

Effects of the Magnetic Resonance Field on Breast Tissue Expanders

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Abstract

Background Tissue expansion for breast reconstruction after mastectomy is a safe and effective procedure. A magnetic resonance imaging (MRI) scan can be requested for patients with a breast expander to evaluate concurrent diseases. The electromagnetic field of the MR can interfere with biomedical devices, resulting in potential hazards, compromising the diagnosis, or creation of artifacts.

Methods Four tissue expanders with an integrated magnetic valve were tested. The temperature increase was measured using an infrared camera in the MR scanner. The expanders were tested (half-full and full of saline solution) both free in air and immersed in a phantom. The ferromagnetic properties of the devices were assessed using the deflection angle method. To evidence artifacts due to the presence of the expander, MR images were acquired for expanders tested in air and in the phantom. A valve localization test was performed after MRI analysis.

Results A slight increase in temperature was demonstrated, without any clinical significance. The deflection angle due to the magnetic field depends on the distance from the bore of the magnet. The angle is higher when the device is closer to the bore. The presence of the magnetic valve influences the MRI signal, creating artifacts on the acquired images, even far from the valve itself. The valve localization test allowed verification of correct valve functioning for all the expanders after the MRI analysis.

Conclusions Under selected conditions, MRI scans can be feasible. Heating is not expected to be a major concern, whereas valve displacement could happen in certain clinical conditions. The presence of artifacts is almost unavoidable.

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Tissue expansion for two-stage breast reconstruction after mastectomy is a safe and effective procedure [1] that can reduce the surgical aggressiveness of reconstructive surgery. After the mastectomy, the breast tissue expander, a silicon bag with an integrated metallic valve on the top, is placed beneath the pectoralis major muscle [2]. The device then is filled with periodic injections of saline solution through a magnetic valve that can be easily located using a magnetic finder device provided by the manufacturer.

Tissue expansion usually is completed with the device left in place for a variable period of 6–18 months. During this span, a magnetic resonance imaging (MRI) scan can be requested for evaluation of possible concurrent diseases including traumas and neurologic diseases. An MRI scan also can be requested for oncologic purposes related to breast cancer in the contralateral breast or other concomitant tumors.

Using MRI, a common diagnostic technique, the image is reconstructed from the radiofrequency (RF) signal, from the precession of the magnetic moments of hydrogen protons [3, 4]. The MRI technique is an excellent means for imaging soft tissues in the human body.

An MR scanner produces three electromagnetic fields: a static magnetic field B_0 , a pulsed gradient magnetic field, and a RF magnetic field. These fields can interfere with biomedical implantable devices containing ferromagnetic components (i.e., pacemakers, implantable defibrillators, some types of stent, and heart valve prostheses). In fact, potentially dangerous magnetic field interactions can occur when ferromagnetic materials (i.e., iron-containing alloys) are exposed to the static magnetic field [5].

The potential hazards for patients involve heating of the device's metal components and the surrounding tissues, mostly due to the RF magnetic field resulting from the induced eddy currents, displacement of the implant, device malfunction or failure, and distortion (i.e., artifacts) of MR images.

With respect to breast tissue expanders, the metallic valve of the expander could interfere with the magnetic field, creating diagnostic artifacts. The tissue expander itself could be displaced during the scan, and the radiofrequencies could increase the temperature of the saline solution. In fact, the ferromagnetic component of the injection valve could be strongly attracted by the magnetic fields produced by the MR system, thus causing dislodgment of the valve itself. Furthermore, the eddy currents induced by the RF excitation pulses could cause heating of the valve and consequently of the surrounding tissues, causing burns and producing pain [6–10].

This experimental study aimed to simulate *ex vivo* the effects of MRI (1.5 tesla) *in vivo* on four breast tissue expanders with incorporated magnetic valves.

