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● *Original Contribution*

PARAFFIN-GEL TISSUE-MIMICKING MATERIAL FOR ULTRASOUND-GUIDED NEEDLE BIOPSY PHANTOM

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Abstract—Paraffin-gel waxes have been investigated as new soft tissue–mimicking materials for ultrasound-guided breast biopsy training. Breast phantoms were produced with a broad range of acoustical properties. The speed of sound for the phantoms ranged from 1425.4 ± 0.6 to 1480.3 ± 1.7 m/s at room temperature. The attenuation coefficients were easily controlled between 0.32 ± 0.27 dB/cm and 2.04 ± 0.65 dB/cm at 7.5 MHz, depending on the amount of carnauba wax added to the base material. The materials do not suffer dehydration and provide adequate needle penetration, with a Young's storage modulus varying between 14.7 ± 0.2 kPa and 34.9 ± 0.3 kPa. The phantom background material possesses long-term stability and can be employed in a supine position without changes in geometry. These results indicate that paraffin-gel waxes may be promising materials for training radiologists in ultrasound biopsy procedures. (E-mail: vieira@if.ufg.br) © 2013 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Paraffin-gel waxes, Carnauba wax, Tissue-mimicking, Breast phantoms, Biopsy training, Ultrasound imaging, Elasticity.**

INTRODUCTION

Tissue-mimicking phantoms are commonly used for training sonographers and residents to improve the accuracy of breast lesion diagnosis. These phantoms have shape, size and acoustic proprieties equivalent to the biological tissue. Some tissue-mimicking materials (TMMs) investigated for ultrasound phantoms are agar based (Blechinger et al. 1988; Browne et al. 2003; Cannon et al. 2011; Culjat et al. 2010; de Korte et al. 1997), gelatin based (Blechinger et al. 1988; Culjat et al. 2010; de Korte et al. 1997; Madsen et al. 1978, 1982), condensed milk–based gel (Browne et al. 2003; Madsen et al. 1998), poly(vinyl alcohol) cryogel (PVA-C) (Culjat et al. 2010; Surry et al. 2004), and urethane rubber (Blechinger et al. 1988; Cannon et al. 2011; Culjat et al. 2010; de Korte et al. 1997; Ma et al. 2004; Madsen et al. 1978, 1982, 1998; Surry et al. 2004). Commercially available tissue-mimicking phantoms are made of urethane rubber (ATS Laboratories, Bridgeport, CT, USA), agarose with water and condensed-milk gel (Gammex-RMI, Middleton, WI, USA), and Zerdine (CIRS Inc., Norfolk, VA, USA).

Ultrasound-guided needle biopsy is a freehand and real-time image guidance technique that is commonly used for visualizing anatomic structures during a biopsy procedure (Harvey et al. 2000; Smith et al. 2001). Because of the complexity evolved in such procedure, a considerable amount of training is needed before performing it on a patient. This training stage is essential to improve the individual's ability to target the correct biopsy site and track the needle during the procedure, and also to remove a sample during the fine-needle aspiration (FNA) of lesions. Needle biopsy training helps reduce the duration of each biopsy, thus causing less trauma to the patient (Harvey et al. 1997; Nicotra et al. 1994) Breast biopsy phantom is a cost-effective training aid for physicians to develop the necessary confidence and skills to perform the biopsy procedure on a patient, with desirable care and tolerability. Therefore, it plays a major role during the ultrasound-guided needle biopsy training period.

