

Article

Low-Cost and Easily Fabricated Ultrasound-Guided Breast Phantom for Breast Biopsy Training

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Featured Application: A breast phantom that simulates essential training experience and can be easily fabricated in hospital for residents to improve their skills and confidence level in performing ultrasound-guided needle biopsies.

Abstract: We aimed to develop an inexpensive and easy-to-fabricate gelatin-based training phantom for improving the breast biopsy skill and confidence level of residents. Young's modulus and acoustic properties of the gelatin tissue phantom and simulated tumors were investigated. Six residents were requested to evaluate the effectiveness of the breast phantom. The results showed that 83% ($n = 5$) of the participants agreed that the ultrasound image quality produced by the breast phantom was excellent or good. Only 17% ($n = 1$) of the participants claimed that there was room for improvement for the haptic feedback they received during the placement of the core needle into the breast phantom. The mean pre-instructional score was 17% (SD 17%) for all participants. The mean post-instructional score was 83% (SD 17%), giving an overall improvement of 67%. In conclusion, the mean needle biopsy skill and confidence levels of the participants substantially increased through simulation training on our breast phantom. The participants' feedback showed the phantom is sufficiently realistic in terms of ultrasound imaging and haptic feedback during needle insertion; thus, the training outcome can be linked to the performance of residents when they perform a live biopsy.

Keywords: acoustic properties; breast biopsy; haptic feedback; training phantom; ultrasound imaging



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1. Introduction

Impalpable breast lesions found in breast cancer screening can be diagnosed through percutaneous image-guided breast biopsy. This technique has achieved dramatic improvements in terms of effectiveness and accuracy of diagnosis over the past few decades and is now commonly performed for palpable and nonpalpable lesions. The number of open surgical biopsies has declined due to the high accuracy of this minimally invasive needle biopsy [1].

The human breast is a heterogeneous structure containing different layers of tissues, predominantly fat and glandular tissues. Factors such as age, menstrual cycle, pregnancy, lactation, hormone therapy and menopause affect the distribution of these various tissues. Pathophysiologic processes such as the tumor development change the intrinsic elasticity of soft tissues [2].

Young's modulus, the modulus of elasticity, has been used in several studies to quantify the mechanical properties of breast tissues [3–8]. These studies have reported that the stiffness of tumor tissue is much higher than that of normal breast tissues. Moreover, fibrous, glandular and tumor tissues have higher Young's moduli than adipose tissue. Ramião et al. summarized the results of mechanical testing of ex vivo breast tissue: The

average Young's modulus is 0.69–24 kPa for normal fat tissue, 0.73–271.8 kPa for normal glandular tissue, 3.4–2162 kPa for tumor tissue (ductal carcinoma in situ) and 10–1366.5 kPa for tumor tissue (invasive ductal carcinoma) [9]. This wide variation in Young's modulus is found both across and within various tissue types. The variation is particularly large in normal fat and fibroglandular tissues.

The acoustic properties of real tissues vary among people and are not constant even within a person's body, giving rise to considerable variation in the literature [10,11].

Ultrasound-guided breast biopsy is commonly used for tissue diagnoses of sonographically visible breast lesions. Nevertheless, many radiology residents in their graduate residencies have no hands-on experience in performing the procedure [12]. Until now, the traditional apprenticeship training method on live patients has been practiced in the medical field instead of simulation training. The Accreditation Council for Graduate Medical Education has strongly encouraged enhancing safety, predictability and respect for patients by increasing the use of simulation training in graduate medical education [13]. Hence, there is a clinically unmet need for training phantoms.

In several residency training programs, turkey breast or gel breast phantoms are commonly used for simulation training of freehand ultrasound-guided breast procedures, as discussed below. Pimento within the olive was embedded within a turkey breast to simulate the target for biopsy training [14]. To develop a breast phantom that has more realistic tactility and appearance in ultrasound images, a chicken breast phantom was embedded with polyvinyl acetate lesions to mimic the heterogeneity of real breast tissue [15].

Gelatin-based phantoms are the most described simulation technique in the literature [12,16–22]. In these studies, pitted olives with pimentos, capers, grapes, peas, potatoes and strawberries were used to simulate breast masses for ultrasound-guided core biopsy; rubber glove fingers filled with water and bath oil beads coated with nail polish were used to simulate breast cysts for ultrasound-guided fine-needle aspiration. Plastic beads were embedded in the gelatin-based phantom developed by the Nicholson group [23]. Ruschin et al. proposed a gelatin-based breast phantom consisting of a simulated tumor with realistic imaging properties [24]. The background used in breast tissue simulation was made of ballistic gelatin powder and Metamucil, whereas the simulated tumors were composed of barium sulfate, copper sulfate, Metamucil and ballistic gelatin.

Madsen et al. developed a gelatin-agar-based breast phantom that could closely mimic the acoustic properties and density of real breast tissues [25]. The same authors later suggested dispersing safflower oil in solid aqueous gelatin to allow elastography in a gelatin-agar-based breast phantom [26]. The method combined oil, gelatin and agar to fabricate the glandular tissue, fat tissue, skin and Cooper's ligaments. The difference in Young's modulus between normal and abnormal breast tissues was mimicked by adjusting the proportions of the oil and gelatin. Dang et al. proposed another gelatin-agar-based phantom that could reproduce the acoustic and elastic properties of fat tissue, glandular tissue, fibrous tissue and carcinoma [27].

We also found a type of tissue-mimicking material for ultrasound-guided breast biopsy training that used paraffin-gel wax. Vieira et al. developed a paraffin-gel wax-based phantom embedded with cyst and tumor models [28].

Another group of studies developed polyvinyl chloride (PVC)-based phantoms. A two-layered breast phantom (breast fat and mixed fatty-fibroglandular tissue) was developed using customizable PVC plastisol formulations that could mimic the acoustic and optical properties of different breast tissues [29]. Besides, a multi-layered breast phantom [30] was built using a custom PVC plastisol formulation to simulate fat, fibroglandular tissue and blood vessels with tissue realistic acoustic and optical properties. The phantom also included embedded tumors that were modeled as clusters of small blood vessels and skin that was mimicked using a silicon layer. Finally, PVC-based material was used to mimic the glandular breast tissue and the 3D printing technique was used to construct

a custom-designed breast phantom mold and the embedded inserts (microcalcifications, fiber lesions and tumors with different sizes) [31].