Methods

In this study, we tested the following four breast tissue expanders with integrated magnetic valve (Fig. 1): the McGhan 67-133SV13 (anatomic/short height/variable projection, Lot n. 1554172) with a volume of 300 ml, the Silimed 20769-300 (anatomic/full height, SN 3359220) with a volume of 300 ml, the McGhan 67-133FX13

(anatomic/full height/extra full projection, Lot n. 1237867) with a volume of 500 ml, and the Silimed 20759-650 (anatomic/moderate height/full projection, SN 3269118) with a volume of 650 ml. The tissue expanders were tested empty, half-full, and full using a sterile physiologic solution (saline solution 0.9 % w/v NaCl). Each tissue expander was used to perform the three different tests in MRI.

The valve temperature increase was measured in the center zone of the MR scanner (Philips Achieva, 1.5 tesla) used for diagnostic purposes at the Istituto per la Cura e lo Studio dei Tumori, Milan, Italy. The high SAR protocol (SAR, 2.6 W/kg) used in this study mimicked heating conditions worse than those in a clinical setting, in which the maximum SAR value is 2 W/kg.

Temperature measures were performed using an infrared camera (Flir BCam SD) with a thermal sensitivity of 0.1 °C at 25 °C. The expanders were tested (half-full and full of saline solution) both free in air and immersed in a gelled saline phantom, as reported in ASTM standard F2182-09 [11]. The phantom consists of sodium chloride (Sigma Aldrich, S7653) and polyacrylic acid (PAA; Sigma Aldrich, 436364) in distilled water and can be used to simulate conductivity and thermal properties similar to those of the body, which has diffusivity of about $1.3 \times 10^{-7} \text{ m}^2/\text{s}$ and a heat capacity close to that of water ($H_C = 4160 \text{ J/kg}^\circ\text{C}$). Furthermore, the viscosity of the gelled phantom must be great enough so that the phantom material does not allow bulk transport or convection currents, resulting in worse heat dissipation than in the human body. The phantom gel should have conductivity of 0.40–0.60 S/m at temperatures of 20–25 °C.

The ferromagnetic properties of the devices were assessed using the deflection angle method described in ASTM standard F2052-06 [12]. The deflection force is due to the effect of the field gradient in which the device is immersed. It is higher on the bore of the magnet and attracts the device to the magnet center. The expander was suspended by a nylon wire to a custom-made polymethylmethacrylate (PMMA) structure containing a plastic protractor (sensitivity = 1°).

In each test, the deflection angle was measured by three operators, followed by calculation of the average and standard deviation values. The angular deflection from the vertical was measured at different distances from the bore of the magnet (0, 40, and 80 cm from the magnetic source for half-full and full tissue expanders vs 40 and 80 cm for the empty devices).

To evidence possible artifacts due to the presence of the expander, MR images were acquired for full expanders tested in air or in the phantom. An impulse sequence T2W-TSE-sag (T2-weighted turbo spin-echo sagittal) was applied to the devices to evidence the presence of water inside the expander and in the phantom.