This study presented paraffin-gel waxes as a novel tissue-mimicking material for ultrasound-guided biopsy

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training. The paraffin gels are derived from high-molecular-weight saturated aliphatic hydrocarbons obtained from crude petroleum. These gels are a transparent and soft compound composed of 95% mineral oil and 5% polymer resin (Lacerda 2004). Paraffin gels are used in a wide range of daily applications, most notably in the candle industry. Another material investigated was carnauba wax; here, it was used to control the contrast of the lesions in the ultrasound images. Carnauba wax is extracted from the Carnauba palm tree found in the northeast region of Brazil. This wax is used widely in the cosmetics, medicine, electronic component, and capsule industries and serves as a well-known car polish wax. Because of its low solubility in water, carnauba wax is evaporation-resistant, thus resulting in a highly durable material. Carnauba wax's melting point is 86°C, which is higher than the melting point of paraffin waxes, and it has the highest stiffness among the natural waxes (Shellhammer et al. 1997).

Breast phantoms made using gel waxes as the TMMs have several advantages compared with other gels. Paraffin-gel waxes, for example, do not dehydrate, are non-toxic, are not susceptible to bacterial attack, have a good chemical stability and can maintain their form for a long time in a broad range of temperatures.

In this study, paraffin gel was investigated as the base material of breast phantoms to mimic the consistency, form and acoustic texture of the human breast. Measurements of the speed of sound, attenuation coefficients and Young's modulus are reported.

MATERIAL AND METHODS

Breast phantom

The breast tissue phantom was formed from medium-density type (MDT) paraffin-gel wax (Gel Candle, São Paulo, Brazil); 4% w/w of glass microspheres (3M, Campinas, Brazil), ranging from 20 μm to 75 μm in diameter, with an average diameter of 45 μm, were embedded in the paraffin-gel wax. An image of the phantom is shown in Figure 1. The breast phantom was designed to have size and shape similar to the breast of an average patient in the supine position. The phantom has a height of 5 cm and a mean base diameter of 12 cm.

The background material was prepared using MDT paraffin gel with a density of 0.81 g/cm^3 and a melting point of 61.4°C. The TMM background was prepared by melting 610 g of MDT gel wax in a container with a controlled temperature of 80°C. After 20 min, a clear molten solution was obtained. The glass microspheres were then added to the material and continuously stirred to obtain a uniform dispersion. The solution was cooled to 64°C, and the molten material was poured into an aluminum mold in the shape of a hemispheric dome to mimic the mammary gland.

Fig. 1. Photograph of the paraffin-gel breast phantom.

The phantom was prepared in layers. First, a homogeneous layer was prepared in the nipple region, and then solid masses (described later) were placed randomly on this layer. After this, the whole phantom was covered with the same paraffin molten solution. While cooling, the breast mold was attached to a rotation apparatus at two revolutions per minute (2 rpm) to prevent gravitational sedimentation of the solid masses and to keep the glass powder distributed throughout the emulsion.

Abnormal masses

The solid masses were made using high-density type (HDT) gel, with density of 0.84 g/cm^3, which has a melting point of 82.8°C. The material for mimicking abnormal tissues was prepared using a mixture of HDT paraffin-gel wax, carnauba wax and glass microspheres with a diameter of 20–75 μm. The carnauba wax was used to control the level of ultrasound attenuation, and chalk powder was used as scatter medium because of its low gravitational sedimentation. The following ingredients were used to make the abnormal masses similar to cancer, fibroadenoma and cysts:

- Benign mass were prepared with 4% w/w of granular semi-refined paraffin wax (58–60°C) for candle making mixed with the HDT paraffin gel.
- For lobular carcinoma, 17% w/w of carnauba wax was added to the HDT gel.
- Calcified fibroadenomas were made of HDT paraffin gel with 12% weight per weight (w/w) of carnauba wax and 5% w/w of glass microspheres.
- The ductal carcinomas were prepared with 4% w/w of granular semi-refined paraffin wax mixed with the HDT paraffin gel with 0.5% w/w of chalk powder used as scatter.

- Fluid cyst models were made of motor oil (STP, São Paulo, Brazil), and solid cyst models were created with HDT paraffin gel. Both types of cyst models were prepared without using any scattering material.

