Building Ultrasound Phantoms With Modified Polyvinyl Chloride

A Comparison of Needle Insertion Forces and Sonographic Appearance With Commercial and Traditional Simulation Materials

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Introduction: Training using ultrasound phantoms allows for safe introduction to clinical skills and is associated with improved in-hospital performance. Many materials have been used to simulate human tissue in phantoms including commercial manikins, agar, gelatin, and Ballistics Gel; however, phantom tissues could be improved to provide higher-fidelity ultrasound images or tactile sensation. This article describes a novel phantom tissue mixture of a modified polyvinyl chloride (PVC) polymer, mineral oil, and chalk powder and evaluates needle cutting and ultrasonic properties of the modified PVC polymer mixture compared with a variety of phantom tissues.

Methods: The first experiment measured axial needle forces of a needle insertion into nine phantom materials, including three formulations of modified PVC. The second experiment used a pairwise comparison survey of ultrasound images to determine the perceived realism of phantom ultrasound images.

Results: It was found that the materials of Ballistics Gel and one of the PVC mixtures provide stiff force feedback similar to cadaver tissue. Other phantom materials including agar and gelatin provide very weak unrealistic force feedback. The survey results showed the PVC mixtures being viewed as the most realistic by the survey participants, whereas agar and Ballistics Gel were seen as the least realistic.

Conclusions: The realism in cutting force and ultrasound visualization was determined for a variety of phantom materials. Novel modified PVC polymer has great potential for use in ultrasound phantoms because of its realistic ultrasound imaging and modifiable stiffness. This customizability allows for easy creation of multilayer tissue phantoms.

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Ultrasound phantoms are widely used for the training of medical and surgical procedures such as central venous catheterization (CVC). Training with phantoms allows for a safe introduction to a variety of clinical skills and is associated with improved in-hospital performance.[1,2] According to a review of upper torso manikin simulators by Farjad Sultan et al,[3] the ideal manikin or phantom reproduces the texture and resistance of human tissue, has sufficient ultrasound penetration, is easy to reproduce and repair, is nonperishable, transportable, and affordable, and has clearly distinguishable targets. Realistic ultrasound imaging is needed to teach trainees how to identify target structures in a patient. Realistic needle forces during phantom training are important because they improve the haptic senses of the trainees.

In attempt to fulfill these needs, a wide variety of artificial ultrasound phantoms have been developed. Commercial simulators such as the CAE Healthcare (Sarasota, FL) Blue Phantom and Kyoto Kagaku's (Kyoto, Japan) CVC Insertion Simulator are widely used. These are durable and can withstand dozens of needle insertions but cost between US $1000 and $5000 a unit. Low-cost organic-based phantoms such as agar and gelatin must be refrigerated, have short shelf lives and provide very weak needle force feedback to the user.[4,5] Another low-cost solution, Clear Ballistics (Fort Smith, AR) Ballistics Gel, does not decompose such as the organic-based solutions but has a low echogenicity, producing dark ultrasound images.[6,7]

The use of modified PVC for ultrasound phantoms was first proposed by Li et al[8,9] who used glass beads to increase echogenicity. A novel low-cost ultrasound phantom made from a mixture of polyvinyl chloride (PVC), diethyl hexyl adipate plasticizer softener, mineral oil, and chalk powder has been developed. The purpose of this article is to describe

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the method for creating this modified PVC phantom tissue with chalk powder and to compare the properties of this tissue against a variety of commonly used phantom materials. The first goal is to measure and compare the axial needle forces during a needle insertion into the different phantom tissues. The second goal is to administer a pairwise image comparison survey to experts in the ultrasound-guided CVC procedure to compare the ultrasonic properties of the materials. Finally, the discussion and conclusion sections describe the implications of the results as well as the strengths and weaknesses of the varying phantom materials.