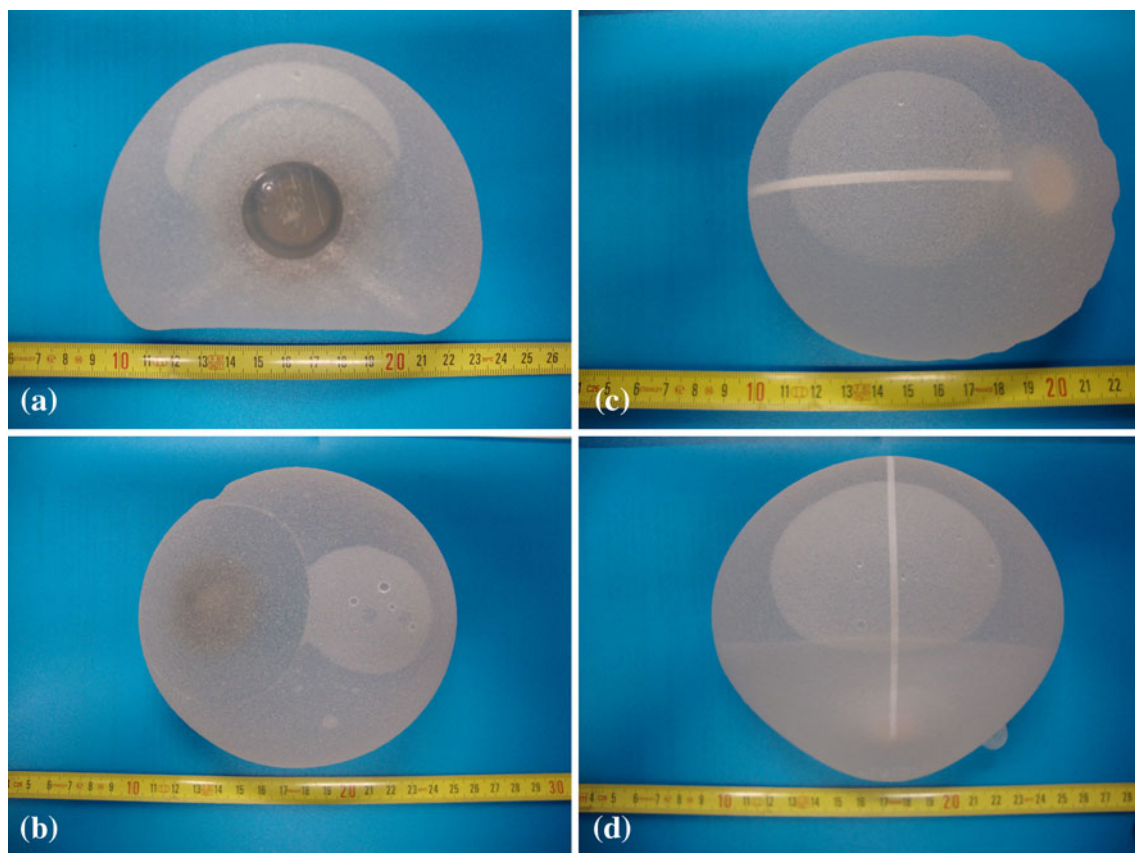


Fig. 1 Tissue expanders considered in this work. **a** McGhan 67-133SV13, 300 ml (McGhan 300). **b** McGhan 67-133FX13, 550 ml (McGhan 550). **c** Silimed 20769-300 ml (Silimed 300). **d** Silimed 20759-650 ml (Silimed 650)

After the aforementioned tests, functionality of the device was verified to investigate the possible delocalization of the magnetic valve caused by the interaction with the electromagnetic field of the MR environment. The test for the localization of the valve was performed on the expanders immersed in the phantom to mimic the physiologic condition (i.e., presence of body tissues between the device and the magnetic finder). For the McGhan and Silimed tissue expanders, the appropriate magnetic finder provided by the manufacturer was used.

Results

The temperature increase values for the half-full and full expanders tested in air and in the phantom are reported in Table 1. The temperature increase in air for half-full expanders was investigated only for the two McGhan tissue expanders because the Silimed expanders were attracted by the magnetic field, with the high magnetic attraction preventing maintenance of the expander in the correct position. In air, the temperature increase ranged from 0.2 °C for the full McGhan 300 expander to 0.4 °C for the full

Table 1 Values for temperature increase with half-full and full tissue expanders tested in air and in the phantom

Tissue expander		ΔT (°C) in air	ΔT (°C) in phantom
McGhan, 300 ml	Half-full	+0.3	+0.3
	Full	+0.2	+0.2
Silimed, 300 ml	Half-full	NP	+0.5
	Full	+0.4	+0.4
McGhan, 550 ml	Half-full	+0.4	+0.2
	Full	+0.3	+0.3
Silimed, 650 ml	Half-full	NP	+0.2
	Full	+0.3	+0.2

NP test was not performed due to high attraction force caused by the magnetic field

Silimed 300 and half-full McGhan 550 expanders. In the phantom (Table 1), temperature increases ranged from 0.2 °C for the half-full McGhan 550 and the half-full and full Silimed 650 expanders to 0.5 °C for the half-full Silimed 300 expander.