These lesions were spherical in shape to simulate solid masses with diameters ranging from 5 to 10 mm. Aniline dye (Anilina Ortoquímica, n° 145, São Paulo, Brazil) was added to all solid masses, which can be identified after a successful biopsy puncture. The abnormal tissues were manufactured using two-part acrylic molds with matching hemispheric depressions, which were immersed into the appropriate molten material. Molds were removed from the molten material, clamped and left in a water bath to cool down slowly. Initially, the water bath temperature was set to 62.4 ± 0.1°C and controlled by a digital thermostat (Tlj29, Coel, São Paulo, Brazil) to avoid temperature gradients, which could trap air bubbles in the TMM lesions. This procedure was conducted because paraffin gel produces bubbles when quickly cooled.

Speed of sound measurement

Measurements of the speed of sound and the attenuation coefficient were made using a narrowband substitution technique described in previous studies (Madsen et al. 1978, 1982, 1998). These acoustical parameters of the TMM were evaluated using a set of six planar unfocused immersion transducers (Panametrics; Olympus NDT Inc., Waltham, MA, USA). An ultrasonic pulser-receiver system (Model 5800 PR; Panametrics, Waltham, MA, USA) was used to drive the transducers to produce narrowband pulses with center frequencies ranging from 2.5 to 10 MHz and a pulse repetition frequency (PRF) of 200 Hz.

Nine samples of TMM were made using PVC cylindrical tubes that were 7.5 cm in diameter and 2.47 cm thick. The flat boundaries of these cylinders were covered using a thin (100 μm) plastic wrap (Atual Ind. E Comércio LTDA, Barueri, SP, Brazil). The acoustic pressure of the transmitted pulse was measured using a needle hydrophone (HNP-0400, Onda Corporation, Sunnyvale, CA, USA) with a 1 mm^2 sensitive area. The hydrophone was aligned with the ultrasonic transmitter transducer and maintained at a distance between 35 and 40 cm. Gel samples were placed between the transmitting transducer and the receiving hydrophone with the parallel faces of the sample perpendicular to the direction of ultrasonic pulse propagation. The flat face of the sample was positioned 5 cm from the transmitting transducer.

Experiments were performed in a tank (100 cm × 64 cm × 37 cm) filled with distilled water. The temperatures of all samples were stabilized in the water tank at 22 ± 1°C. The temperature of the water tank was measured using a digital thermometer (TM879, Equitherm, Rio Grande do Sul, Brazil).

The substitution technique allows determination of the change in the sound pulse transit time when a sample is substituted by a reference material in which the speed of sound is known. Distilled water was used as the reference material. The speed of sound of the TMM was calculated using eqn (1):

$$c_s = c_w\left(1+\frac{c_w\Delta\tau}{d}\right)^{-1} \tag{1}$$

where c_s is the speed of sound in the sample, c_w is the speed of sound in water, d is the sample thickness and $\Delta\tau$ is the time shift in the pulse wave propagation when the sample is immersed in the water. The waveforms received from the transmitter transducer were recorded for off-line analysis using custom software (MATLAB, The MathWorks Inc., Natick, MA, USA) to estimate the time shift by employing the Hilbert transform/cross-correlation function.

Attenuation coefficient measurement

The attenuation coefficient was measured using eqn (2):

$$\alpha = \frac{20}{d}\log\left(\frac{A_0}{A}\right) \tag{2}$$

where A_0 and A are the amplitude of pressure of the transmitted pulse before and after the insertion of the sample into the water crossing the path of the pulse, respectively.

The attenuation caused by plastic wrap and displaced water at 1 MHz is about 0.05 dB/cm, which corresponds to 1.7% of the total transmitted signal power. This correction factor was not included in the attenuation coefficient values appearing in this article. The magnitude of the transmitted ultrasonic pulse was estimated using a fast Fourier transform (FFT) analysis applied to the output signal from the hydrophone. FFT analysis was made to find the maximum energy of narrowband pulses with center frequencies ranging from 2.5 to 10 MHz.