A silicone-based breast phantom was constructed with components emulating a breast parenchyma/chest wall (silicone rubber mixed with agricultural grade silicone oil), epidermis (mesh fabric layer applied with silicone rubber), areola/nipple (epidermis mixture and a silicone baby bottle nipple as the mold) and a tumor (marble) [32].

Commercial products of breast phantom for practicing ultrasound needle biopsy are professionally made and can contain different types of lesions [33–35]. However, they are mainly developed for ultrasound imaging and may not provide realistic haptic feedback. None of these products contains a fat tissue layer to simulate the multi-layer structure of the human breast. More importantly, the commercial phantom products are unaffordable (more than USD 150 per set) for most hospitals as a training tool and are not available in all countries.

A comprehensive analysis of the aforementioned tissue-mimicking phantoms is provided in Table 1. Turkey and chicken breast phantoms are cheap (about USD 15) and can be obtained easily [14,15]. While acquiring turkey/chicken breasts is simple, extra steps, such as cleaning and thawing, can be troublesome and not user friendly. Gelatin-based phantoms are also easy to prepare and cheap (less than USD 20) [12,16–24]. This type of phantoms is currently not well studied in terms of its tunability of acoustic and mechanical properties and a way to make it a multilayer structure. Gelatin-agar- [25–27], paraffin-gel wax- [28], PVC- [29–31] and silicone rubber-based [32] phantoms are considered as more advanced types of phantoms that can closely resemble acoustic and mechanical properties of human tissues. These phantoms are adjustable in terms of acoustic and mechanical properties and capable of being made in a multilayer structure. The gelatin-agar based phantoms were also shown to mimic various types of lesions [25–27]. However, these advanced phantoms all require a much more complex fabrication process, which can involve procedures of mixing multiple materials, long preparation time, long waiting time for materials to set/cure in middle steps and high-temperature heating (180–200 °C). The cost of the materials needed for the advanced phantoms (USD 60 and above) is higher than turkey/chicken and gelatin-based phantoms. Commercial products are ready to use and have good contrast between background and target tissue in ultrasound imaging. However, they are very expensive and unaffordable by clinics. Moreover, they may not resemble acoustic and mechanical properties of human tissues and currently have no multilayer structure available.

Table 1. A comparison of existing methods and commercial products of tissue mimicking breast phantom.

Available Phantoms	Types	Fabrication Process	Cost	Tissue-Mimicking Capability
[14,15]	Turkey/chicken	Simple but extra preparation needed	Low	<ul style="list-style-type: none"> ◆ Geometry is limited ◆ Acoustic and mechanical properties are similar but not adjustable
[12,16–24]	Gelatin	Simple	Low	<ul style="list-style-type: none"> ◆ Acoustic and mechanical properties are adjustable but not well studied ◆ No various lesion types ◆ No multilayer structure
[25–27]	Gelatin-agar	Complex	Medium	<ul style="list-style-type: none"> ◆ Can resemble acoustic and mechanical properties ◆ Various lesion types ◆ Multilayer structure
[28]	Paraffin-gel wax	Complex	Medium	<ul style="list-style-type: none"> ◆ Can resemble acoustic and mechanical properties ◆ Various lesion types ◆ Multilayer structure

Table 1. Cont.

Available Phantoms	Types	Fabrication Process	Cost	Tissue-Mimicking Capability
[29–31]	PVC	Complex	Medium	<ul style="list-style-type: none"> ◆ Can resemble acoustic and mechanical properties ◆ Various lesion types ◆ Multilayer structure
[32]	Silicone rubber	Complex	Medium	<ul style="list-style-type: none"> ◆ Can resemble acoustic and mechanical properties ◆ Various lesion types ◆ Multilayer structure
[33–35]	Commercial product	Ready to use	High	<ul style="list-style-type: none"> ◆ Can resemble acoustic and mechanical properties ◆ Various lesion types ◆ Multilayer structure

Many phantom users have reported that the existing phantoms do not provide adequate discrimination for basic imaging characteristics (e.g., resolution and contrast resolution) [36]. The study also suggested that the existing methods and test objects remain unable to relate image quality to clinical performance. In that sense, the influence of fat is largely underestimated. Test objects do not generally show the type of artifacts that normally appear in real tissue, nor do they represent complex tissue structures [36].

Ultrasound plays a vital role in breast cancer screening and has been used to distinguish benign lesions from malignant lesions and provide guidance during interventional biopsies. Therefore, the ultrasound operator must be properly trained. This can be implemented by the use of anthropomorphic training phantoms. Gelatin-based phantoms [12,16–24] have the advantages of becoming a cost-efficient solution for the needle biopsy simulation training. Their acoustic and mechanical properties are adjustable but not well investigated yet. The existing low-cost gelatin-based phantoms all have simple geometry and construction and do not represent the human breast tissue structure [12,14–24]. Therefore, this study aims to develop a low-cost and easy-to-fabricate gelatin phantom embedded with simulated tumors that provide realistic haptic feedback. Test objects were constructed in three dimensions to obtain realistic ultrasound images. Additionally, mechanical and acoustic properties of the test objects characterized in this study are provided in this study as a reference for future research.

2. Materials and Methods

2.1. Breast Phantom Manufacture

A double-layered gelatin-based phantom consisting of malignant tumors, benign tumors and cysts was produced. Gelatin tissue samples were produced by tuning the concentration of gelatin until its Young's modulus was similar to that of fat or glandular tissues. The simulated tumors were chosen on the basis of feedback from an experienced doctor to provide a realistic haptic feedback force during core needle placement.

Molds: Two hemisphere-shaped molds with different diameters, 90 mm (mold A) and 120 mm (mold B), were designed using the computer-aided design software SolidWorks (SolidWorks 2018; Dassault Systèmes SolidWorks Corporation), as shown in Figure 1. The molds were manufactured through three-dimensional printing using polylactide.

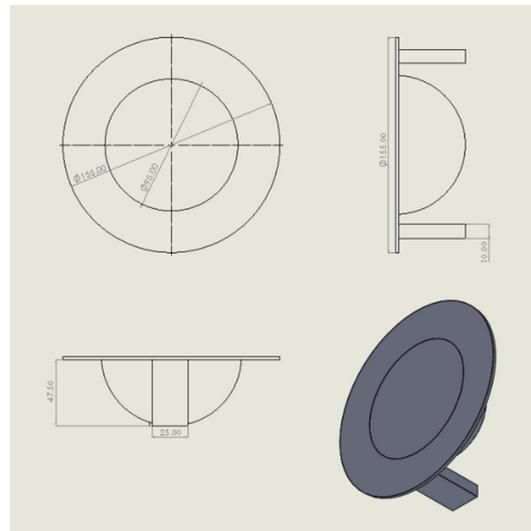


Figure 1. Three-dimensional engineering drawing of mold A). Unit: mm.

