Breast Tissue Expander With Radiofrequency Identification Port: Assessment of MRI Issues

Mungunchimeg Bayasgalan[1]
Alexandre Mendonça Munhoz[2,3,4]
Frank G. Shellock[5]

OBJECTIVE. Breast tissue expanders with magnetic ports are MRI unsafe, preventing patients from benefiting from the diagnostic capabilities of MRI. A tissue expander was recently developed with a radiofrequency identification (RFID) port used for needle location and expansion that may be acceptable for a patient undergoing MRI. The purpose of this investigation was to evaluate MRI issues using standardized techniques and well-accepted methods for this tissue expander with RFID port.

MATERIALS AND METHODS. The breast tissue expander with RFID port (Motiva Flora Tissue Expander, Establishment Labs) was assessed for magnetic field interactions (translational attraction and torque, 3 T), MRI-related heating (1.5 T/64 MHz and 3 T/128 MHz), artifacts (3 T), and functional changes associated with different MRI conditions (1.5 T/64 MHz and 3 T/128 MHz).

RESULTS. Magnetic field interactions were minor (deflection angle of 2° and no torque) and thus will not pose a risk. At 1.5 T/64 MHz and 3 T/128 MHz, the highest temperature elevations (1.7°C and 1.9°C, respectively) were physiologically inconsequential. The tissue expander with RFID port exhibited relatively small artifacts on MRI. Exposures of the tissue expander with RFID port to different MRI conditions did not impact the ability to localize the RFID port or to read the electronic serial number.

CONCLUSION. The findings indicated that this tissue expander with RFID port is "MR Conditional" for a patient referred for MRI at 1.5 T or 3 T. Importantly, the relatively small artifact associated with this implant offers potential advantages for patients undergoing MRI compared with tissue expanders that have magnetic ports that create substantial signal losses and distortions on MR images.

Keywords: breast imaging, MRI, MRI safety, MRI testing, tissue expander

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[1]Department of Biological Sciences, University of California Irvine, Irvine, CA.

[2]Plastic Surgery Division, Hospital Sírio-Libanês, São Paulo, Brazil.

[3]Breast Surgery Group, Plastic Surgery Division, University of São Paulo School of Medicine, São Paulo, Brazil.

[4]Hospital Moriah, São Paulo, Brazil.

[5]Department of Radiology and Medicine, Keck School of Medicine, University of Southern California, 1500 San Pablo St, 2nd Fl, Los Angeles, CA 90033. Address correspondence to F. G. Shellock (frank.shellock@mrisafety.com).

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Modern breast reconstruction procedures provide numerous options for patients related to postmastectomy rehabilitation [1, 2]. Among the techniques, implant-based breast reconstruction is the most broadly used method worldwide [2–4]. Data from the American Society of Plastic Surgeons revealed that approximately 102,000 breast reconstructions were performed in the United States in 2018 [4]. Notably, 70% of operations were accomplished in a two-stage method, with the first stage incorporating breast tissue expanders in association with mastectomy [4].

Since their commercial introduction, breast tissue expanders have progressed, and every component of these devices have undergone technical improvements [5]. The injection port is an integral part of the tissue expander design that incorporates a magnet that allows the surgeon to identify the site for injection of normal saline to achieve expansion [6].

Unfortunately, commercially available tissue expanders with magnetic ports are classified as MRI unsafe (i.e., contraindicated for MRI), preventing patients access to a vital diagnostic imaging procedure [7–10]. In addition to creating substantial artifacts (i.e., signal loss and distortion) on MR images, the tissue expander with a magnetic port has been described in case reports as causing magnet polarity reversal, infusion port dislodgment, and in one patient an unsubstantiated complaint of a burning sensation related to the MRI [10–13]. Considering the issues and problems that tissue expanders with magnetic ports present for patients that may require MRI, especially for the management of breast-related conditions (i.e., diagnosis, staging, and surveillance of breast cancer; assessment of ruptured silicone breast im-

plant), there is an apparent need for advancements in tissue expander design.