The use of eqn (2) to calculate an attenuation coefficient from the results of the substitution technique measurement assumes that the attenuation is caused by a simple multiplicative exponential factor. This is only true for specific measurement geometries. Otherwise, errors can be made if the sample is not in the proper position in the transducer beam pattern. As stated by Goldstein (2004), the near and far field distances are functions of the transducer frequency, element diameter and sound speed of the test material as describe by $z_{NFD} = 0.2Y_0$ and $z_{FFD} = 6.41Y_0$, respectively. The Fraunhofer zone beyond the last axial maximum at $Y_0 = a^2/\lambda$ is called the far zone, where a is the element aperture and λ represents the ultrasound wavelength.

The far field is the area beyond (z_{FFD}) where the sound field pressure gradually drops to zero. However, variations in the pressure within the near field can make it difficult to accurately evaluate flaws using amplitude-based techniques. The distance z_{NFD} serves as a convenient demarcation between the complicated near field found close to the transducer and simpler far field found at large distances from the transducer.

To avoid positioning the hydrophone in the region of strong interference effects, calculations of the near-field distance were carried out assuming an ultrasonic velocity in water of 1.488 cm/s at 22°C, using the actual transducer element diameters and its respective central frequencies. The minimum and maximum near-field distance found was 1.35 cm at 2.5 MHz and 17.3 cm at 8 MHz, respectively. This knowledge was used to design the experimental setup where the flat face of each sample was positioned 5 cm from the transmitting transducer and the hydrophone was placed outside the near-field zones. This experimental setup permits the attenuated axial pressure to be represented by a plane wave multiplicative attenuation factor as described by eqn (2).

Elastic modulus measurement

Mechanical tests were performed to evaluate the elastic modulus of two gel wax samples made of MDT and HDT paraffin-gel wax at room temperature (22°C). A Bose EnduraTEC ELF 3200 system (Bose Corporation ElectroForce Systems Group, Minnetonka, MN, USA) with a 1-kg load cell and Teflon platens larger than the sample surface was used. These samples were cylinders 2.6 cm in diameter and 1 cm thick. A low-amplitude (1% of the total sample height), 1–50 Hz oscillatory compressive load was used to determine the complex Young's modulus from the oscillatory dynamic mechanical analysis. The samples were pre-compressed by 1%, and safflower oil was used to lubricate the platens during the tests to minimize friction between the plates and the sample.

RESULTS

Speed of sound

The change in sound speed for the frequency ranging from 2.5–10 MHz in the MDT and HDT paraffin-gel samples is shown in Figure 2. The speed of sound of the MDT and HDT paraffin-gel samples remained constant (linear fit) with average frequency values of 1424.9 ± 0.6 m/s and 1432.4 ± 1.1 m/s, respectively. These results have an uncertainty that is the mean of the standard deviations of the set of sound speed values of each sample separately. The reference speed of sound in the distilled water at 22°C was 1488.319 ± 0.015 m/s, which is in agreement with experimental results (Del Grosso and Mader 1972; Marczak 1997).

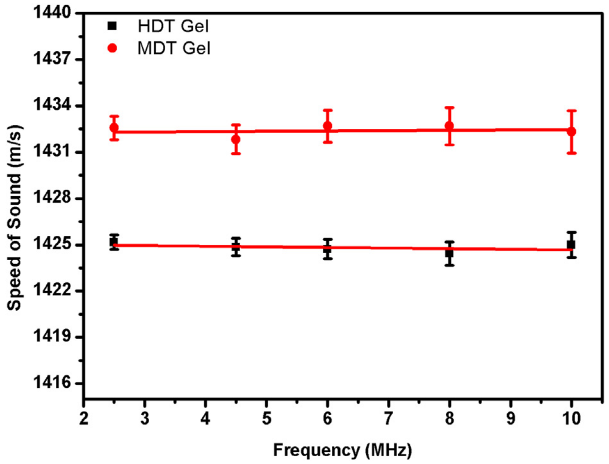

Fig. 2. Speed of sound as a function of frequency in MDT and HDT paraffin-gel samples. HDT = high-density type; MDT = medium-density type.

