Assessment of MRI Issues for a 3-T “Immune” Programmable CSF Shunt Valve

OBJECTIVE. A newly developed CSF shunt valve that incorporates a magnetically adjustable mechanism designed to resist unintended setting changes was evaluated for problems during 3-T MRI.

MATERIALS AND METHODS. Standardized protocols were used to assess magnetic field interactions, MRI-related heating, artifacts, and functional changes related to multiple exposures and various MRI conditions in nine different samples at 3 T.

RESULTS. The magnetic field interactions were not excessive. MRI-related heating, which was studied at a relatively high, MRI system–reported whole body–averaged specific absorption rate (2.9 W/kg), was at a level that should not pose a hazard to a patient. Although artifacts were large in relation to the dimensions of this programmable CSF shunt valve, the results were consistent with similar devices containing permanent magnets. Multiple exposures and various MRI conditions at 3 T did not damage or affect the functional aspects of the devices, and no unintentional changes to the valve setting were observed.

CONCLUSION. In consideration of the test results, this new programmable CSF shunt valve is not adversely affected by the 3-T MRI environment and is acceptable for a patient undergoing MRI at 3 T or less when specific guidelines are followed, including verifying the valve setting according to manufacturer recommendations immediately after the MRI procedure.
of a newly developed programmable CSF shunt valve in patients referred for MRI, we conducted this investigation to evaluate factors that may affect this implant in the 3-T MRI environment (i.e., the worst case for a clinical MRI system). The factors included magnetic field interactions (translational attraction and torque), MRI-related heating, artifacts, and functional changes associated with multiple exposures and various MRI conditions [12–14].

Materials and Methods
Programmable CSF Shunt Valve
A magnetically programmable CSF shunt valve (Codman Certas Programmable Valve, Codman, a Johnson & Johnson Company), which is in regulatory review, was evaluated in a 3-T MRI environment (Fig. 1). This device is used to regulate intraventricular pressure by means of a ball-and-cone mechanism under the control of a calibrated flat spring and can be noninvasively adjusted with an external tool whereby permanent magnet elements are used to alter the force applied to the ball. Hard magnets fixed within a moveable cam react to the presence of the magnetic field of the tool by first translating vertically to an unlocked position and subsequently rotating in response to the movement of the external tool. Removal of the tool from the moveable cam returns the cam to a locked position in which rotation from one setting to another is prevented.

Owing to its design, this valve inherently does not respond to large magnetic fields, such as those associated with MRI systems. The requirement that the cam first be attracted upward to allow its rotation and subsequently be rotated to a different setting is not allowed by the combined influence of the orientation of the magnets in the cam or the limited freedom of cam movement imposed by the fixed axle on which the cam translates and rotates. Exposure of the cam to a large magnetic gradient while it is in the locked, or down, position results in a rotational influence that is prevented by the constraining features of the mechanism. Furthermore, exposure of the cam to a strong static magnetic field causes the cam to bind on its axle because it is being drawn to rotate out of the permissible plane. This process hinders both translation and rotation of the cam around the axle.

The adjustable CSF shunt valve accommodates eight settings by which the moveable cam provides an incrementally different offset to the flat spring, changing the performance of the valve (i.e., the valve setting). Metallic materials for the programmable valve include 316L stainless steel, unalloyed titanium, tantalum, and neodymium (Nd-Fe-B magnets) (Fig. 1). Inflow and outflow catheters made from silicone are used with this CSF shunt system.

Fig. 1—Schematic shows programmable CSF shunt valve subjected to 3-T MRI. Silicone housing and upper casing of adjustment mechanism are transparent to show following components: two neodymium magnets (1), 316L stainless steel retention spring (2), 316L stainless steel spring (3), tantalum bead (4), titanium axle (5).

Magnetic Field Interactions
Previously described test procedures [12, 13, 18] were used to evaluate the programmable CSF shunt valve with two silicone catheters attached for translational attraction and torque in association with a 3-T active shielded horizontal-field MRI system (Excite, software G3.0–052B, GE Healthcare).