Recently, a breast tissue expander was developed with an injection port that incorporates passive radiofrequency identification (RFID) technology to detect the integrated filling port's position for tissue expansion. In general, the presence of metal causes concerns related to the use of MRI in a patient with an implant [14]. In general, all implants with any metallic contents must undergo appropriate testing that entails characterization of magnetic field interactions, MRI-related heating, and artifacts to ensure patient safety relative to the use of MRI technology [14–18]. In addition, when implants have a functional component like an RFID device, that component must be assessed because the electromagnetic fields associated with MRI may alter the reliability or damage the component [19]. Therefore, the purpose of this investigation was to evaluate a new tissue expander with RFID port for potential MRI issues.

Materials and Methods

Breast Tissue Expander With Radiofrequency Identification Port

A proprietary smooth-surface breast tissue expander containing an injection port with a passive RFID device (995-mL volume Motiva Flora Tissue Expander, Establishment Labs) underwent evaluation in this study (Fig. 1). The tissue expander with RFID port has a shell of silicone, a port (or needle stop) of polyetheretherketone (PEEK), and the RFID (used for needle localization and provides an electronic number specific to the implant) of copper wire. PEEK is a polyaromatic semicrystalline thermoplastic polymer with mechanical properties favorable for biomedical applications. An important aspect of PEEK is that it provides the required biocompatibility for injection port application because it is strong enough to prevent the fill needle from passing through it, thus preventing any damage to the injection site of the breast tissue expander. The tissue expander with RFID port that underwent MRI testing was 16.5 cm tall and 16.0 cm long with a volume of 995 mL.

Assessment of Magnetic Field Interactions

A sample of the tissue expander with RFID port was used to test magnetic field interactions using standard techniques to evaluate translational attraction and torque using a 3-T MRI system (software 14X.M5, Excite, HDx, GE Healthcare) [15–20]. The tissue expander with RFID was evaluated for magnetic field interactions in the unfilled condition. A tissue expander is usually filled with normal saline to achieve the desired tissue expansion; filling the implant with saline would act as a counterweight to magnetic field interactions. The unfilled condition is a worst-case condition for these tests and thus the unfilled condition represents a worst case with respect to the tests for translational attraction and torque that were performed.

A

B

Fig. 1—Photographs of tissue expander with radiofrequency identification (RFID) port that underwent MRI testing.
A and **B,** Top (**A**) and side and bottom (**B**) views show tissue expander with RFID port.

Translational attraction—Translational attraction was tested using the deflection angle test as described in other studies [15–20]. The tissue expander with RFID port was attached using lightweight string to the test apparatus that had an inverted protractor to measure the deflection angle. The test apparatus with the tissue expander with RFID port was positioned in the MRI system at the point of the highest patient-accessible spatial gradient magnetic field [15–20]. The deflection angle for the tissue expander with RFID port from the vertical direction to the nearest 1° was measured three times and a mean was calculated.

Torque—The tissue expander with RFID port was tested at 3 T for magnetically induced torque using the suspension method as described by the American Society for Testing and Materials International [21]. The tissue expander with RFID port was suspended by a lightweight string from its center of mass using a special test apparatus that permitted it to rotate or align to the direction of the static magnetic field of the MRI system [21]. The test apparatus with tissue expander with RFID port was positioned at the isocenter of the scanner to properly determine torque [15–19, 21]. The results were determined to be either negative (no torque) or positive (torque present) [21].

Assessment of MRI-Related Heating

Phantom and experimental set-up—The tissue expander with RFID port was assessed for MRI-related heating at 1.5 T/64 MHz and 3 T/128 MHz with a focus on the metallic component of the implant, according to previously described techniques [15–19, 22]. A plastic phantom was filled to a depth of 10 cm with semisolid, gelled saline (i.e., 1.32 g/L NaCl and 10 g/L polyacrylic acid in distilled water) that was prepared to simulate human tissue [15–19, 22]. The tissue expander with RFID port was positioned in the gelled saline–filled phantom to yield the worst-case temperature rise for the experimental conditions used in this investigation (i.e., at a position with a high uniform electric field that is tangential to the implant, ensuring an extreme radiofrequency-related heating condition for this experimental setup) [15–19].