Attenuation coefficient

The attenuations in the phantom background and abnormal masses are shown in Figure 3. The attenuation coefficient of the TMM materials shows a non-linear relationship with frequency. A polynomial function was applied to relate the attenuation data to frequency. These data were fitted by the function $\alpha = \alpha_0 f^n$, where f is the frequency in MHz and α_0 has the units dB/(cm-MHz)^n.

The abnormal masses mimicking benign cancer and ductal carcinoma have shown an attenuation coefficient similar to each other and equivalent to the phantom background: α_0 = 0.19 dB/(cm-MHz)$^{1.61}$. For that reason, data for the benign cancer and ductal carcinoma model abnormal masses are not shown in Figure 3.

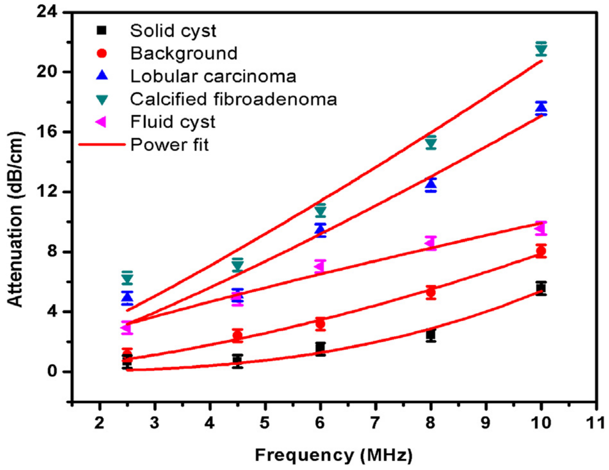

Fig. 3. The relationship between attenuation and ultrasound frequency of the background material and abnormal tissues. The mean uncertainty in the measurements is approximately ± 0.40 dB/cm.

Literature indicates that 5–15 MHz linear transducers are used in the highest quality breast sonograms that show images of a lesion within the transducer focal zone (Tejerina Bernal et al. 2012). In accordance with these data, the acoustic properties of the tissue-mimicking materials were evaluated at 7.5 MHz.

Table 1 depicts measurements of the speed of sound ranging from 1425.4–1480.3 m/s, with a mean standard deviation of ± 1.2 m/s. This value was computed using the standard deviations of the normal and abnormal tissue-mimicking materials. The gels with higher concentrations of carnauba wax, such as the lobular carcinoma with 17% w/w carnauba wax, produced higher speed of sound than gels with lower carnauba wax content. The attenuation coefficient could be controlled between 0.32 and 2.04 dB/cm at 1 MHz by varying the concentration of carnauba wax and glass microspheres.

Elastic modulus

Figure 4 depicts Young's storage modulus measured at various frequencies for the paraffin-gel samples. These data show that paraffin-gel waxes have a modulus that is frequency-dependent at a pre-compression strain level of 1%. The abnormal masses made of HDT gel are stiffer than the phantom background tissue (MDT gel) at all frequencies in the tested range.

B-scan ultrasound imaging

To evaluate the speckle pattern and acoustic echogenicity of the breast phantom and the abnormal masses, a set of ultrasound B-scan images, which are shown in Figure 5, were taken using a commercially available ultrasound unit (Logiq Book XP, GE Healthcare, Milwaukee, WI, USA) with a 6-MHz linear-array transducer.

Three radiologists with experience in diagnostic ultrasound and freehand ultrasound-guided core-needle biopsy participated in this study. These radiologists conducted a series of biopsy procedures to evaluate the inclusion morphology and assess the contrast between the needle and the phantom image texture. A long-throw 10-cm, 16-gauge (≈1.3-mm) needle was used. Ultrasound-guided breast phantom core-needle biopsy images were taken before and after the needle traversed the target. Two images of the procedure are shown in Figure 6.