Translational Attraction
The deflection angle test was used to assess translational attraction [12, 13, 18]. The programmable CSF shunt valve was attached to a special test fixture to measure the deflection angle in the MRI system. The test fixture consisted of a sturdy structure capable of holding the device in position without movement and contained a protractor with 1° graduated markings rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically. The programmable CSF shunt valve was suspended from a thin lightweight (weight less than 1% of the device) string attached at the 0° indicator position on the protractor. The test apparatus was positioned in the 3-T MRI system at the point of the highest spatial gradient magnetic field. For the 3-T unit used in this investigation, the highest spatial gradient magnetic field was 720 gauss/cm [18]. Sources of forced air movement within the MRI system bore were turned off during the measurements. The maximum deflection angle from vertical to the nearest 1° was measured three times for the valve, and an average value was calculated [18, 19].

Qualitative Assessment of Torque
A previously described qualitative assessment technique [12, 13, 18] was used to determine the presence of magnetic field–induced torque on the programmable CSF shunt valve. The test apparatus was a flat plastic device with a millimeter grid. The programmable CSF shunt valve was placed on the device in an orientation 45° relative to the static magnetic field of the 3-T MRI system. The apparatus was then positioned in the center of the MRI unit, where the effect of torque is the greatest, and the valve was observed for possible alignment or rotation relative to the 3-T static magnetic field. The programmable CSF shunt valve was then moved 45° relative to its previous position and observed for alignment or rotation. This process was repeated to encompass a full 360° rotation of positions for the valve. The following qualitative scale was applied to the results [12, 13, 18]: 0, no torque; +1, mild or low torque, the device slightly changed in orientation but did not align to the magnetic field; +2, moderate torque, the device aligned gradually to the magnetic field; +3, strong torque, the device showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the device exhibited very rapid and very forceful alignment to the magnetic field.

MRI-Related Heating
Phantom and experimental setup—MRI-related heating was assessed for the programmable CSF shunt valve with a plastic phantom (length, 61 cm; width, 43 cm) filled to a depth of 10 cm with semisolid, gelled saline solution (0.8 g/L NaCl plus 5.85 g/L polyacrylic acid in distilled water) prepared to simulate human tissue according to American Society for Testing and Materials (ASTM) International designation F2182–09 [12, 13, 18, 20]. The valve was placed in the phantom at a position midline on the left side, slightly (5 mm) below mid depth (vertical orientation) of the gelled saline solution to create a worst case for MRI-related heating of an implant [18], according to ASTM International designation F2182–09 [20]. For the particular 3-T 128-MHz MRI system and experimental setup used in this investigation, the left side of the phantom was found to be associated with a greater temperature increase than the right side of the head-torso phantom for a given implant or device. Therefore, the programmable
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CSF shunt was placed on the left side to produce a worst-case temperature increase for the described measurement conditions on the basis of results of a previous analysis of device heating for this particular MRI system (i.e., due to asymmetry in heating patterns for this phantom and the MRI system) [18]. Because this phantom and experimental setup lack blood flow, they simulate an extreme condition used to assess MRI-related heating for this device.

Temperature recording system and placement of thermometry probes—Temperature measurements were obtained with a fluoroptic thermometry system (model 3100, LumaSense Technologies). The fluoroptic thermometry probes (diameter, 0.5 mm) were positioned as follows on the programmable CSF shunt valve to record representative temperatures: probe 1, sensor portion of the probe placed in contact with one end of the device; probe 2, sensor portion of the probe placed in contact with opposite end of the device; probe 3, sensor portion of the probe placed in contact with middle portion of the device. The positions of the thermometric probes were inspected and verified immediately before and after the MRI-related heating assessment.

MRI conditions—MRI was performed at 3 T and 128 MHz with the aforementioned system. The body radiofrequency coil was used to transmit radiofrequency energy. MRI parameters were selected to generate a relatively high level of radiofrequency energy [18], producing an MRI system–reported whole body–averaged specific absorption rate of 2.9 W/kg for 15 minutes of image acquisition. The landmarking position (center position or anatomic region for the MRI procedure) and section locations were selected to encompass the entire area of the programmable CSF shunt valve.