METHODS

Creating Novel Modified PVC Phantoms

Four ingredients are used to create the novel modified PVC ultrasound phantom mixture: M-F Manufacturing (Fort Worth, TX) regular liquid plastic PVC polymer and diethyl hexyl adipate plasticizer softener, mineral oil, and chalk powder. Different ratios of PVC to softener to mineral oil are used to create phantoms with varying echogenicity and needle force characteristics. Mixture 1 used a volume ratio of 9:1:2 of PVC polymer to softener to mineral oil. Mixture 2 used a ratio of 11:0:1. Mixture 3 used a ratio of 3:0:1. All 3 mixtures added 1 g of chalk powder for every 150 mL of total mixture volume. Doping agents, such as chalk powder, are used to increase the echogenicity of a material and can be added to many phantom materials. The PVC, softener, and mineral oil are mixed thoroughly under a fume hood in a pot and slowly heated to approximately 175°C, stirring frequently to ensure even heating and homogenous mixing. When the material begins to thicken and turn from a milky white color to translucent, chalk powder is slowly added while stirring, taking care to minimize clumping of the powder. Once the material has turned translucent, it is removed from heat and poured into the desired phantom mold. Any required internal structures (such as silicone tubing to act as vessels) should be positioned in the phantom material before the material solidifies. The mold is then left to cool in room temperature. If multiple layers of modified PVC are desired, it is best to wait to pour the additional layer until after the previous layer has hardened, but while it is still warm. This improves adhesion between layers and prevents them from mixing. Finally, extract the solidified and cooled material to complete the phantom (see Table, Supplemental Digital Content 1, http://links.lww.com/SIH/A362; for a summary of these instructions).

The manufacturer of the PVC polymer recommends that ventilation, such as a vent or fume hood, is used during heating the material to minimize inhalation of vapor, which may cause minor irritation to eyes or skin when exposed to excessive amounts. A respirator is recommended for use in areas with restricted ventilation. It is also important to not heat the PVC polymer more than 235°C, which can cause the material to burn and decompose releasing toxic fumes.

Experimental Procedure

Two different experiments were conducted to compare the properties of the new PVC ultrasound phantoms against a variety of commonly used phantom materials. The first