Simulated tumors: A rubber glove finger filled with colored solution was used to simulate cysts with a diameter of approximately 20 mm. Benign tumors were simulated using regularly shaped dried sweet potato and dried agar konjac with a diameter of 10 mm. The malignant tumor, which is the target of needle biopsy, was simulated using a pickled shallot carved into an irregular shape.

Glandular tissue: Gelatin powder (40 g) was dissolved in 200 mL of 70 °C tap water. The solution was mixed at 60 rpm for 5 min. The air bubbles were removed. Red and blue food coloring was added to give the gel solution an opaque appearance. The gel solution was poured into mold A until it was 90% full to simulate the breast contour. The gel solution was refrigerated at 4 °C for 30 min until it reached a semi-molten consistency. The simulated tumors (Figure 2a) were placed shallow in the mold. The gel solution was poured into the mold again until it was fully filled to cover the simulated tumors. The semi-molten gel was then refrigerated for another 2 h. The completely solidified glandular tissue was removed from the mold and prepared for use later.

Fat tissue: Gelatin powder (15 g) was dissolved in 300 mL of 70 °C tap water. The solution was mixed at 60 rpm for 5 min. Air bubbles were removed. Red and blue food coloring was mixed in to give the gel solution an opaque appearance. A height of 12.5 mm from the base of mold B was marked. The gel solution was poured into mold B up to the marked line (Figure 2b). The gel solution was refrigerated for 30 min at 4 °C. Solidified glandular tissue from mold A was placed on top of the solidified gel in mold B and it was made sure that the space between mold B and the glandular tissue was uniform (12.5 mm for spacing distance), as depicted in Figure 2b. Gel solution was poured into the mold again until the uniform space between mold B and the glandular tissue was fully filled. The gel solution was refrigerated for another 4 h until it had completely solidified. A successfully developed multilayered breast phantom embedded with simulated tumors is shown in Figure 2c.

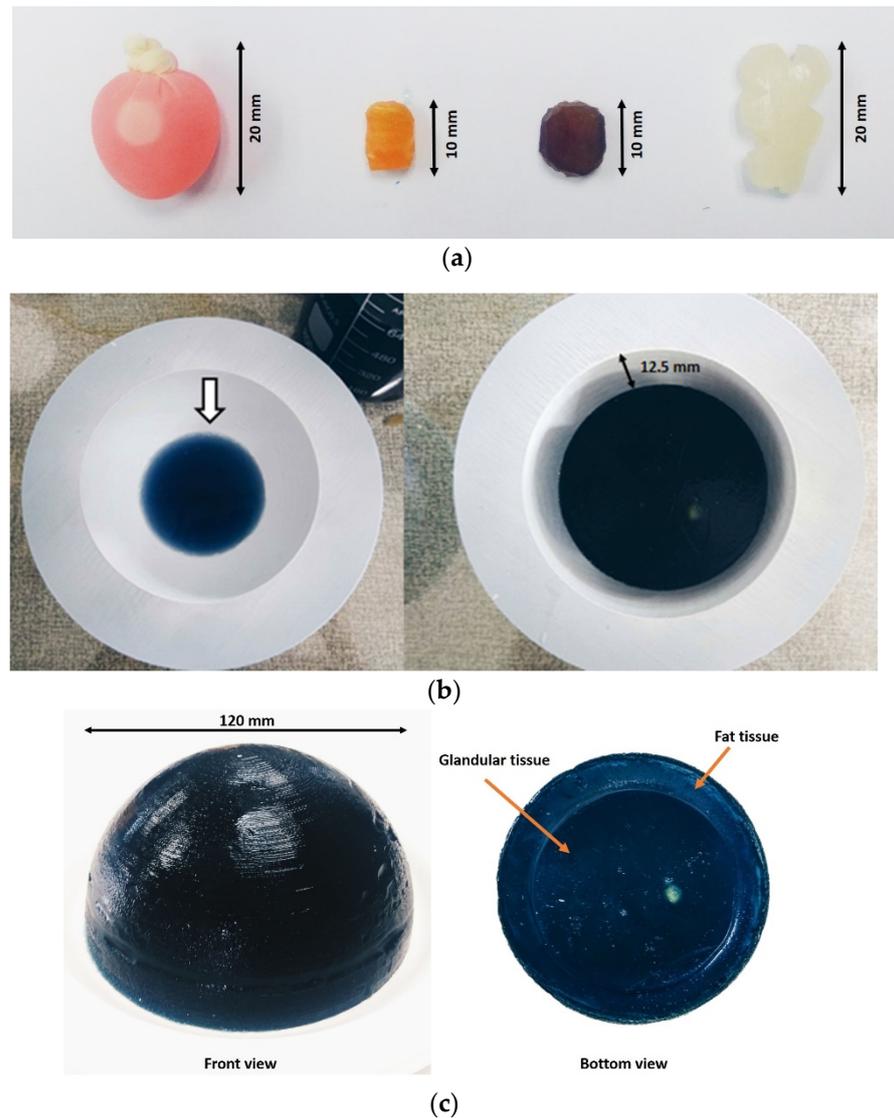


Figure 2. (a) Rubber glove finger filled with colored solution, dried sweet potato, dried agar konjac and carved shallot were used to simulate tumors (from left to right); (b) gel solution was poured until the line mark (indicated by black hollow arrow) located at a height of 12.5 mm from the base (left) and spacing distance of 12.5 mm between the solidified glandular tissue and mold B (right); (c) gelatin-based phantom which consists two layers with different stiffness and embedded with simulated tumors.

2.2. Mechanical Property Characterization

Cylindrically shaped gelatin tissue samples (wt. 16.67% and wt. 4.76%) with 76-mm diameter and 25-mm height were fabricated and tested to characterize their mechanical behavior under deformation. The indentation test was conducted at room temperature (24 °C) by using MTS INSIGHT-1 to obtain the relationship between the compressive force and displacement [37]. An indenter of 12 mm in diameter moved downward with a velocity of 0.5 mm/s until a depth of 6 mm was reached while the force and displacement were recorded. The Young's modulus (E) of the gelatin tissue sample was calculated as follows [37]:

$$E = \frac{(1 - \nu)^2 F}{2ak} \frac{1}{w} \quad (1)$$

where F is the force applied to the indenter at the maximum indentation depth, ν is the Poisson's ratio of the sample, w is the indentation depth, a is the radius of the indenter

and κ is a nondimensional parameter, which can be defined by a given combination of ν , a/h and w/h (h is the thickness of sample). The development of this equation can be found in [37]. In our experimental setup, κ was calculated as 1.3624 according to the parameter table also provided in [37], given that the Poisson's ratio of the gelatin tissue sample was approximately 0.5, a/h was 0.24 and w/h was 4%.