Temperature recordings—A fluoroptic thermometry system (Lumasens Technologies) was used to measure temperatures related to MRI for the tissue expander with RFID port [15–19]. Three thermometry probes (0.5 mm diameter, model SFF-2, Lumasens Technologies) were placed to record temperatures on the metallic component of the implant (i.e., the RFID port) as follows: probe 1, placed at one end of the RFID port; probe 2, placed at the opposite end of the RFID port; probe 3, placed at the middle portion of the RFID port. A

Fig. 2—Photograph shows Q Inside Reader (Establishment Labs) used to interface with radiofrequency identification of tissue expander to identify unique electronic serial number assigned to specific implant. (Used with permission from Establishment Labs)

reference probe was positioned 30 cm away from the tissue expander with RFID port [15–19].

MRI conditions—The MRI-related heating tests were conducted on the tissue expander with RFID port at 1.5 T/64 MHz (Magnetom, Siemens Healthcare) and 3 T/128 MHz (Excite, Software 14X.M5, GE Healthcare) with the MRI systems using a transmit-and-receive radiofrequency (RF) body coil. Parameters were selected to create relatively high levels of RF power deposition for the MRI-related heating experiments [15–19, 22]. An MRI system-reported, whole body–averaged specific absorption rate (SAR) of 2.7 W/kg was applied at 1.5 T/64 MHz and an MRI system-reported, whole body–averaged SAR of 2.9 W/kg was applied at 3 T/128 MHz.

Protocol—The gelled saline–filled phantom with the tissue expander with RFID port was placed in the 1.5-T and then the 3-T scanner rooms, respectively, and allowed to equilibrate to the environmental conditions for more than 24 hours for each heating assessment. Baseline temperatures were recorded at 5-second intervals for 5 minutes, and MRI was then performed for 15 minutes, recording temperatures at 5-second intervals [15–19, 22]. Temperatures after MRI were recorded for 2 minutes at 5-second intervals. Proper fluoroptic thermometry probe positioning relative to the tissue expander with RFID was confirmed immediately before and after each MRI-related heating test. The highest temperature changes are reported in this article.

TABLE 1: Pulse Sequences and Imaging Parameters Used to Expose Samples of the Tissue Expander With Radiofrequency Identification Port to MRI Conditions at 1.5 T/64 MHz and 3 T/128 MHz

Parameter	T1-SE	T2-SE	T1-FSE	T2-FSE	GRE, 3D	FGRE, 3D	GRE, MTC	EPI
TR	700	3000	700	5000	20	3.7	628	3400
TE	10	100	9	113	5	1.1	10	103
Flip angle (°)	NA	NA	NA	NA	25	NA	25	NA
FOV (cm)	30	30	30	30	30	30	30	30
Matrix size	256 × 256	256 × 256	256 × 256	256 × 256	256 × 256	256 × 256	256 × 256	256 × 256
Thickness (mm)	10	10	10	10	3	3	10	10
Section gap (mm)	1.0	1.0	1.0	1.0	0.6	0.6	1.0	1.0
Imaging plane	Axial	Axial	Axial	Axial	Volume	Volume	Axial	Axial

Note—T1-SE = T1-weighted spin-echo, T2-SE = T2-weighted spin-echo, T1-FSE = T1-weighted fast spin-echo, T2-FSE = T2-weighted fast spin-echo, GRE = gradient-recalled echo, FGRE = fast gradient-recalled echo, MTC = magnetization transfer contrast, EPI = echo-planar imaging, NA = not applicable.

TABLE 2: Artifacts at 3-T MRI for the Tissue Expander With Radiofrequency Identification Port

Characteristic	Pulse Sequence			
	T1-Weighted Spin-Echo		Gradient-Recalled Echo	
Imaging plane	Long axis	Short axis	Long axis	Short axis
Signal void size				
Linear distance (mm)[a]	3	3	5	5
Area (mm^2)	1203	770	1256	831

[a]Maximum linear distance relative to the size and shape of the implant.