Table 1. Acoustic properties of paraffin-gel models mimicking various normal and abnormal tissues at 22°C and measured at 7.5 MHz

Tissue-mimicking model	Speed of sound (m/s)	Attenuation coefficient dB/(cm-MHz)
Breast (background)	1440.1 ± 1.3	0.63 ± 0.21
Benign cancer	1432.1 ± 1.1	0.51 ± 0.23
Lobular carcinoma	1480.3 ± 1.7	1.66 ± 0.42
Calcified fibroadenoma	1457.0 ± 2.4	2.04 ± 0.65
Ductal carcinoma	1438.9 ± 0.7	0.68 ± 0.45
Fluid cyst	1425.4 ± 0.6	1.07 ± 0.26
Solid cyst	1431.5 ± 0.3	0.32 ± 0.27

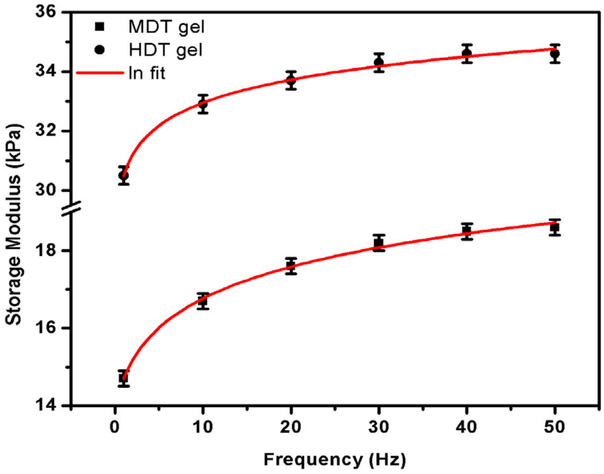

Fig. 4. Young's storage modulus estimated for the medium- and high-density type paraffin gels at room temperature (22°C). The mean uncertainty in the measurements is approximately ± 0.30 kPa. HDT = high-density type; MDT = medium-density type.

DISCUSSION

Paraffin-gel waxes have been investigated as a tissue-like ultrasound phantom. The TMM has an attenuation coefficient of 0.63 dB/cm at 7.5 MHz and 22°C, which is close to soft tissue at body temperature. For example, at 7.5 MHz, which is commonly used for breast screening, the attenuation coefficient reported for breast fat is approximately 0.62 dB/cm at a frequency of 1 MHz (D'Astous and Foster 1986). It provides a good approximation for the attenuation of many soft tissues using a typical diagnostic sonographic scanner that operates in the frequency range of 2.5–10 MHz.

The TMM described here had attenuation coefficients with a power law frequency dependence of 1.61 and a mean speed of sound of 1440.1 ± 1.3 m/s, which precludes recommendation an ultrasound quality assurance (QA) phantom, where a speed of sound of 1540 m/s is recommended (Ma et al. 2004; Mokhtari-Dizaji 2001). However, as a breast phantom, the TMM described here may be useful for demonstrative or teaching purposes. Browne and co-workers (2003) reported attenuation coefficient frequency dependence around two orders of magnitude ($f^{1.83}$) and a speed of sound of 1460 m/s for urethane rubber (Browne et al. 2003).

