Septal repair implants: evaluation of magnetic resonance imaging safety at 3 T

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Abstract

Specialized implants are used for transcatheter closure of septal defects, including atrial and ventricular septal defects, and patent foramen ovale. These metallic devices may pose a risk to patients undergoing magnetic resonance imaging (MRI) procedures especially if performed at 3 T. Therefore, this investigation evaluated MRI safety at 3 T for septal repair implants (CardioSEAL Septal Repair Implant and STARFlex Septal Repair Implant, NMT Medical, Boston, MA, USA) by characterizing magnetic field interactions, heating and artifacts. These implants exhibited minor magnetic field interactions; heating was not excessive (+0.5°C); and artifacts will only create a problem if the area of interest is in the same area as or near these devices. Thus, the findings indicated that it would be safe for a patient with these implants to undergo MRI at 3 T or lower. Importantly, because of the minor magnetic field interactions, MRI may be performed immediately after implantation.

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1. Introduction

Transcatheter closure of septal defects using specialized devices is a well-accepted procedure that has a high success rate and few complications [1–4]. The percutaneous closure of patent foramen ovale (PFO) with similar implants is gaining popularity due to the potential for septal abnormalities to pose a risk factor for cryptogenic stroke [5,6]. Paradoxical embolism from a venous source through a right to left shunt is usually considered responsible for these embolic events. In addition, PFO has been implicated in the etiology of platypnea–orthodeoxia syndrome, decompression illness in scuba divers and migraine headache.

Because implants used for the closure of septal defects and PFO contain metallic materials, there is concern with regard to the safe use of magnetic resonance imaging (MRI) procedures in patients with these devices, especially considering the gaining popularity of MR systems that operate at 3 T and the associated risks [7–11]. The primary concerns include the possibility of movement and excessive heating of metallic objects [7–11]. Furthermore, artifacts may impact the diagnostic use of MRI [7–11]. Therefore, the purpose of this study was to evaluate the magnetic field interactions, heating and artifacts of two septal repair implants in association with a 3-T MR system.

2. Materials and methods

2.1. Septal repair implants

Two metallic implants were evaluated in association with the use of a 3-T MR system: the CardioSEAL Septal Repair Implant (40 mm, largest version; material, MP35N; NMT Medical, Boston, MA, USA) and the STARFlex Septal Repair Implant (38 mm, largest version; materials, MP35N and nitinol; NMT Medical). These devices, commonly referred to as septal repair implants, are used to repair septal defects and to occlude PFO.

The CardioSEAL Septal Repair Implant (Fig. 1) has the longest clinical use history of all currently available septal occluders. This double-umbrella implant provides a highly conformable design with a very low septal profile and a low

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metal surface area. The polyester tissue scaffold is well proven to promote endothelialization. The CardioSEAL framework is fabricated from MP35N, a cobalt-based alloy known for its excellent corrosion resistance and MRI safety. The CardioSEAL is available in five sizes: 17, 23, 28, 33 and 40 mm (size is determined by the diagonal length of the metal arms).

The STARFlex Septal Repair Implant (Fig. 1) is similar to the CardioSEAL in design and materials, with the addition of an ultra-fine diameter wire (0.0015 in.) nitinol coil spring. The centering spring positions the STARFlex in the center of the defect. The self-centering function of STARFlex allows the use of smaller-sized devices relative to septal defect sizes. The STARFlex is available in 23-, 28- and 33-mm sizes. The 23-, 28- and 33-mm devices have four arms per side whereas the 38-mm size has six.

2.2. Magnetic field interactions

The septal repair implants were assessed for translational attraction and torque in association with an active-shielded 3-T MR system (Excite, Software G3.0–052B, General Electric Healthcare, Milwaukee, WI, USA).

2.2.1. Translational attraction

Translational attraction was determined for each implant using the deflection angle measurement technique, as previously described [8–10]. Each implant was attached to a special test fixture to measure the deflection angle in the 3-T MR system. The test fixture consisted of a sturdy structure capable of holding each implant in a proper position without movement of the fixture and incorporated a protractor with 1° graduated markings [8–10]. Each implant was suspended from the protractor by a lightweight string (weight, <1% of the weight of the implant) attached at the 0° indicator. The length of the string was 20 cm, which was long enough so that each implant could be suspended from the test fixture and hang freely in space.