2.3. Acoustic Property Characterization

The acoustic testing system comprised a pulse receiver (Model 5072PR; OLYMPUS), a three-axis motor stage, a data acquisition card (PXI-5152; National Instruments) and the programming environment LabView (Figure 3). A broadband immersion transducer with frequencies centered at 5 MHz was used in this system.

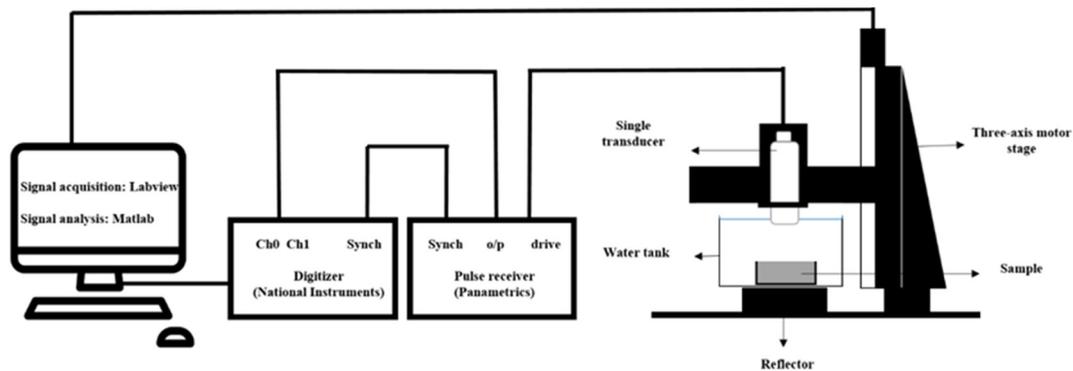


Figure 3. Scanning acoustic microscope (SAMA) system.

The single transducer worked as both a transmitter and receiver (pulse-echo approach) to measure the speed of sound, attenuation coefficient, and relative backscatter power of the sample. The measurements were conducted in a degassed-water-filled tank, the glass bottom of which acted as a reflector plane. The three-axis motor stage accurately positioned the transducer in the tank to focus on the reflector. The ultrasonic pulse was transmitted through the water to the reflector. The transducer received the reflected pulse, and the data were saved and analyzed in MATLAB R2018b. For each measurement of a sample, two data sets were obtained by scanning the reflector with and without the sample placed between the transducer and reflector (reference data and sample data, respectively). Three measurements were performed on each sample. All acoustic measurements were performed in degassed water at room temperature of 24 °C.

The time interval between the peaks of the radio frequency pulses was computed using MATLAB. A Perspex mold was placed inside the water tank, between the transducer and reflector, when the sample was not in place. The following equation was used to calculate the speed of sound of the sample [38]:

$$c_m = \left(\frac{T_w - T_m}{t_2 - t_1} + 1 \right) c_w \quad (2)$$

where c_w is the speed of sound in water measured by scanning the reflector plane at 1 mm height differences, as illustrated in Figure 3; T_m and T_w are the travel times with and without the sample in the propagation path of the pulse signal obtained from the sample and reference data, respectively; and t_1 and t_2 are the travel times of the pulse signal from the transducer to the front and rear faces of the sample, respectively. The derivation of this equation can be referred to [38].

The logarithmic difference between the spectra was used to calculate the attenuation coefficient, α (dB/cm), as shown in Equation (3) [39], where d is the thickness of the sample

and $A(f)$ and $A_0(f)$ are the magnitude spectrum of the sample and reference at frequency f , respectively.

$$\alpha(f) = -\frac{20}{2d} \log_{10} \frac{A(f)}{A_0(f)} \quad (3)$$

A backscattered radio frequency (RF) signal was captured between the front face of the sample and reflector plane for backscatter power measurement. Welch's method was used to estimate the spectral power density and obtain the normalized distribution of power per unit frequency to the total received power in the backscattered RF signal. The relative backscatter power of the sample at frequency f , $\mu(f)$, was calculated using the reference power spectrum, $P_0(f)$, of the reference RF signal as follows [40]:

$$\mu(f) = -10 \log_{10} \frac{P(f)}{P_0(f)} \quad (4)$$

2.4. Breast Hantom Validation Workshop

A workshop was organized to evaluate the effectiveness of the developed single-layered phantom in improving participants' core needle biopsy skill (Figure 4a). A clinical ultrasound system with an 8 MHz high-frequency linear probe, core needles and a gelatin-based breast phantom (Figure 4b) were prepared. Six participants with different experience levels were invited to perform preinstructional biopsy. The including criteria was physicians who are in their residency training, fellows, or attendings. The including criteria was physicians who are in their residency training, fellows, or attendings. The workshop has no specific excluding criteria. The participants were asked to take an experience level questionnaire (Appendix A) to determine if they were inexperienced, moderately experienced, or experienced. We ensured that all three levels of participants were recruited in this workshop. An experienced doctor then delivered a hands-on tutorial to the participants. The participants were given 10 min to practice the biopsy as many times as desired. A postinstructional biopsy was then performed by the participants after their practice session.

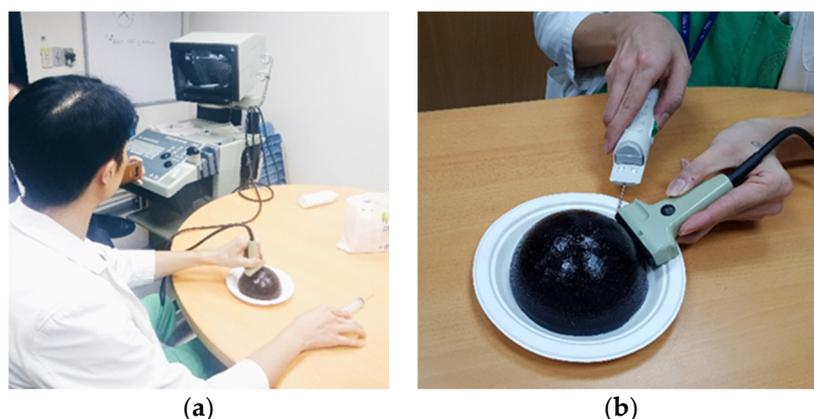


Figure 4. (a) Workshop for evaluating the efficiency of the phantom in improving core needle biopsy skill of participant. (b) Single-layered gelatin-based phantom (glandular tissue embedded with simulated tumors).