A disadvantage of working with paraffin gel as a tissue-mimicking material is the difficulty of changing the speed of sound of the material. Human breast fat at a temperature of 22.5°C exhibits a speed of sound of

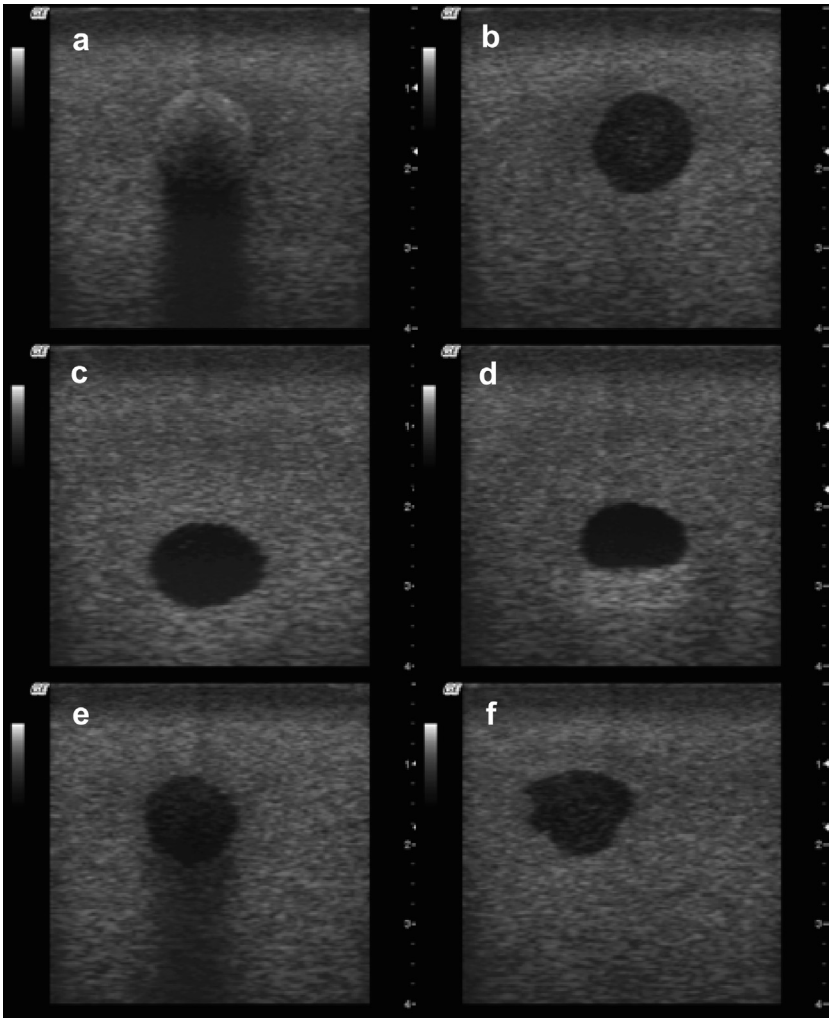

Fig. 5. Ultrasonic images of the breast phantom with abnormal masses: (a) calcified fibroadenoma, (b) benign mass, (c) solid cyst, (d) fluid cyst, (e) lobular carcinoma, (f) ductal carcinoma.

approximately 1436 m/s (Rajagopalan et al. 1979). In the present study, the ultrasound propagation speeds in the background materials at 22°C ranged from 1425.4 m/s for fluid cysts to 1480.3 m/s for lobular carcinomas.

In this study, two types of paraffin-gel waxes distinguished by material melting point have been investigated for the background material and abnormal masses for breast phantoms. The paraffin-gel waxes used in this study exhibited different degrees of stiffness. The mechanical proprieties of the investigated TMM indicated that versions could be used to realistically simulate abnormal structures. The phantom background material elastic moduli were similar to the values found in the literature for human tissue.

For example, breast tissue exhibited an elastic modulus of 18.0 ± 0.7 kPa at a loading frequency of 1 Hz and pre-compression strain level of 5% (Krouskop et al. 1998). However, the old Krouskop reference seems to contradict more careful studies conducted by Samani and collaborators where the breast fat Young's modulus value is about 3.25 ± 0.91 kPa (Samani et al. 2007).