Measurements were obtained at the position in the 3-T MR system that produced the greatest magnetically induced deflection angle [8–10]. This point was determined using gauss line plots, magnetic field measurements and visual inspection to identify the location of the highest spatial magnetic field gradient. For the 3-T scanner used in this study, the direction of the static magnetic field was horizontal and the highest spatial gradient occurred at a position that was 74 cm from the isocenter of the scanner. The magnetic spatial gradient at this position is 720 G/cm. The deflection angle from the vertical direction to the nearest 1° was measured three times for each implant, and an average value was calculated [8–10].

2.2.2. Torque

The next evaluation of magnetic field interactions was conducted to qualitatively determine the presence of magnetic field-induced torque for each implant using a previously described methodology [8,10]. This procedure used a flat plastic material with a millimeter grid on the bottom [8,10]. Each implant was placed on the test apparatus in an orientation that was 45° relative to the static magnetic field of the 3-T MR system. The test apparatus with the implant was then positioned in the center of the scanner, where the effect of torque from the static magnetic field is greatest [8,10]. Each implant was observed for possible alignment or rotation relative to the static magnetic field. The implant was then moved 45° relative to its previous position and again observed for alignment or rotation [8,10]. This process was repeated to encompass a full 360° rotation of positions for each implant. The following qualitative scale was applied to the results [8,10]: 0 = no torque; +1 = mild or low torque (the implant slightly changed in orientation but did not align to the magnetic field); +2 = moderate torque (the implant aligned gradually to the magnetic field); +3 = strong torque (the implant showed rapid and forceful alignment to the magnetic field); +4 = very strong torque (the implant showed very rapid and very forceful alignment to the magnetic field).

2.3. MRI-related heating

2.3.1. Phantom and experimental setup

An in vitro assessment of MRI-related heating at 3 T was conducted on each septal repair implant. This procedure used a plastic phantom designed to approximate the size of the human head and torso, with dimensions as follows [8,10–12]: head portion width, 16.5 cm; length, 29.2 cm; height, 16.5 cm; torso portion width, 43.2 cm; length, 61.0 cm; height, 16.5 cm. The phantom was filled with a gelling agent (hydroxyethylcellulose) in an aqueous solution (91.48% H2O) along with 0.12% NaCl [8,10–12]. This is an appropriate medium for the evaluation of an implant at 3 T (unpublished observations). A plastic frame with small adjustable posts was placed at the bottom of the phantom and used to position each implant according to its intended in vivo use (i.e., septal defect/PFO). Notably, because this experimental setup lacks blood flow, it simulates an extreme condition used to assess MRI-related heating for these implants.
2.3.2. Temperature recording system

Temperature measurements were obtained using a fluoroptic thermometry system (Model 3100, Luxtron, Santa Clara, CA, USA) [8,10–12]. This thermometry system has small probes (Model SFF, 0.5 mm in diameter) that respond rapidly to temperature alterations (response time, 0.25 s). The fluoroptic thermometry probes were positioned relative to each implant to record sites that would generate the greatest heating of the surrounding medium during MRI (i.e., based on results from pilot experiments that were conducted) as follows: Probe 1, placed in contact with one end of the septal repair implant contacting metal; Probe 2, placed in contact with the contralateral end of the septal repair implant contacting metal; Probe 3, placed in contact with the middle portion of the septal repair implant contacting metal. In addition, another probe (Probe 4) was placed in the gelled saline at a position approximately 20 cm from the implant but within the area of MRI to record a reference temperature during the heating experiment (Probe 4). The thermometry probes were visually inspected immediately before and immediately after the MRI-heating experiments to ensure that they were properly positioned, as stated above.

2.3.3. MRI conditions

MRI was performed at 3 T on the phantom with each implant using a transmit radio frequency (RF) body coil and the following parameters: fast spin-echo pulse sequence; axial plane; repetition time, 425 ms; echo time, 14 ms; echo train length, 4; flip angle, 90°; bandwidth, 16 kHz; field of view, 40 cm; imaging matrix, 256×256; section thickness, 10 mm; number of section locations, 20; phase direction, anterior to posterior; imaging time, 15 min. The landmarking position (i.e., the center position or anatomical region for the MRI procedure) and section locations were selected to encompass the entire area of each implant under evaluation. The imaging parameters produced an MR system-reported value for the whole body averaged specific absorption rate (SAR) of 3.0 W/kg.