Table 2 presents the results obtained in the deflection tests for the empty, half-full, and full expanders. For the empty expanders, tests at 0 cm from the bore were not

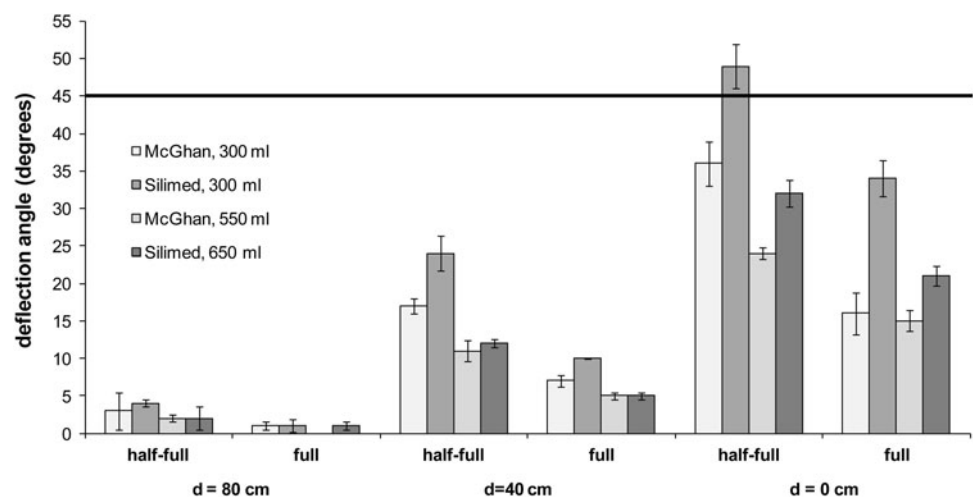
Table 2 Deflection angle obtained for tests performed on the empty, half-full, and full tissue expanders

Tissue expander		d = 80 cm θ (°)	d = 40 cm θ (°)	d = 0 cm θ (°)
McGhan, 300 ml	Empty	13.0 ± 2.6	48.0 ± 1.3	NP
	Half-full	3.0 ± 2.5	17.0 ± 1.0	36.0 ± 2.9
	Full	1.0 ± 0.5	7.0 ± 0.8	16.0 ± 2.8
Silimed, 300 ml	Empty	19.0 ± 0.8	60.0 ± 0.6	NP
	Half-full	4.0 ± 0.5	24.0 ± 2.3	49.0 ± 3.0
	Full	1.0 ± 0.9	10.0 ± 0.0	34.0 ± 2.4
McGhan, 550 ml	Empty	5.0 ± 1.3	34.0 ± 1.3	NP
	Half-full	2.0 ± 0.5	11.0 ± 1.4	24.0 ± 0.8
	Full	0.0 ± 0.0	5.0 ± 0.5	15.0 ± 1.4
Silimed, 650 ml	Empty	11.0 ± 0.3	43.0 ± 2.0	NP
	Half-full	2.0 ± 1.6	12.0 ± 0.5	32.0 ± 1.8
	Full	1.0 ± 0.6	5.0 ± 0.5	21.0 ± 1.3

NP deflection test was not performed

For each expander, the average and standard deviation values of the deflection angle θ are reported for the three considered distances from the bore. The deflection angle values shown in bold type exceeded the threshold value ($\theta = 45^\circ$) reported in the ASTM standard

performed because the magnetic attraction was so high that the expander was deflected to the scanner wall (i.e., deflection angle $>90^\circ$). At 40 cm, for the Silimed expanders (either 300 or 650) and the McGhan 550, the deflection angle was higher than the threshold value ($\theta = 45^\circ$) reported in the ASTM standard about the safety of the device in MR. For the half-full expanders (Table 2, Fig. 2), the deflection angles ranged between 2° and 4° at 80 cm from the bore. At 40 cm, the values ranged from 11° to 24° , and at 0 cm, the angles were in the range 24° to 49° .

