and M. Alciati. 2004. "Performance and Reporting of Clinical Breast Examination: A Review of the Literature." *CA Cancer Journal for Clinicians* 54 (6): 345–361.
- Mehta, Niyati N., Shelley H. Miyasaki, Jan Hirsch, and Richard L. Fidler. 2014. "Easy-to-Implement Oral Cavity Modification to Expand Simulation-Based Training in Airway Management." *Simulation Healthcare* 9 (4): 260–263.
- Saslow, D., J. Hannan, J. Osuch, M. Alciati, C. Baines, M. Barton, and J. Bobo, et al. 2004. "Clinical Breast Examination: Practical Recommendations for Optimizing Performance and Reporting." *CA Cancer Journal for Clinicians* (54): 327–344.
- Semeraro, Federico, Antonio Frisoli, Massimo Bergamasco, and Erga L Cerchiari. 2009. "Virtual Reality Enhanced Mannequin (VREM) that is Well Received by Resuscitation Experts." *Resuscitation* 80 (4): 489–492.
- Simpson, Jory 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, Charles. 2002. "Multisensory Attention and Tactile Information-Processing." *Behavioural Brain Research* 135 (1): 57–64. doi: 10.1016/S0166-4328(02)00155-9.
- U.S. Preventive Services Task Force. 2015. "The Guide to Clinical Preventive Services 2012, Appendix F: Screening for Breast Cancer." U.S. Department of Health & Human Services. Accessed 8 December. <http://archive.ahrq.gov/professionals/clinicians-providers/guide-lines-recommendations/guide2012/appendix-f.html>.
- U.S. Preventive Services Task Force. 2012. "Final Recommendation Statement: Breast Cancer: Screening." <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening#clinical-considerations>.
- Veitch, Daisy, and Melissa Bochner. 2014. "Development of a Realistic Model for Teaching Breast Examination." *The Breast* 23 (4): S2–S3.