At the beginning of the workshop, the participants' levels of experience with ultrasound-guided core needle biopsy were assessed through three questions, resulting in a score range of 0–7. The participants were then categorized as inexperienced (score of 0), moderately experienced (1–4) or experienced (5–7), see Appendix A.

The effectiveness of the gelatin-based breast phantom at improving the participants' confidence in performing challenging ultrasound-guided core needle biopsy was assessed through a self-assessment questionnaire (Appendix B). Before the simulation training, each participant completed a questionnaire scored using a 10-point Likert scale to assess his or

her confidence in performing the ultrasound-guided breast biopsy without causing chest wall injury (Appendix C).

During the practical session, a participant's skill level of performing core needle biopsy was evaluated by comparing their preinstructional and postinstructional scores. A total of two points could be awarded for each needle biopsy operation if the biopsy was found to be a success in ultrasound imaging (+1) and a sufficient portion of the simulated malignant tumor had been retrieved in the biopsy needle (+1). However, a through-and-through puncture or penetration of the phantom backing was considered a chest wall hit, which resulted in the deduction of one point (−1). The participants were encouraged to perform as many practice biopsies as necessary before and after instruction. The percentage score was the total score of the participant divided by the highest possible score based on the number of biopsies performed. The percentage scores of participants before and after instruction were compared. The percentage mean scores of preinstructional and postinstructional tests were plotted on standard distribution curves.

After the simulation training, each participant repeated the questionnaire to assess their confidence in performing the ultrasound-guided breast biopsy. The satisfaction of the participants with the gelatin-based breast phantom was evaluated. Feedback was collected regarding the ultrasound image quality produced by the phantom and haptic feedback of the phantom that the participants received during core needle placement (Appendices D and E). Through this survey, the aspects of the phantom that residents valued the most could be better understood.

A further study on the multilayered gelatin-based phantom (fat tissue, glandular tissue embedded with simulated tumors) was conducted. The ultrasound images of embedded objects and simulated tissue layers were examined. The user feedback was also collected.

3. Results

3.1. Mechanical and Acoustic Property Characterization

The mechanical and acoustic properties of the gelatin-based phantom and its simulated tumors were investigated. Gelatin tissue samples with wt. 16.7% and wt. 4.76% were fabricated to simulate glandular tissue and fat tissue, respectively. Force and displacement graphs for gelatin tissue samples were acquired from indentation tests performed at room temperature (24 °C). The Young's moduli of the glandular and fat gelatin tissue samples were 15.4 and 2.3 kPa, respectively, which fall reasonably in the ranges for real normal fibroglandular tissue and normal fat tissue, as listed in Table 2 [9]. Moreover, the difference in stiffness between these two types of tissues could be distinguished. The speed of sound, attenuation coefficient and relative backscatter power of each sample were measured at a frequency of 5 MHz at room temperature. The range of acoustic properties discovered in the samples is displayed in Table 3. It should be explained that the ultrasound relative backscatter power value is a ratio function of the difference in acoustic characteristic impedance between the medium (water) and target tissue (sample) and the acoustic characteristic impedance is determined by the density of tissue multiplied by the speed of sound. Hence, the negative relative backscatter power value in the table indicates acoustic impedance of the sample is relatively low compared to the water.

Table 2. Mechanical and acoustic properties for fat tissue, glandular tissue and tumor from literature review [9].

Breast Tissue Composition	Young's Modulus (kPa)	Speed of Sound (m/s)	Attenuation Coefficient (dB/cm)
Normal fibroglandular tissue	0.73–271.8	1553 ± 35	2.0 ± 0.7 at 7 MHz
Normal fat tissue	0.69–24	1479 ± 32	0.6 ± 0.1 at 7 MHz
Malignant lesions	6.41 ± 2.86	1550 ± 35	1.0 ± 0.2 at 7 MHz

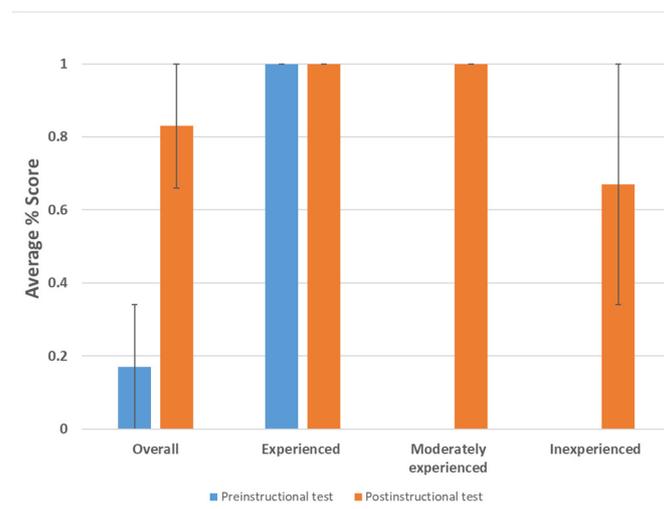
Table 3. Experimental results of mechanical and acoustic properties for simulated glandular tissue, fat tissue and tumor.

Sample	Young's Modulus (kPa)	Speed of Sound (m/s)	Attenuation (dB/cm)	Relative Backscatter Power (dB)
Glandular tissue	15.4	1684.26 ± 36.16	2.69 ± 0.07	3.11 ± 0.18
Fat tissue	2.3	1534.49 ± 1.22	2.34 ± 0.03	0.49 ± 0.10
Rubber glove with colored solution	-	1506.50 ± 6.07	4.50 ± 0.49	-0.46 ± 0.70
Dried sweet potato	-	1475.50 ± 17.82	4.12 ± 0.20	12.62 ± 0.48
Dried agar konjac	-	1428.49 ± 1.81	3.46 ± 0.54	3.04 ± 0.26
Shallot	-	1503.83 ± 1.19	6.98 ± 0.11	7.21 ± 0.15

3.2. Breast Phantom Validation Workshop

Single-layered gelatin-based phantoms (glandular tissue embedded with simulated tumors) were evaluated by six participants in the validation workshop. All the participants completed the pretraining and posttraining questionnaires. The participants ranged from trainees to experienced doctors, with varying levels of experience in ultrasound-guided biopsy: 50% ($n = 3$) of the participants were inexperienced, 33% ($n = 2$) were moderately experienced and the remaining 17% ($n = 1$) were experienced.