Fig. 2 Deflection angle values for half-full and full tissue expanders. The black straight line evidenced the threshold value (ASTM standard F2052-06)

For all the investigated distances, the half-full Silimed 300 expander exhibited the maximum deflection angle. In particular, at 0 cm, for the Silimed 300 expander, a deflection angle higher than the threshold value reported in the ASTM standard was observed ($\theta = 49^\circ$ and 45° , respectively). For the full expanders (Table 2, Fig. 2), at 80 cm from the bore, the deflection angles ranged from 0° to 1° ; at 40 cm, the values were in the range of 5° to 10° ; and at 0 cm, the angle values ranged from 15° to 34° . At either 40 and 0 cm from the bore, the maximum deflection was observed for the Silimed 300 expander.

In the analysis of the artifacts, for the different slices acquired during the MRI of expanders tested in air, the loss of the MR signal for Silimed 650 (Fig. 3a), was over the magnetic valve and tissue expanders, even to the phantom near the expander used to increase the mass of the scanner objects (i.e., low mass does not allow the acquisition of MR images). The loss of the MR signal due to the McGhan 300 tissue expander was localized (Fig. 3b), even if the expander was not visible in the MR image. When the expanders were tested in the phantom, the artifacts were more remarkable for the Silimed 300 (Fig. 3c) and lower for the McGhan 300 (Fig. 3d) and the McGhan 550.

The valve localization test allowed to verify a correct functioning of the valve for all four tissue expanders after all the tests performed in the MRI apparatus, and the valve was correctly localized. The localization of the valve was verified by the magnet of the finder located perpendicular to the base (Fig. 4a, c) near the valve, whereas far from the valve, the magnet was deflected (Fig. 4b, d).

Discussion

During the last decade, MRI has become an established diagnostic tool in several fields. The concurrence with