Assessment of Artifacts

MRI artifacts were assessed at 3 T for the tissue expander with RFID port, with a focus on the metallic component of the implant (RFID port). The implant was attached to a plastic plate and placed in a gadolinium-doped (5% concentration) saline-filled plastic phantom [15–19]. The pulse sequences used to evaluate artifacts were T1-weighted spin-echo pulse sequence (TR/TE, 500/20; matrix size, 256 × 256; section thickness, 5 mm; FOV, 24 cm; number of signals acquired, 2; bandwidth; 32 kHz) and gradient-recalled echo (GRE) pulse sequence (TR/TE, 100/15; flip angle, 30°; matrix size, 256 × 256; section thickness, 5 mm; FOV, 24 cm; number of signals acquired, 2; bandwidth, 32 kHz) [15–19, 23, 24]. The imaging planes were oriented to encompass the long and short axes of the tissue expander with RFID port. Although other possible MRI parameters exist, the pulse sequences used to characterize artifacts for the tissue expander with RFID port are the same as those used in many previous studies and therefore permits a comparison with other implants that have undergone similar artifact assessment [15–19].

Planimetry software provided with the MRI system (accuracy and resolution, ± 10%) was used to determine the size of the artifact relative to the size and shape of the implant (i.e., a linear distance) and the cross-sectional area of the largest artifact for each pulse sequence and imaging plane [15–19].

Assessment of Function

To determine if the RFID component of the tissue expander exhibited a change in function or sustained damage associated with MRI, multiple samples of the tissue expander with RFID port were evaluated for their functional aspects immediately before and after exposures to different MRI conditions using a protocol described in other studies [15–18]. Functional testing of the tissue expander with RFID port involved the use of two different devices: the Q Inside Reader (Establishment Labs) and the Motiva Flora Port Locator (Establishment Labs). The Q Inside Reader is used to interface with the RFID to identify the unique electronic serial number (ESR) assigned to the implant (Fig. 2). When the Q Inside Reader is held close to the tissue expander with RFID port, the device verifies that the implant has the correct ESR and displays the value on a digital display. The port locator is used with the tissue expander with RFID port to locate the injection site and uses an RFID wireless system composed of a tag and a reader (Fig. 3). A passive RFID tag is located inside the needle stop of the tissue expander and uses radio waves to communicate its location to the port locator. The port locator (the reader) has an antenna that emits radio waves and receives signals back from the RFID tag. This wireless system locates the center of the injection port through a series of colored LED lights to guide the user to find the correct location of the injection port. This device is used by moving it in a circular motion as close as possible to the tissue expander. Once the injection port is located, a green LED light illuminates on the Motiva Flora Port Locator indicating the exact location of the port.

After performing the functional testing as described before MRI exposure, six samples of the tissue expander with RFID port were attached in three different orientations (i.e., axial, sagittal, and coronal orientations, two in each position) to a plastic, copper sulfate–filled phantom. MRI was then performed at 1.5 T/64 MHz and 3 T/128 MHz using a transmit-and-receive RF body coil and eight different pulse sequences, running sequentially, for approximately 2 minutes per pulse sequence [15–18] (Table 1). The section locations for MRI were

selected to encompass all samples to ensure thorough exposure to the MRI conditions. Immediately after the MRI exposures, functional testing was conducted on each sample of the tissue expander with RFID port. Prior MRI investigations have reported that this technique is an acceptable test strategy for biomedical implants [15–18].

Results

Magnetic Field Interactions

The mean deflection angle was 2° ± 0° (SD) and the torque result was negative for the tissue expander with RFID port.

MRI-Related Heating

The evaluation of MRI-related heating for the tissue expander with RFID port showed highest temperature rises of 1.7°C and 1.9°C in association with MRI performed at 1.5 T/64 MHz and 3 T/128 MHz, respectively.

Artifacts

Table 2 presents the artifact test results for the tissue expander with RFID. Despite the metallic component of this implant (i.e., the RFID port), the artifacts on the MR images were seen as relatively minor localized signal losses without distortion, corresponding to the size and shape of the RFID port. The gradient-recalled echo pulse sequence produced greater artifacts than the T1-weighted spin-echo pulse sequence. Figures 4 and 5 show examples of the gradient-recalled echo pulse sequence for the tissue expander with RFID port. The maximum size of the artifact as seen on the GRE images extended approximately 5 mm relative to the size and shape of the implant.