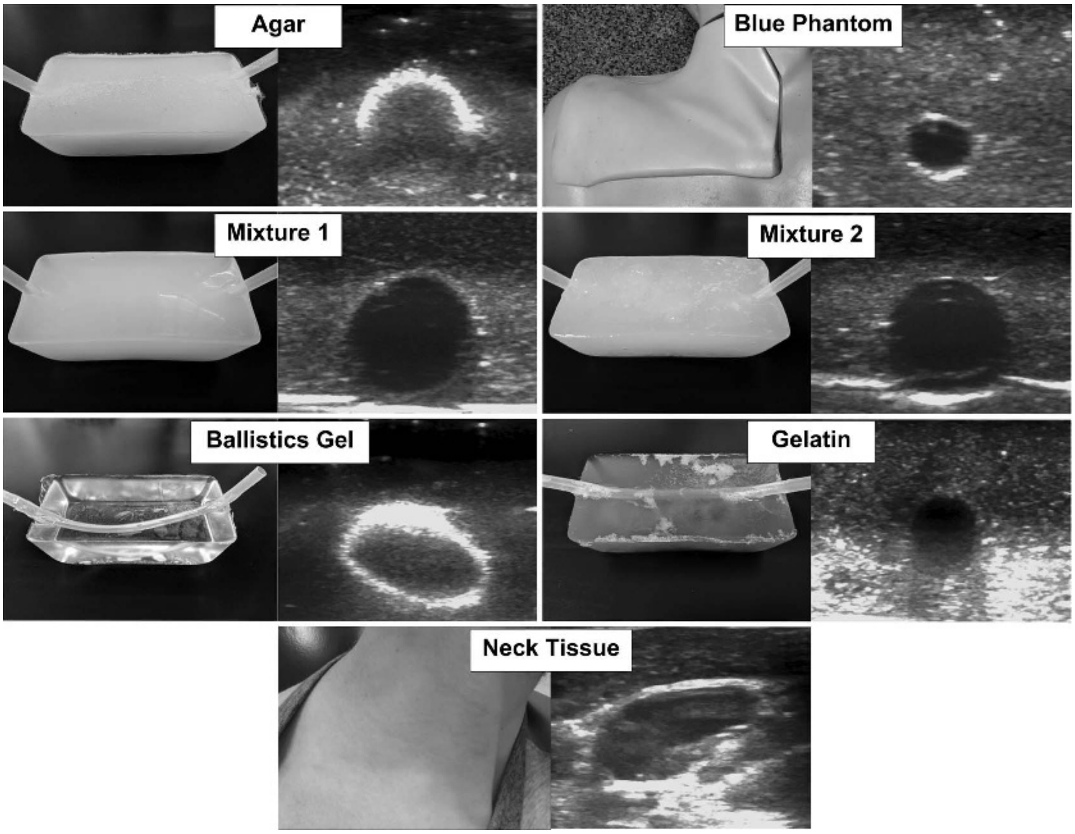

FIGURE 1. Materials used for ultrasound pairwise comparison testing. One of the two ultrasound images used for each material is shown. The ultrasound machine used was a GE Healthcare Logiq e with a gain set to 70, frequency of 10.0 MHz, and depth ranging from 3.0 to 4.5 cm. Focal zone was set to the center of the image. A GE 8L-rs linear vascular transducer was used to scan the material.

used an 18-gauge introducer needle (Teleflex, Wayne, PA) mounted to a linear actuator (Dunkermotoren, Bonndorf, Germany) to measure the axial force of a needle being inserted into phantom tissue. An ATI industrial automation (Apex, NC) Nano17 force transducer was placed in line with the needle to measure the axial needle force. The needle was inserted four times into the tissue at a steady rate of 10 mm/s and to a depth of 50 mm using the controlled velocity provided by the linear actuator. For each experimental insertion, the data acquisition equipment recorded the position and force during the entire insertion at a rate of 1000 samples/s. The following materials were tested: a Blue Phantom Ultrasound Training Model, Clear Ballistics' Ballistics Gel, agar, gelatin, and the three PVC mixtures proposed (Fig. 1). Needle insertions were also conducted with the Kyoto Kagaku CVC simulator, but due to shape of the phantom tissue samples, these were limited to a maximum depth of 40 mm. Methods for creating phantoms from Ballistics Gel, agar, and gelatin were acquired from commonly cited articles by Amini et al,[7] Bude and Adler,[4] and Earle et al,[5] respectively.[4,5,7]

Next, ultrasound image quality and realism of seven phantom materials, including the novel material proposed, were evaluated through a pairwise image comparison survey administered to 15 experts in ultrasound-guided CVC insertion. An expert in ultrasound-guided CVC is defined as someone who has conducted more than 50 ultrasound-guided CVC insertions.[10,11] The images of each material had the same dimension with the simulated vein centered in the image and identical ultrasound machine settings as shown in Figure 1. The ultrasound machine used was a GE Healthcare Logiq e with a gain set to 70, frequency of 10.0 MHz, and depth ranging from 3.0 to 4.5 cm. Focal zone was set to the center of the image. A GE 8L-rs linear vascular transducer was used to scan the material. Silicone rubber tubing with a 50 Shore A hardness, inside diameter of 0.25 inches, and outside diameter of 0.3125 inches were placed in the Ballistics Gel, agar, gelatin, and PVC samples to simulate the right internal jugular vein. The material of the tubing used in the commercial manikins is unknown. Tubing was filled with water to simulate blood. Experts in ultrasound-guided CVC insertion were presented with an identical set of 84 paired ultrasound images presented in a randomized order. Images were displayed side by side on a computer screen, and participants were asked to select which of the two images more closely resembles an ultrasound image of a right internal jugular vein or "no difference." For each pair, the image selected would receive a score of 1, whereas the other image would receive a 0. If "no difference" was selected, both images received a score of 0.5. The seven phantom materials compared were Blue Phantom Ultrasound Training Model, Clear Ballistics' Ballistics Gel, agar, gelatin, PVC mixtures 1 and 2, and an ultrasound image of living neck tissue from a volunteer patient.

Statistical Analysis

Statistical analysis for the first experiment, needle insertion force, included calculating the mean and the standard deviation, at depths of 5, 10, 16.6, 20, 30, 40, and 50 cm across four insertions in each of the tested materials. A measurement depth of 16.6 mm was chosen because this is the depth where the maximum axial needle force of 1.413 N occurred during a steady 17-mm needle insertion into cadaver neck tissue.[10]

For the second experiment, the pairwise ultrasound image comparison, a side by side comparison composed of two ultrasound images from each of the seven materials used in the experiment, was conducted. Images of the same material were not paired against each other. The results from the paired image data were then fit to a Bradley-Terry logit model with a 95% confidence interval to compare results relative to the cadaver tissue.[12]

RESULTS

As demonstrated in Figure 2, Ballistics Gel, Blue Phantom, and PVC mixture 2 tissues provided the greatest needle resistance and most closely resembled the resistance provided by