Experimental protocol—The programmable CSF shunt valve was positioned in the plastic phantom by use of a grid and small plastic post setup, as previously described [12, 13, 18]. The fluoroptic thermometric system was calibrated, and the fluoroptic thermometric probes were applied. The phantom was filled with the gelled saline solution and allowed to equilibrate to environmental temperature for more than 24 hours. The MRI system fan was not on during the MRI-related heating assessment. The room and MRI system bore temperatures were at constant levels throughout the experimental session. After recording of baseline temperature (5 minutes), MRI was performed for 15 minutes and temperature was recorded at 10-second intervals. The highest temperature changes recorded with the fluoroptic thermometric probes were reported for the programmable CSF shunt valve.

The background temperature in the phantom also was recorded. Thus the temperature change was recorded at the phantom in association with MRI-related heating of the gelled saline–filled phantom without the device present. For recording of background temperature, a fluoroptic thermometric probe was placed in the phantom at a midline position on the left side slightly (5 mm) below the mid depth (vertical orientation) of the gelled saline solution [18, 20].

Artifacts

MRI artifacts were evaluated at 3 T for the programmable CSF shunt valve by acquisition of MR images with the device attached to a plastic frame and then placed in a gadolinium-treated, saline solution–filled plastic phantom [12, 13, 18]. MRI was performed with the aforementioned 3-T system, a transmit-receive radiofrequency head coil, and the following two sequences: T1-weighted spin-echo pulse sequence (TR/TE, 500/20; matrix size, 256 × 256; section thickness, 10 mm; field of view, 28 cm²; number of signals acquired, 2; bandwidth, 16 kHz) and gradient-recalled echo pulse sequence (100/15; flip angle, 30°; matrix size, 256 × 256; section thickness, 10 mm; field of view, 28 cm²; number of signals acquired, 2; bandwidth, 16 kHz). The imaging planes were oriented to encompass the long and short axes of the programmable CSF shunt valve. The frequency-encoding direction was parallel to the plane of imaging.

The image locations obtained through the programmable CSF shunt valve represented the largest, or worst-case, artifacts on the basis of review of multiple section locations in each imaging plane for this device, and these images were selected for evaluation. Planimetric software was used to measure (accuracy and resolution, ±10%) the cross-sectional area of the largest artifact size for each pulse sequence and for each orientation of the section location. The image display settings (e.g., window and level, magnification) were carefully selected and used in a consistent manner for acquisition of valid measurements of the artifacts. This method has been used in many previous reports involving the characterization of artifacts for metallic implants [12, 13, 18].

Evaluation of Effects of 3-T MRI on Function

Experiments were performed to assess the effects of the 3-T static magnetic field of the MRI system and various MRI conditions selected to be representative of typical techniques used for clinical MRI examinations to determine whether nine different samples of the programmable CSF shunt valve were damaged or whether there was a change in function [12, 13]. The different MRI exposures, conditions, and orientations of the devices were used to cover a range of possible scenarios.

Conditions for 3-T static magnetic field exposure—Nine samples of the valve were attached three per orthogonal orientation (axial, sagittal, and coronal) to a plastic copper sulfate–filled phantom (length, 30 cm; width, 20 cm; height, 10 cm). The samples were carefully attached to the phantom, placed on the patient table of the MRI system, and inserted in (past isocenter and out the back of the unit to the farthest point) and out (approximately 0.5 m past the opening of the bore of the MRI system) of the unit 10 times [12, 13]. Immediately before and after each exposure, each programmable CSF shunt valve was subjected to functional testing for the ability both to indicate and to adjust the valve setting.

Setup and conditions for MRI exposure—Nine samples of the programmable CSF shunt valve were placed on the plastic copper sulfate–filled phantom in a manner similar to that used for the 3-T static magnetic field exposure tests. MRI of the phantom with the nine valves was performed at 3 T with a transmit-receive body radiofrequency coil and eight different pulse sequences, running sequentially, for approximately 1 minute per pulse sequence with a 10-second delay between sequences [12, 13] (Table 1). The landmarking position (center position or anatomic region for the MRI procedure) and multiple section locations were selected to encompass all samples to ensure thorough exposure to these MRI conditions. After this exposure, each programmable CSF shunt valve was subjected to functional testing, which included confirming the ability to indicate the valve setting and the ability to adjust the valves to other settings.