The mean preinstructional score of the participants was 17% (SD 17%). The mean postinstructional score was 83% (SD 17%), in which an overall improvement of 67% was achieved (Figure 5). Among individual groups, the experienced group performed perfectly before and after the instruction; all subjects in the moderately experienced group showed an improvement from 0% to 100%; two of the three inexperienced subjects also improved from 0% to 100%, while one remained at 0%. No chest wall hits were found in any group in the preinstructional and postinstructional tests.

**Figure 5.** Pre-instructional and post-instructional test results.

Overall, the confidence level of all participants in the workshop substantially increased. A comparison between the pretraining and posttraining evaluation scores is shown in Figure 6. Among individual groups, the experienced group improved the confidence level from 80% to 90%; the moderately experienced group showed an improvement from 55% (SD 5%) to 85% (SD 5%); the inexperienced group improved from 20% (SD 10%) to 47% (SD 20%).

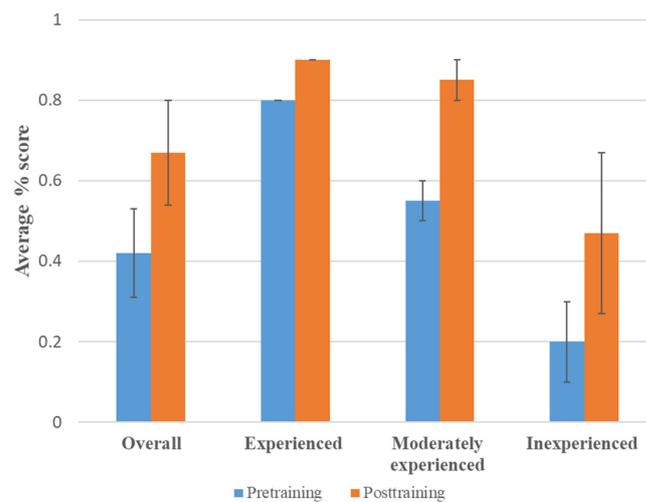


Figure 6. Survey results for pre-training and post-training confidence level of the participants ($n = 6$) who participated in the US-guided core needle biopsy.

The results of the survey (Table 4) showed that, overall, the developed phantom satisfied the participants. Furthermore, 83% ($n = 5$) of the participants agreed that the ultrasound image quality produced by the breast phantom was excellent or good. However, only 17% ($n = 1$) of the participants claimed that there was room for improvement for the haptic feedback they received during the placement of the core needle into the breast phantom. In this survey, the aspects of the breast phantom that the participants valued the most were investigated. The most valuable aspects were ultrasound image quality (25%), haptic feedback (25%), ease of use (25%), cost (15%) and design (10%).

Table 4. Survey on single-layered gelatin-based breast phantom.

Survey (Single-Layered Phantom)	Number of Respondents (Total $n = 6$)				
	Excellent	Good	Neutral	Poor	Very Poor
1. Overall how satisfied would you rate the developed phantom?	2 (33%)	3 (50%)	1 (17%)	-	-
2. How was the ultrasound image quality produced by the phantom?	1 (17%)	4 (66%)	1 (17%)	-	-
3. Was the haptic feedback you received during the placement of core needle into the phantom was a realistic feel?	1 (17%)	2 (33%)	2 (33%)	1 (17%)	-

A further study on the multilayered gelatin-based phantom (fat tissue, glandular tissue embedded with simulated tumors) was conducted (Table 5). Example ultrasound images of the tumors embedded in the gelatin-based phantom are shown in Figure 7a–d. All participants agreed that the ultrasound image produced by the multilayered breast phantom was similar to that of actual breast fat tissue. The artefact caused by the boundary between the fat and glandular tissues could be clearly visualized (Figure 7e). Moreover, all the participants also claimed that the haptic feedback they received during placement of the core needle into the multilayered gelatin-based phantom was more realistic than that for the single-layered phantom.

Table 5. Survey on multilayered gelatin-based breast phantom.

	Survey (Multilayered Phantom)	Number of Respondents (Total $n = 6$)	
		Yes	No
1.	Was the ultrasound image produced by the multilayered phantom similar to the fat tissue for real breast?	6 (100%)	-
2.	Was the haptic feedback of multilayered phantom you received during the placement of core needle into it was more realistic than the single-layered gelatin based phantom?	6 (100%)	-