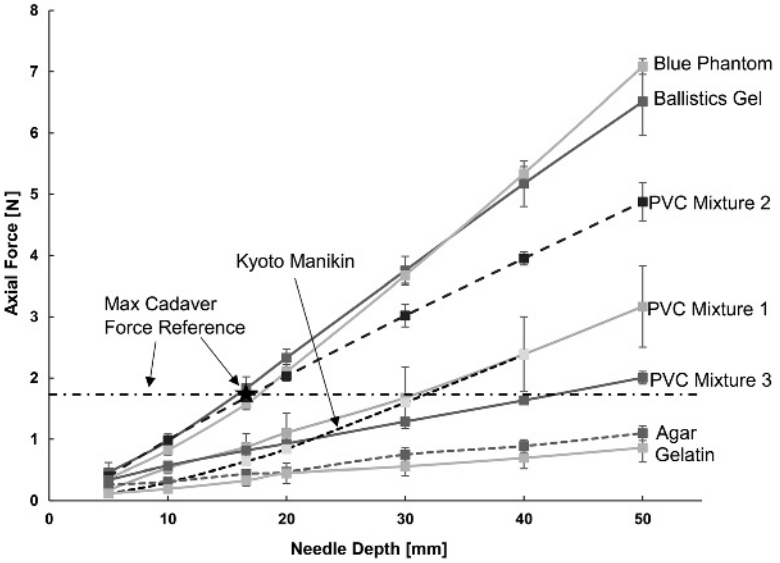

FIGURE 2. Average axial needle insertion force for seven ultrasound manikin materials. Star indicates maximum needle force during 17-mm cadaver needle insertion. Error bars indicate standard deviation (figure data are not continuous, lines used to increase visual clarity).

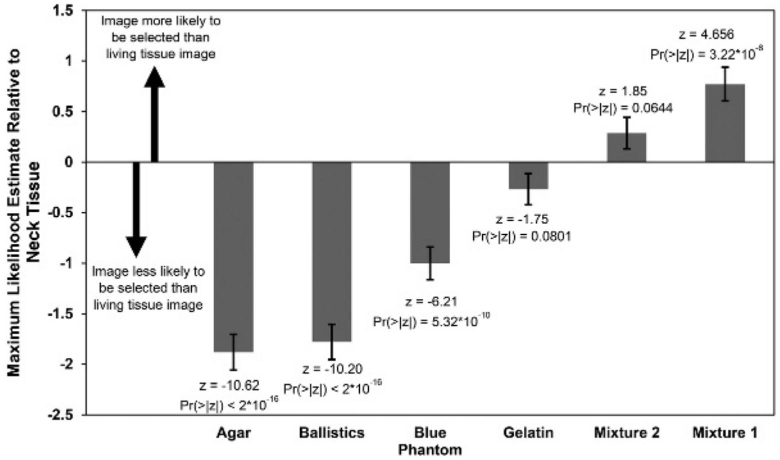

FIGURE 3. Final ranking results of the pairwise image comparison with the Bradley-Terry fitting parameters (λ) compared against a baseline fit parameter of 0 for living tissue.

cadaveric tissue at a depth of 16.6 mm. Gelatin and agar tissue phantoms showed the least resistance throughout the insertions. Increasing the amount of mineral oil in the PVC mixture decreases the resisting needle force in the PVC mixtures. Adding softener to the PVC also decreases the resistance.

The results of the pairwise comparison survey are shown in Figure 3 along with the maximum likelihood estimates of the fitting parameters of a Bradley-Terry logit-linear model (λ). A baseline fit of $\lambda = 0$ is applied to the living neck tissue for comparison. Images with a positive λ are more likely to be selected when pictured against living tissue, whereas images with a more negative λ are less likely to be selected when viewed against the living tissue. The best performing material overall was PVC mixture 1, which used a combination of both softener and mineral oil additives. No statistically significant difference in the frequency of expert identification was found between PVC mixture 2 and living tissue. The images produced by gelatin, Blue Phantom, Ballistics Gel, and agar were all statistically less likely to be chosen than images of the living tissue. The worst performing materials were the agar and Ballistics Gel.