Results

Magnetic Field Interactions

The results for assessment of magnetic field interactions for the programmable CSF shunt valve indicated that the mean deflection angle was 16° and the torque was +1 (mild or low torque, the device slightly changed orientation but did not align to the magnetic field).

MRI-Related Heating

The highest temperature changes recorded with the fluoroptic probes were 1.8°C (probe 1), 1.8°C (probe 2), and 1.6°C (probe 3) for the programmable CSF shunt valve. The highest background temperature change was 1.5°C.

Artifacts

Artifact test results are summarized in Table 2. The artifacts were predominantly losses of signal intensity larger than the size and shape of the programmable CSF shunt valve. The gradient-echo pulse sequence produced larger artifacts than the T1-weighted spin-echo pulse sequence. Figure 2 shows examples of artifacts for the gradient pulse sequence in long-axis and short-axis orientations relative to the device.
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Effects of MRI on Function
The settings of the nine programmable CSF shunt valves did not change, and the valves were not damaged in multiple exposures to the static magnetic field of the 3-T MRI system. With regard to exposure in the eight 3-T MRI conditions, the nine valves withstood appropriate adjustments, indicating that there was no damage and that the functional aspects of these devices were unaffected. No unintentional setting changes were found after any of the test scenarios relative to the 3-T MRI environment.

Discussion

Magnetic Field Interactions
The average deflection angle was 16° at 3 T for the new programmable CSF shunt valve. This information should be considered in accordance with the following information provided by ASTM International [19], as follows: “If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). Therefore, this valve passed the aforementioned acceptance criterion for a 3-T MRI system. The qualitatively measured torque was relatively low (+1). This valve therefore does not cause a hazard to a patient in a 3-T MRI environment with respect to rotational alignment to the static magnetic field.

The magnetic field interactions (translational attraction and torque) found at 3 T for this programmable CSF shunt valve were comparable to levels reported for other magnetically activated valves [12, 13]. Of further note is that besides possible magnetic field problems, the intended in situ application of this valve may be taken into consideration [14]. Counterforces acting on this programmable CSF shunt valve that result from the use of sutures and attached inflow and outflow catheters associated with implantation in a patient will help prevent movement of this device during exposure to the MRI environment.

In view of the findings on magnetic field interactions for this new valve, there are no safety issues for patients undergoing MRI on systems operating at 3 T or less. Furthermore, a patient with this programmable CSF shunt valve would be allowed to undergo an MRI procedure at 3 T or less immediately after implantation because of the relatively minor magnetic field interactions that are present.

MRI-Related Heating
The highest temperature change recorded for the programmable CSF shunt valve during MRI performed at a relatively high MRI system—reported whole body–averaged specific absorption rate (2.9 W/kg) was 1.8°C. By comparison, the amount of heating that occurred at the same position in the phantom under the same MRI conditions without this implant was 1.5°C (i.e., the background temperature increase). This temperature level will not cause a hazard for a patient with this implant with the MRI parameters used in the heating test. In addition, because a static medium (i.e., no perfusion) was used for the evaluation, an acceptable margin of safety may be presumed, as has been the case for other programmable CSF shunt valves [12, 13]. Although it may be possible to use MRI parameters to reach a whole body–averaged specific absorption rate of 4 W/kg, this is an unlikely value to achieve in performance of a clinical MRI examination involving the area where this valve is implanted (i.e., brain and head).

Substantial implant heating may be generated during MRI but only in an object made from conducting material of a certain length or in the shape of a closed loop with a relatively large diameter [14]. For the programmable CSF shunt valve used in this study, all metallic components are relatively small and encased in nonmetallic
nonmagnetic material that effectively insulates and isolates them from the patient (Fig. 1). Therefore, as found in the evaluation of MRI-related heating, the temperature increase for this valve will not be substantially higher than the background temperature, even under extreme or worst-case experimental conditions at 3 T.