Function

The assessment of the functional aspects of the tissue expander with RFID port showed that the ability to read the ESR and to successfully locate the injection port were unaffected by the exposures to 1.5-T 64-MHz and 3-T 128-MHz MRI conditions.

Discussion

The management of breast defects after mastectomy and individualized selection of a technique are important factors in achieving a satisfactory outcome for patients [1]. Considering the relevant psychosocial impact of breast cancer and the consequent postsurgical defect, considerable clinical research has been developed to optimize rehabilitation in these patients [1].

Reconstructive procedures for breast defects continue to progress, with the objective of enhancing aesthetics with minimal morbidity [1, 2]. Among the reconstructive procedures available for total breast reconstruction, implant-based techniques are the most broadly used method on a worldwide basis [2–4]. Since their introduction in the 1980s, tissue expanders have improved in terms of shape and texturing of the elastomer surface, as well as the filling port composition [5]. The injection port is an integral design feature of the tissue expander and typically incorporates a small magnet that enables the surgeon to accurately identify the site for injection of normal saline [6]. Unfortunately, the presence of magnets in these implants creates problems related to the use of MRI and thus the implants are labeled "MRI unsafe" (i.e., as indicated in the instructions for use for these implants), precluding patients' access to a vital diagnostic imaging procedure [14, 25, 26]. Although MRI for patients with tissue expanders that have magnetic ports may be performed under highly limited conditions, few MRI facilities are willing to scan patients with these and other implants that are labeled MRI unsafe by manufacturers [10, 25–28].

Fig. 3—Photograph shows Motiva Flora Port Locator (Establishment Labs) used to identify injection port of tissue expander. This wireless system locates center of injection port through series of colored light-emitting diode (LED) lights to guide user to find correct location of injection port. Once injection port is located, green LED light illuminates to indicate location of port. (Used with permission from Establishment Labs)

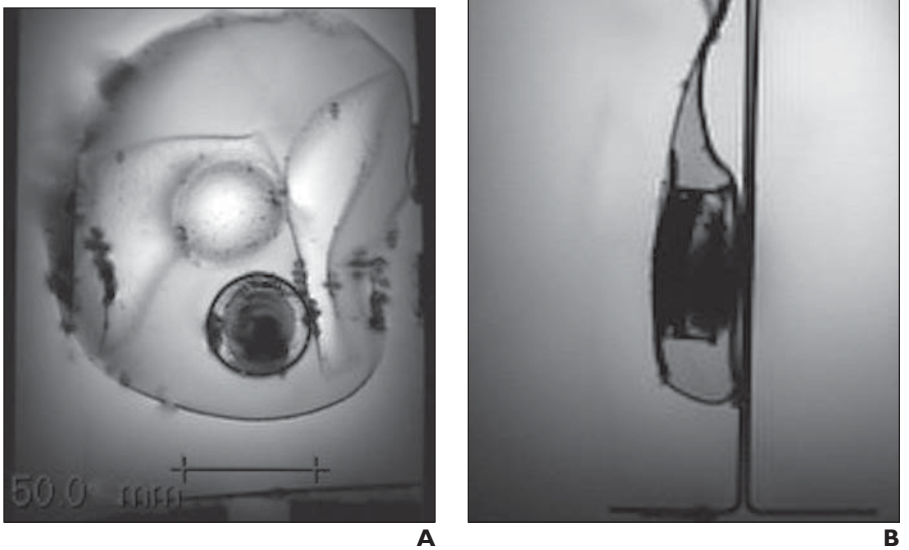

Fig. 4—MRI of tissue expander with radiofrequency identification (RFID) port.
A, MR image of phantom shows tissue expander with RFID port obtained using gradient-recalled echo pulse sequence in long-axis imaging plane.
B, MR image of phantom shows tissue expander with RFID port obtained using gradient- recalled echo pulse sequence in short-axis imaging plane.