Abnormal tumor-mimicking tissues made of HDT paraffin gel had a mean stiffness of approximately 36.5 ± 1.8 kPa, which is in agreement with previously described findings on abnormal tissue *in vivo* (McKnight et al. 2002). According to the radiologists who performed the ultrasound experiments for this study, the abnormal masses were easily identified in the phantom background, thus allowing successful ultrasound-guided fine-needle aspiration procedures. The ultrasonic images of the phantoms had moderate echogenicity, similar to those taken from human breast fat. The radiologists also reported no difficulty in visualizing the needle sonographically during the biopsy of the phantom, although tracks produced by the biopsy needle were progressively echoic. It was observed that each solid mass might be punctured

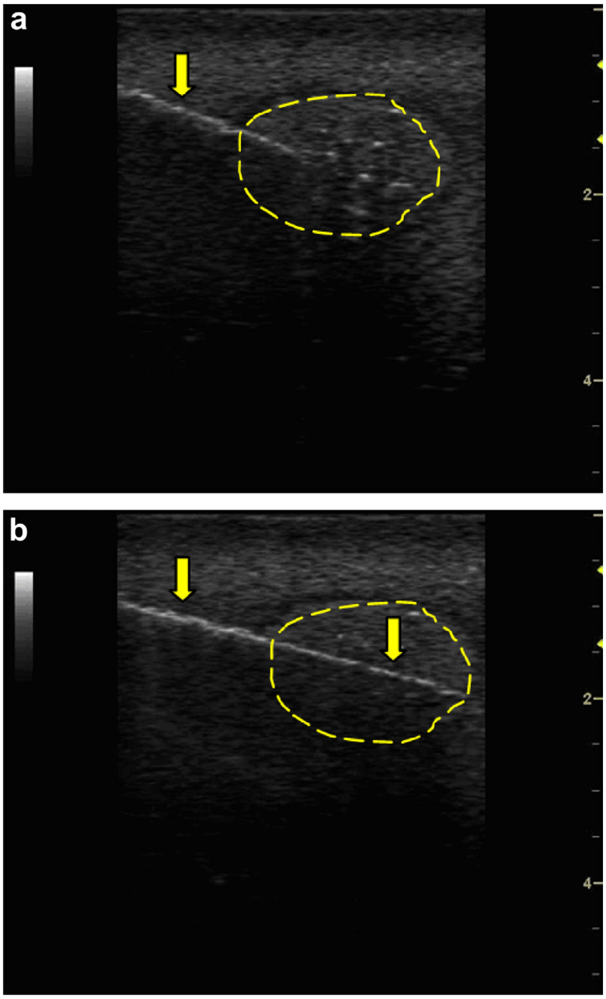

Fig. 6. Ultrasound images of the needle (*straight arrows*). (a) The tip at the margin of the target tissue (*dashed line*); (b) ultrasound image documents that the needle has traversed the abnormal mass.

approximately 40 times, before air tracks became visible and interfered with the ultrasound images quality.

To minimize the damage created by the needle, investigations will be conducted using a dedicated controlled thermal heating system. The ongoing refinement of the thermal system could play an important role in rebuilding the phantom to allow it to be usable for a longer period.

For 6 y, the form and dehydration of the breast phantoms have been qualitatively monitored. The results indicated that because of the chemical stability of the paraffin wax, the phantoms can maintain their shapes for a long time. As expected, the phantom did not suffer dehydration because the paraffin does not use water as a solvent.

CONCLUSIONS

A paraffin-gel wax-based phantom with embedded model cysts and tumors was designed and developed in this study. This phantom can be used for training radiologists and sonographers in ultrasound-guided biopsy or fine-needle aspiration procedures. The great advantages of paraffin-gel waxes over alternative materials are their longevity and structural rigidity. The normal and abnormal TMMs acoustic parameters and elasticity were in accordance with values reported in the literature. Carnauba wax produced promising results as a new material that can be added to vary the attenuation coefficient of the investigated materials. The mechanical proprieties of the abnormal tissues can be assessed by manual palpation, thus making the phantom useful for elastography applications.

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