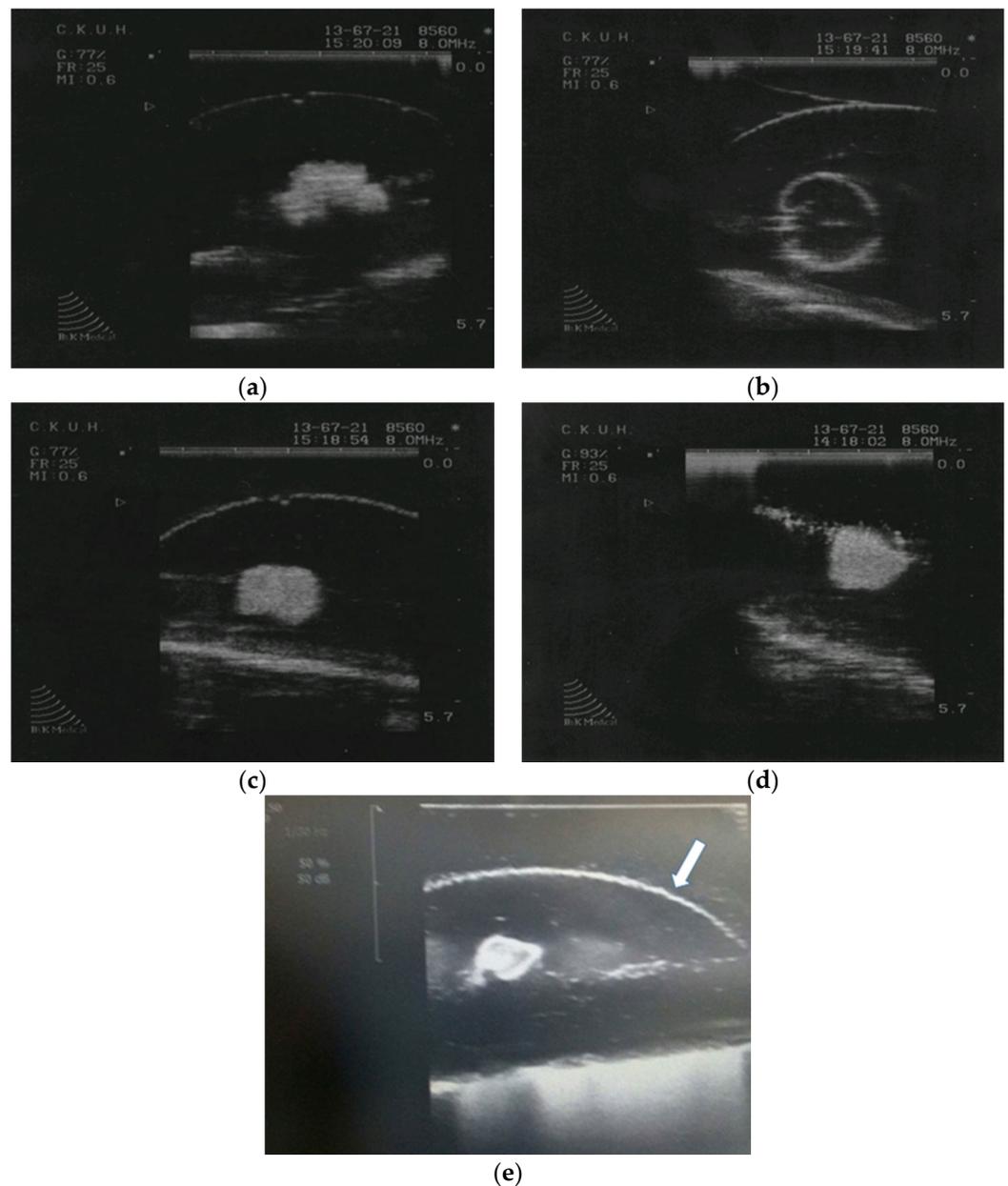


Figure 7. Ultrasound images for embedded tumors and artefact in multi-layered gelatin-based phantom. (a) Malignant tumor (Shallot); (b) Cyst (Rubber glove finger filled with colored solution); (c) Benign tumor (Dried agar konjac); (d) Benign tumor (Dried sweet potato); (e) Artefact caused by the boundary between the fat and glandular tissues is indicated by the white arrow.

4. Discussion

The learning curve for performing ultrasound-guided breast biopsy could be overcome by performing simulation training using a breast phantom. Considerable improvements were achieved in the moderately experienced and inexperienced groups through training using the developed breast phantom. Compared with the preinstructional performance, the postinstructional score revealed a 4.88-fold improvement (Figure 5), with the largest improvement achieved in the moderately experienced group. The experienced group, comprising one participant who had prior training in ultrasound-guided biopsy and frequently performed office-based ultrasound in his or her practice already had the highest percentage score in the preinstructional test and this was unchanged in the postinstructional test.

The breast-phantom-based training was well received by the participants and significantly increased their confidence in performing the ultrasound-guided breast biopsy. The outcome could be seen in the improved percentage mean scores of the postinstructional test for the moderately experienced and inexperienced groups.

Overall, the gelatin-based breast phantom developed in this study satisfied the participants. The Young's modulus of the phantom tissue samples measured from the indentation test fell reasonably in the reported ranges of the Young's modulus for real normal fibroglandular tissue and normal fat tissue [9]. Simulated glandular tissue has higher Young's modulus compared to the simulated fat tissue; hence, the glandular tissue will produce a stiffer haptic feedback. However, our survey suggested that there should be a larger difference in haptic feedback between benign and malignant tumors, which can be understood as the Young's moduli in the literature having large variation.

Acoustic parameters and ultrasound images for our simulated tumors have been provided as a reference for future studies. All the acoustic parameters were measured with 5 MHz single element transducer (in-house developed ultrasound system). Meanwhile, the ultrasound images were captured using the clinical available ultrasound system (8 MHz) in hospital to confirm the visual outcome. Acoustic parameters such as speed of sound are dependent on the sample's density and acoustic impedance; hence, the frequency of the transducer used will not affect the results. Moreover, our study showed that samples with a higher Young's modulus would pose a higher value in acoustic parameters (i.e., speed of sound, attenuation coefficient and relative backscatter power) and appears brighter in ultrasound imaging.

The participants could differentiate between the shapes of cysts and benign and malignant tumors in ultrasound images. The multilayered gelatin-based breast phantom produced an ultrasound image similar to that produced by the fat tissue in real breasts. Artifacts caused by the boundary between the fat and glandular tissues in a real breast were successfully duplicated in our multilayered gelatin-based phantom (Figure 7e). Acoustic properties and ultrasound images for our simulated tumors have been provided as a reference for future studies.

Numerous low-cost DIY breast phantoms have been proposed. Turkey/chicken breast embedded with peas and gelatin-based phantoms are the most commonly used models in ultrasound-guided breast biopsy simulation training [12,14–24]. While turkey and chicken breast can be easily obtained from the supermarket, their preparation process, such as cleaning and thawing, can be troublesome and is not user friendly. Different types of ready-to-use materials have been used to simulate tumors. Aspects such as shape, brightness and contrast of the embedded simulator in ultrasound images are prioritized when selecting a material, but the haptic force produced by the embedded simulator during needle insertion may be overlooked. We were also unable to find a low-cost DIY breast phantom that contains all three types of simulators: A benign tumor, malignant tumor and cyst. Moreover, we only found one in these low-cost breast phantoms that has different layers of breast tissue, but the lack of simulated tumors makes this phantom unsuitable for breast biopsy training [26]. Our gelatin-based breast phantom is a low-cost and multilayered breast phantom embedded with simulated benign tumors, malignant tumors and cysts for breast biopsy simulation training. The total cost of our phantom including the mold

fabrication was approximately USD 7. The price of our training phantom is thus extremely low compared with that of the existing methods and commercially available ultrasound-guided breast phantoms.

Environmental temperature control is crucial to maintaining the stability of a gelatin-based phantom. The Young's modulus of a gelatin-based phantom decreases as the temperature increases. The indentation tests were conducted at 24 °C and the results showed that the Young's modulus of the components in the phantom fell reasonably within the reported ranges. The temperature of the breast phantoms used in the validation workshop could not be ideally controlled. Each phantom was kept in a cooler until being offered to a participant to operate. In this scenario, the temperature of each phantom was measured as 19 °C immediately before the operation. Based on the results of the indentation tests and validation, we recommend that users handle the proposed gelatin-based phantom at 19 °C–24 °C. A gelatin sample with a low concentration, such as a fat-tissue-mimicking sample, will start losing its original form when the sample temperature exceeds 25 °C.