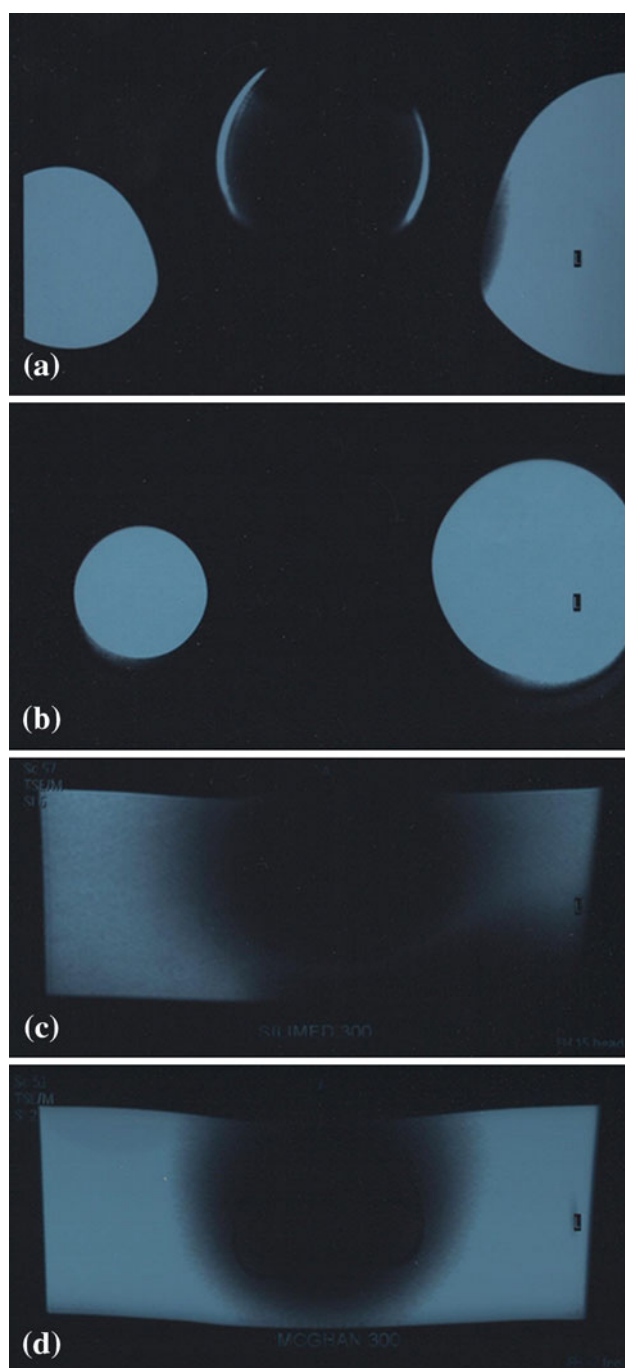


Fig. 3 Artifacts in magnetic resonance (MR) images caused by the presence of the tissue expanders. **a** Silimed 650 tested in air. The expander influenced the MR image also far from the expander itself. **b** McGhan 300 tested in air. **c** Silimed 300 tested in the phantom. **d** McGhan 300 tested in the phantom

tissue expansion can occur not only for breast cancer diagnosis and assessment but also in traumatic conditions, for neurologic diseases, and for other concomitant cancers.

In recent years, the compatibility of MRI with many implantable devices (e.g., aneurysm clips, stents, heart

valves, orthopedic prosthesis) has been demonstrated [13]. Only one study has investigated the compatibility of tissue expanders in MRI [9]. That study analyzed the possible heating, the magnetic attraction, and the artifacts of three tissue expanders with a nonferromagnetic valve. An increase in temperature of 0.2 °C was demonstrated, as well as no attraction to the MRI magnet and significant artifacts on MRI images [9].

In 1997, ASTM International started to define a standard to investigate the compatibility of implantable medical devices with MRI. Currently, five ASTM standards have been published regarding the heating due to the RF [11], the magnetic attraction force [12], the magnetic couple [14], the artifacts [15], and the terminology for the classification of medical devices [16].

The risk of performing MRI with metallic objects has been reported only in the presence of nonmagnetic vascular clips that might move, possibly generating severe hemorrhages and increasing the risk of death [17]. Coarse evidence is available regarding patients with tissue expanders for breast reconstruction undergoing MRI. In the literature, only some clinical cases are reported, with description of the possible consequences related to a MRI performed for patients with tissue expanders. A single case of burning pain during the MRI procedure, which ended once the analysis was completed [6], and a unilateral dislodgement in a patient with bilateral expanders have been reported [10].

A further report by Zegzula and Lee [7] described port dislodgement in a patient who required an MRI for pain in the lumbar spine region after breast reconstruction. At further expansion, localization of the valve was not possible. Chest X-rays demonstrated that the valve was located in the lower part of the implant, so the patient was brought back to the operating theater. Once the implant was removed, it was observed that the port was pulled off and floating within the shell. Ascherman [8] reported port dislodgement due to a polarity inversion of the valve.

Implant manufacturers do not recommend performing MRI for patients with a tissue expander and suggest that physicians in charge of implantation should warn other colleagues about the risks of the procedure. In this ex vivo study, we tested four temporary tissue expanders by two of the most important manufacturers in the world. One of the main concerns reported in the literature is the possible increase in temperature due to RF. This may have played a role in the burning sensation described in one of the case reports in the current literature [6].

Device heating was investigated either in air or in a dummy to simulate body conditions. Our experience demonstrated that although an increase in temperature ranging from 0.2 to 0.5 °C had been estimated, this cannot be considered dangerous and perceived by the patient.