2.3.4. Experimental protocol

Each septal repair implant was positioned on the plastic frame using the adjustable posts. The plastic frame was then placed on the bottom of the phantom. The fluoroptic thermometry system was calibrated and the probes were positioned, as previously described. The phantom was filled with the gelled saline and allowed to equilibrate to the environmental temperature (i.e., inside the MR system). The room temperature and the temperature of the bore of the MR system were at a constant level throughout the heating experiment. The MR system’s fan was not on. After recording baseline temperatures (5 min), MRI was performed for 15 min, with temperatures recorded at 10-s intervals. This method of evaluating MRI-related heating for an implant is consistent with the technique described by the American Society for Testing and Materials (ASTM) International [12] and used in prior investigations [8,10,11].

2.4. Artifacts

Artifacts seen on MR images were determined for each septal repair implant. This procedure involved attaching the implants to a flat plastic frame and placing the frame inside a gadolinium-doped, saline-filled plastic phantom [8,10]. Gadolinium-doped saline was used to provide a high signal background for the evaluation of these metallic implants and has been used in prior artifact evaluations [8,10]. MR images were obtained using a 3-T MR system, a transmit/receive RF body coil and the following parameters:

1. T1-weighted spin-echo pulse sequence (repetition time, 500 ms; echo time, 20 ms; matrix size, 256×256; section thickness, 10 mm; field of view, 20 cm; number of excitations, 2; bandwidth, 16 kHz) and

2. Gradient echo pulse sequence (repetition time, 100 ms; echo time, 15 ms; flip angle, 15°; matrix size, 256×256; section thickness, 10 mm; field of view, 20 cm; number of excitations, 2; bandwidth, 16 kHz).

The imaging planes were oriented to encompass the long axis and short axis of each implant. The frequency-encoding direction was parallel to the plane of imaging for each imaging condition [8,10].

Planimetry software was used to measure (accuracy and resolution, ±10%) the cross-sectional area of the largest artifact size (determined during pilot experiments from multiple section locations imaged) for each implant, for

<table>
<thead>
<tr>
<th>Implant</th>
<th>T1-weighted spin echo (mm²)</th>
<th>Gradient echo (mm²)</th>
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<tbody>
<tr>
<td></td>
<td>Long axis *</td>
<td>Short axis *</td>
</tr>
<tr>
<td>CardioSEAL</td>
<td>537</td>
<td>747</td>
</tr>
<tr>
<td>STARFlex</td>
<td>547</td>
<td>753</td>
</tr>
</tbody>
</table>

* Imaging plane relative to the septal repair implant.
each pulse sequence and for each orientation of the section location [8,10]. The image display parameters (i.e., window and level settings, magnification and so on) were carefully selected and used in a consistent manner to facilitate valid measurements of artifact size [8,10]. Measurements were obtained to determine the maximum or worse-case artifact area related to the presence of the implants for each MRI. This ensured that the sizes of the artifacts were not underestimated [8,10].

3. Results

3.1. Magnetic field interactions

The average deflection angles and torque values associated with exposure to the 3-T scanner were as follows: a deflection angle of 4° and torque value of 0 (no torque) for the CardioSEAL Septal Repair Implant and a deflection angle of 5° and torque value of 0 (no torque) for the STARFlex Septal Repair Implant.

3.2. MRI-related heating

The results of the MRI-related heating tests indicated that the highest temperature change measured for the CardioSEAL Septal Repair Implant was 0.4°C (measured by Probes 1, 2 and 3). For the STARFlex Septal Repair Implant, the highest temperature change was 0.5°C (Probe 1). Probes 2 and 3 measured the highest temperature change of 0.4°C. The highest temperature change measured by the reference probe was 0.4°C for both MRI-related heating experiments.

3.3. Artifacts

Artifact test results are shown in Table 1. The artifacts were seen as signal voids that were larger than the size and shape of the septal repair implants. For both implants, the gradient echo pulse sequence produced larger artifacts than the T1-weighted spin-echo pulse sequence (Figs. 2 and 3).

Fig. 3. Artifacts for the septal repair implants: gradient echo pulse sequence; long-axis imaging plane (top of figure, CardioSEAL; bottom of figure, STARFlex).