**Artifacts**

Artifacts associated with the programmable CSF shunt valve were relatively large in relation to the dimensions of the device. This finding is not surprising because the device incorporates two small neodymium magnets (Fig. 1). It is well known that implants that incorporate magnets produce large to very large artifacts on MR images, as has been reported for other magnetically activated CSF shunt valves and implants used for other applications [11–14, 16, 21, 22]. The extent of artifact for a magnetically activated shunt valve depends on the specific device, the magnetic susceptibility of the materials, and the imaging parameters used [10–14, 16]. If the anatomic area of interest is close to the programmable CSF shunt valve, as with other such devices [10–14, 16], the diagnostic use of MRI can be compromised, possibly concealing brain abnormalities on MR images [16]. This issue may influence the choice of valve implantation site and the type of valve selected for use [16]. Although it is possible to use imaging parameters to minimize the extent of the artifacts, the parameters have been chosen carefully to allow adequate signal-to-noise and contrast-to-noise ratios to obtain diagnostically useful MR images. The sizes of the MRI artifacts associated with the CSF shunt valve used in this study were consistent with those of similar devices containing permanent magnets [11–13, 16, 21, 22]. With regard to possibly reducing artifacts associated with such implants, use of fast spin-echo sequences, increasing the readout bandwidth, and decreasing the voxel size may be considered.

**Effects of MRI on Function**

A malfunctioning CSF shunt valve can cause serious complications due to overdrainage and elevated intracranial pressure [1, 2, 9]. It is vital to identify possible functional disturbances of magnetically programmable CSF shunt valves because the setting can be changed or the mechanism damaged as a result of exposure to a strong magnetic field, such as that used during MRI [3–15, 22–26]. Previous MRI-based investigations have documented both minor and substantial unintentional changes in valve settings related to exposure to magnetic fields [3–5, 7–9, 15]. There is evidence that even weaker magnets, including those found in toys, hair dryers, telephone speakers, and home use magnetic induction therapy, can alter the settings of programmable CSF shunt valves [23–25], causing some device manufacturers to recommend checking the valve setting on a regular basis [24, 25].

The findings of the tests designed to assess the effects of multiple exposures to the static magnetic field and to different MRI conditions at 3 T showed that there were no changes in the valve settings or damage to the valve. These results are consistent with the intent of this new magnetically adjustable shunt design, but the limitations of this study and the critical importance of the valve setting in hydrocephalic patients would suggest that in clinical use, confirming the unchanged status of the setting after MRI examinations is prudent. As a precaution to ensure patient safety, the manufacturer of the programmable CSF shunt valve recommends checking the valve setting after the patient undergoes MRI.

**Conclusion**

The MRI findings on the new programmable CSF shunt valve indicate there are no significant concerns related to the 3-T MRI environment under the test conditions used for this evaluation, and as such, the device is not adversely affected by this powerful static magnetic field. The effect of higher-strength static magnetic fields on this device are unknown. The following guidelines are recommended [27, 28]. Nonclinical testing has shown that the Codman Certas Programmable Valve is MRI conditional in accordance with ASTM designation F2503–05 [27]. A patient with this implant can safely undergo imaging immediately after implantation under the following conditions.

**Static Magnetic Field**

The static magnetic field must be 3 T or less. The highest spatial gradient magnetic field should be 720 gauss/cm or less.

**MRI-Related Heating**

In nonclinical testing, the valve studied produced the highest temperature change of +1.8°C during MRI performed for 15 minutes of image acquisition (i.e., per pulse sequence) in the 3-T MRI system (128-MHz, Excite, HDx, software 14 ×.M5, GE Healthcare). Therefore, the MRI-related heating experiments for the programmable valve at 3 T with a transmit-receive radiofrequency body coil at an MRI system–reported whole body–averaged specific absorption rate of 2.9 W/kg (associated with a calorimetry-measured whole body–averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was +1.8°C or less.

**MRI Artifacts**

Artifacts were assessed with T1-weighted spin-echo and gradient-recalled echo pulse sequences. The details of these pulse sequences and the corresponding artifact sizes are shown in Table 2. MR image quality can be compromised if the area of interest is in the exact location of or relatively close to the location of the programmable valve. MRI artifacts can be minimized with careful selection of pulse sequence parameters.
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Specific Guidelines
The valve setting must be verified immediately after MRI, according to the manufacturer's recommendations.

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References