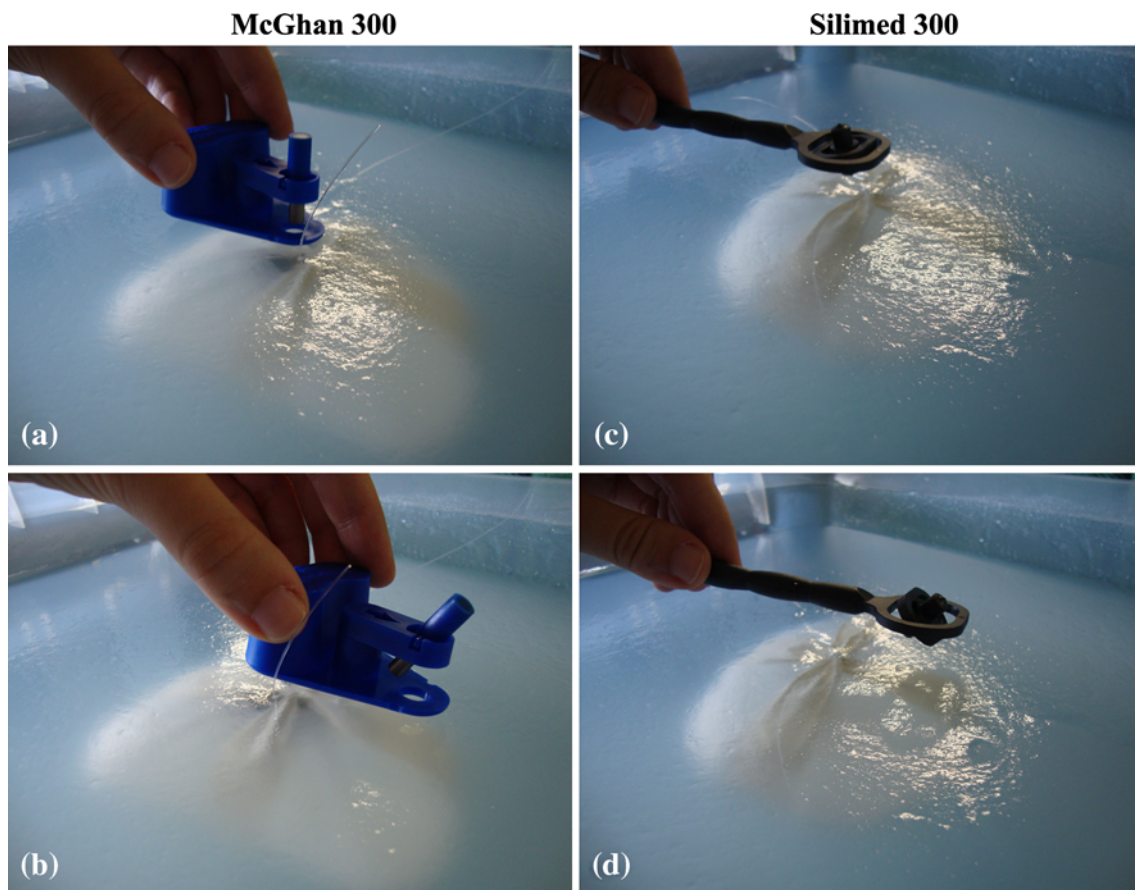


Fig. 4 Tests for valve localization using the magnet finder. McGhan 300 ml near the valve (a) and far from the valve (b). Silimed 300 ml near the valve (c) and far from the valve (d)

We also have tested *ex vivo* the possible impact of the magnetic field on moving of the implant. The risk for deflection of implants close (40 cm) and very close (0 cm) to the magnetic source is significant. The differences highlighted between the McGhan and Silimed expanders, particularly the higher interactions with MR fields observed with Silimed devices, could be due to a different composition of the metallic valve. In fact, the injection valve of the Silimed expanders seems to be composed of materials with more ferromagnetic properties. Deeper investigations into this aspect actually are ongoing.

In conclusion, implants in a magnetic field similar to that of a clinical MRI are at a theoretical risk of displacement. This risk should be reduced *in vivo* by the presence of the tissues surrounding the implant. Certain clinical conditions such as persistent postoperative seromas or a technical failure in the shaping of the submuscular pouch (too large for the selected expander) may compromise the safety of the procedure, with possible implant displacement during an MRI scan.

Conclusions

The experimental results of this study demonstrated that the MRI scan with breast tissue expanders could be feasible under selected conditions. Heating of the device is quite modest and unlikely to be perceived by the patient. Some concerns may be raised by the interaction of the device with the magnetic field, with some clinical conditions perhaps generating a displacement of the valve or the device and artifacts in the MR images. A clinical trial based on the results of this study should be undertaken to evaluate any critical condition in which patients scheduled to undergo MRI should be warned about possible risks.

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