4. Discussion

At the present time, two septal repair implants, the CardioSEAL (NMT Medical) and the Amplatzer (AGA Medical, Golden Valley, MN, USA), have approval from the U.S. Food and Drug Administration. Six septal repair implants have received a CE mark and are commercially available in Europe: the CardioSEAL and STARFlex (NMT Medical), Amplatzer (AGA Medical), HELEX (W.L. Gore & Associates, Flagstaff, AZ, USA), Intrasept (Cardia, Burnsville, MN, USA) and Premere (Velocimed, Maple Grove, MN, USA). Common to all septal repair implants is the use of a metallic framework combined with a tissue scaffold; therefore, MRI safety is of the utmost concern. Although such implants were initially used primarily to close congenital heart defects such as atrial and ventricular septal defects, most current uses are in the closure of PFO. Randomized clinical trials are currently ongoing to study the association of PFO with both ischemic stroke and migraine, and other potential indications have been proposed. If clinical trial results support expanded indications for the use of septal repair implants to close PFOs, then widespread use is expected in a relatively young patient population, as the typical age for most PFO closure studies ranges between 18 and 60 years. As such, there is a high likelihood that patients with implants used for septal repair will require examination by MRI at some point in their lives.

4.1. Magnetic field interactions

The assessment of translational attraction for the two metallic septal repair implants indicated deflection angles of 4° (CardioSEAL) and 5° (STARFlex) in association with exposure to the 3-T MR system. Because the deflection angles were <45° (i.e., passing the ASTM International recommended level) [9], the magnetically induced deflection forces are substantially less than the forces on the implants due to gravity [9]. Furthermore, there was no qualitative evidence of torque observed for these two implants. [Note: Because of the minor deflection angle (4°) and lack of torque determined using the qualitative technique, it was deemed unnecessary to perform quantitative torque tests for these implants.]

Accordingly, patients with the CardioSEAL Septal Repair Implant and the STARFlex Septal Repair Implant may have MRI examinations performed using scanners operating with a static magnetic field strength of 3 T or lower. Of further note is that, because of the minor magnetic field interactions at 3 T, MRI may be performed immediately after these devices are implanted.

4.2. MRI-related heating

Metallic implants may heat excessively during MRI; however, this tends to occur for objects that have an elongated shape or closed-loop configuration [7,8,10,11,13]. According to the MRI-related heating experiments, the highest temperature changes measured for the CardioSEAL
Septal Repair Implant and the STARFlex Septal Repair Implant were 0.4°C and 0.5°C, respectively. The reference probe measured the highest temperature changes that were the same or only slightly higher than these values. As such, MRI-related heating for the septal repair implants at 3 T using a transmit/receive RF body coil at a whole body averaged SAR of 3.0 W/kg for 15 min will not create a risk to patients with these devices.

4.3. Artifacts

Artifacts seen on MR images that are associated with a metallic implant are proportional to the magnetic susceptibility of the materials that are present and typically appear as signal loss and/or distortion that may be larger than the size and shape of the object [7,8,10,14,15]. The strength of the static magnetic field will also impact artifact size insofar as, for a given metallic object, using comparable imaging parameters, artifacts will tend to be larger when imaging at 3 versus 1.5 T [8,10].

For the septal repair implants, the artifacts at 3 T may be problematic with respect to viewing anatomy in the same area as or near these devices. Also, because of the greater amount of metallic material present for the STARFlex implant as compared with the CardioSEAL, artifacts were correspondingly larger. In addition, larger artifacts were seen with the use of the gradient echo pulse sequence as compared with the T1-weighted pulse sequence. This is important to recognize because cardiac MRI frequently uses gradient echo-based pulse sequences and, therefore, the presence of the CardioSEAL or the STARFlex implant may impair the diagnostic capability of MRI performed at 3 T if the desire is to examine cardiac anatomy.

5. Summary

Based on the results of the MRI tests that were performed, the CardioSEAL Septal Repair Implant and the STARFlex Septal Repair Implant will not present an additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3 T or lower and under the MRI-related heating conditions used for this evaluation (whole body averaged SAR of 3 W/kg for 15 min). Therefore, these implants should be considered safe according to the specific conditions used for the MRI safety evaluation. Furthermore, because magnetic field interactions are relatively minor, an MRI procedure performed at 3 T or lower may be conducted in patients with these devices immediately after implantation.

Artifacts for the septal repair implants may present problems if the anatomical region of interest is in or near the area where these implants are located (e.g., heart). As such, consideration should be given to optimizing MRI parameters that are known to minimize artifacts associated with metallic objects [7,15].

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References