This study certainly has limitations. Our participants were few and from a single academic center. Moreover, some facets of real-world experience were not reproduced in our simulation. For instance, the orientation of the patient cannot be adjusted as easily as that of the small training phantom during the biopsy procedure. A gap between the improved performance of participants' biopsy skill level after simulation training and that in the clinical setting may therefore appear. However, our findings can serve as a basis for proving that an unmet clinical need exists and training involving our breast phantom is efficient in improving the confidence and skill level of residents at performing needle biopsy. A follow-up evaluation must be performed to determine whether the training outcome is related to the performance of the participants in the real clinical setting.

5. Conclusions

This study provides a protocol for developing a low-cost and easy-to-fabricate multilayered gelatin-based breast phantom embedded with various types of lesions. The mechanical properties of the gelatin phantom and embedded simulated tumors were studied to ensure that realistic needle-insertion haptic feedback is provided. The gelatin-based phantom enabled residents to improve their confidence level in performing ultrasound-guided needle biopsy. Simulation training on the breast phantom can enable residents to master the needle biopsy skill before advancing to performing procedures on patients. Complications can be reduced through training, especially when the ultrasound-guided biopsy procedure is performed by an inexperienced resident. Acoustic properties and ultrasound images for our simulated tumors are provided as a reference for future study.

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Informed Consent Statement: The consent to participate was informed verbally to all participants on the day of the breast phantom validation workshop. The workshop was to collect user feedback of operating needle biopsy on the developed breast phantom. The need for consent is waived by the IRB in Taiwan (Document No. 8800-4-04-008: educational assessment, teaching skills, or effectiveness evaluations conducted in a general teaching environment by anonymous or unrecognizable means).

Data Availability Statement: The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of Interest: The authors declare no conflict of interest.

Appendix A Participant's Experience Level Questionnaire

Please answer the following questions regarding your experience in using ultrasound guided biopsy. We appreciate your feedback.

1. Have you received previous training in ultrasound guided biopsy?
 - Yes, through training course/workshops
 - Yes, as a part of surgical training
 - No
2. How often do you perform office-based ultrasound in your practice?
 - Frequently
 - Rarely
 - Never
3. How would you rate your experience in performing ultrasound guided biopsies?
 - Frequently on patients
 - Infrequently on patients
 - Only on training phantoms
 - Never performed one previously

Thank you for taking the time to answer this survey.

Appendix B Participant's Core Needle Biopsy Skill Level Assessment

The practical test was evaluated by comparing the pre-instructional and post-instructional scores of the participant.

(a) Pre-instructional practical test assessment

1. Is the participant able to obtain the radiologic evidence of a successful biopsy?
 - Yes
 - No
2. Is there any procurement of material from the simulated lesion on the biopsy needle?
 - Yes
 - No
3. Is the successful biopsy without through-and-through puncture of the phantom or penetration of the phantom backing?
 - Yes
 - No

(b) Post-instructional practical test assessment

1. Is the participant able to obtain the radiologic evidence of a successful biopsy?
 - Yes
 - No
2. Is there any procurement of material from the simulated lesion on the biopsy needle?
 - Yes
 - No
3. Is the successful biopsy without through-and-through puncture of the phantom or penetration of the phantom backing?
 - Yes
 - No

Thank you for taking the time to answer this survey.

Appendix C Participant's Self-Assessment Questionnaire

The purpose of this study is to assess the effectiveness of gelatin based breast phantom in simulating challenging ultrasound guided core needle biopsy procedures. We would specifically like to assess your subjective confidence levels of performing challenging breast biopsy procedures before and after your simulation training on the breast phantoms. We appreciate your feedback.

On a 1 to 10 scale (1 equals no confidence; 10 equals great confidence). Please rate your pre-training and post-training confidence level in performing the ultrasound guided breast biopsy procedures without causing chest wall injury.

(a) Pre-training self confidence level assessment

Successfully performing an ultrasound guided core needle biopsy without causing chest wall injury.

1	2	3	4	5	6	7	8	9	10
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(b) Post-training self confidence level assessment

1	2	3	4	5	6	7	8	9	10
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Successfully performing an ultrasound guided core needle biopsy without causing chest wall injury.

Thank you for taking the time to answer this survey.

Appendix D Gelatin Based Breast Phantom Satisfaction

1. With regards to your experience with the gelatin based phantom in this workshop, how was the ultrasound image quality produced by the phantom?

- Very Poor
- Poor
- Average
- Good
- Excellent

2. With regards to your most recent experience with the gelatin based phantom, was the haptic feedback of phantom you received during the placement of core needle into the phantom was a realistic feel?

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

Please indicate the reason(s) if you strongly disagree or disagree.

3. What aspect(s) of this product that you value the most?

- Design
- Ultrasound image quality
- Haptic feedback
- Cost

- Ease of use
 - Other, please specify: _____
4. Taking into considerations of the features and benefits of the product itself, overall how satisfied would you rate the product?
- Very Dissatisfied
 - Dissatisfied
 - Neutral
 - Satisfied
 - Very Satisfactory

Would you please take a few minutes to describe why you are not satisfied with the product?

Thank you for taking the time to answer this survey.

Appendix E Multilayered Gelatin Based Breast Phantom Satisfaction

1. With regards to your experience with the multilayered gelatin based phantom in this workshop, was the ultrasound image produced by the phantom similar to the fat tissue for real breast?
 - Yes
 - No
2. With regards to your most recent experience with the multilayered gelatin based phantom, was the haptic feedback of phantom you received during the placement of core needle into it was more realistic than the single layer gelatin based phantom?
 - Strongly Disagree
 - Disagree
 - Neutral
 - Agree
 - Strongly Agree

Please indicate the reason(s) if you strongly disagree or disagree.

3. What aspect(s) of this product that you value the most?
 - Design
 - Ultrasound image quality
 - Haptic feedback
 - Cost
 - Ease of use
 - Other, please specify: _____
4. Taking into considerations of the features and benefits of the product itself, overall how satisfied would you rate the product?

- Very Dissatisfied
- Dissatisfied
- Neutral
- Satisfied
- Very Satisfactory

Would you please take a few minutes to describe why you are not satisfied with the product?

Thank you for taking the time to answer this survey.

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