The current study evaluated MRI issues for a newly developed tissue expander that contains an RFID port that enables detection of its location via radio waves. The application of RFID technology is well-described and various types of tags and their related technologies have been refined over the years [24, 29]. Although RFID technology has been widely applied for informational and commercial objectives, it has only recently been described for use in the medical and health care fields, including for use in silicone breast implants [24, 29–31]. Of note is that RFID technology is currently approved by the U.S. Food and Drug Administration, and is categorized as a Class II (special controls) medical device intended to enable access to secure patient identification and corresponding health information [29]. Because this new tissue expander has a metallic component, MRI issues such as magnetic field interactions, heating, and artifacts are of concern, as is the MRI effect on the function of the RFID.

Magnetic Field Interactions

The tissue expander with RFID port displayed extremely minor magnetic field interactions at 3 T, unlike the typical tissue expander that incorporates a magnetic port [25, 26]. Thus, the tissue expander with RFID port (also unlike a tissue expander with a magnetic port) will not present an additional hazard or risk to a patient undergoing MRI at 3 T or less with respect to magnetic field interactions.

MRI-Related Heating

MRI has the potential to create excessive temperature rises in certain metallic implants [14]. To ensure safety in a patient with a metallic implant, MRI-related heating is assessed using in vitro methods that entail recording temperatures with the implant placed in a gelled saline–filled phantom and subjecting it to relatively high RF power levels [14–19, 22]. The findings in this investigation revealed relatively minor temperature rises that were considered to be physiologically inconsequential [32]. Notably, the RFID port in the tissue expander is encased by silicone, which effectively isolates and insulates this metallic component from the patient.

Artifacts

Artifacts seen on MR images associated with tissue expanders that have magnetic ports are well known to be extremely large and extend well beyond the size and shape of these implants, which also show substantial distortion on MR images. This distortion is one of the critical aspects that prevents proper use of MRI in patients with implants [10, 25, 26]. By comparison, artifacts observed with the tissue expander with RFID port were relatively small in relation to the size and shape of the metallic component, which potentially permits diagnostically relevant MRI examinations to be performed in a patient with this implant. Of further consideration is that when a metallic implant is present in a patient, the MRI technologist or radiographer routinely implements one or more strategies to minimize the size of the artifact, including selecting a different pulse sequence (e.g., a fast spin-echo versus a standard spin-echo sequence), decreasing the TE, decreasing the TR, increasing the bandwidth, increasing the number of signals acquired, swapping the phase or frequency encoding direction, decreasing the section thickness, using a STIR sequence for fat suppression versus a frequency-selective fat suppression sequence, or using a software-based technique (e.g., metal artifact reduction sequence)

Assessment of MRI on Function

When using RFID technology for a medical application, the operational aspects of the device must be unimpaired when exposed to various environments, particularly the harsh electromagnetic setting associated with MRI [15, 24]. As such, the testing of the functional aspects of the RFID port used with this tissue expander was a particularly important part of this study. The results showed that each sample of this implant ($n = 12$) was able to display the correct ESR. The ESR associated with the tissue expander with RFID port permits a rapid and unique identification of this implant. More importantly, the injection port could be successfully located in every instance. Thus, the tissue expander with RFID port was unaffected by exposures to various MRI conditions at 1.5 T/64 MHz and 3 T/128 MHz.

Possible Limitations

The tissue expander with RFID port was specifically tested at 1.5 T and 3 T only. The 1.5-T MRI system is the most widely used scanner in the world and the 3-T scanner is the highest static magnetic field in widespread clinical use (7-T scanners are now approved for clinical use but these are currently too few in number throughout to be of concern for these implants). MRI systems operating above or below these static magnetic field strengths and frequencies may have an impact on the tissue expander with RFID port, which is deemed a possible limitation of our investigation.

Conclusion

A newly developed breast tissue expander with RFID port underwent comprehensive MRI testing that included assessments of the implant's functionality. The results revealed that this tissue expander is acceptable, or "MR Conditional" using current MRI labeling terminology, for a patient undergoing an MRI examination at 1.5 T or 3 T [7]. Importantly, the relatively small size of the artifacts in relation to the size and shape of this tissue expander with RFID port offers potential advantages for the use of MRI compared with tissue expanders that have magnetic ports because artifacts associated with magnetic ports create both substantial signal loss and distortion of the MR image.

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