DISCUSSION

The novel modified PVC mixtures outperformed traditional manikin materials. Force testing showed how the modified PVC mixtures can be altered to vary needle forces to be similar to cadaver neck tissue or softer tissues. The modified PVC mixtures also provided more realistic ultrasound images than the four other phantom materials tested and were viewed as similar to living tissue. In addition, the modified PVC mixtures are low cost. The cost of a 2000-mL phantom insert made from the modified PVC mixtures is approximately US $15 compared with thousands of dollars for a commercial phantom. Finally, although the modified PVC mixtures do develop a thin oily surface over time, the quality of the ultrasound images and needle force resistance does not degrade based on our continued experience with the material.

The results of the needle force and pairwise image comparison show the variety of strengths and weaknesses of the different commonly used phantom materials. For example, gelatin was viewed by experts to have significant similarities in ultrasound imaging but had much lower axial needle insertion force compared with cadaver tissue. Inversely, Ballistics Gel and the Blue Phantom both had similar force properties to cadaver tissue but had unrealistic ultrasound images. The worst performing material overall was the agar, which had both poor needle forces, and unrealistic ultrasound images. Surprisingly, both PVC mixtures 1 and 2 scored higher in ultrasound image realism than the living tissue. The ultrasound images of the two PVC mixtures were more uniform, with lower overall contrast between the higher echogenic (whiter) and lower echogenic (blacker), than the images taken from

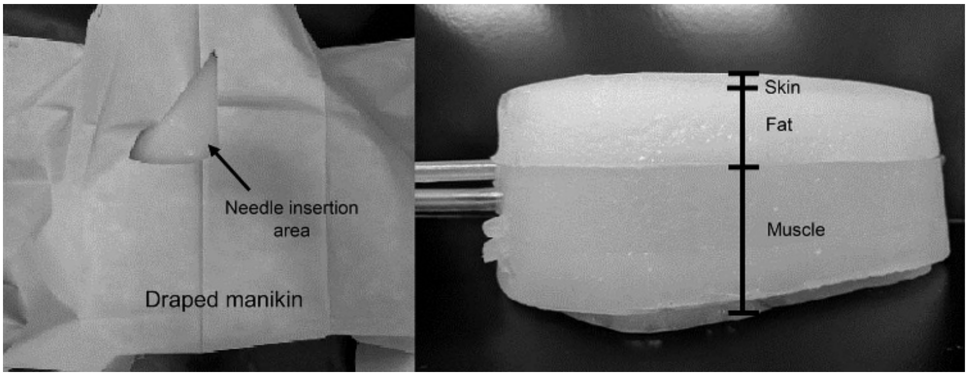

FIGURE 4. Custom obese upper torso central venous catheterization ultrasound manikin with modified PVC phantom insert (left) and side view of multilayered modified PVC phantom insert (right).

the volunteer patient. It is possible that the experts surveyed were expecting the living tissue images to have less contrast compared with the artificial images. Further research could explore why the images of the artificial tissue were observed to be more realistic than the images from the volunteer patient and what features in ultrasound images are experts expecting to find. When comparing all 14 ultrasound images individually, there was consistency among the results. The two highest scoring images overall were from PVC mixture 1, followed by the two images of PVC mixture 2. The two images of the living tissue came next, followed by the two from gelatin, two from Blue Phantom, two from Ballistics Gel, and two from agar. This consistency implies that the images captured were equally representative of the ultrasound visualization of the different samples.

The PVC mixture is more easily adaptable than the other phantom tissues tested. By changing the ratio of PVC to softener to mineral oil, needle insertion force can be adjusted. The amount of chalk powder can also be adjusted to affect the ultrasound echogenicity of the material. The use of less chalk powder will produce darker images because of reduced echogenicity. These adjustments allow for the easy creation of realistic multilayered phantoms as shown in Figure 4. Multilayered phantoms can be customized to represent different patient types such as obese or muscular patients. The ability to offer diverse patient scenarios is a significant strength of the modified PVC mixtures that cannot be offered by the other phantom materials tested. The PVC material was also found to be durable and easily repairable. Through repeated testing, it was found that the large multilayered tissue sample pictured in Figure 4 was able to withstand at least 10 needle insertions before needing to replace the tubing. Tubing replacement was also as simple as sliding the old tubing out of the material and sliding new tubing in. Overall, the novel modified PVC mixtures provide a combination of customizability and effectiveness that is superior to a wide variety of phantom tissue.

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