Magnetically programmable shunt valve: MRI at 3-Tesla

Frank G. Shellocka,b,*, Stephen F. Wilsonc, Christophe P. Maugec

aKeck School of Medicine, University of Southern California, Los Angeles, CA, USA
bInstitute for Magnetic Resonance Safety, Education, and Research, Los Angeles, CA 90045, USA
cResearch and Development, Codman, a Johnson & Johnson Company, Raynham, MA 02767, USA

Received 25 September 2006; revised 6 December 2006; accepted 7 December 2006

Abstract

A magnetically programmable cerebrospinal fluid (CSF) shunt valve (Codman Hakim Programmable Valve, Codman, a Johnson & Johnson Company, Raynham, MA) was assessed for magnetic field interactions, heating, artifacts and functional changes at 3-Tesla. The programmable valve showed minor magnetic field interactions and heating (+0.4°C). Artifacts were relatively large in relation to the size and shape of this implant and, as such, may create a problem if the area of interest is in proximity to this implant. While multiple exposures and various magnetic resonance imaging (MRI) conditions at 3-Tesla changed the settings of some valves (i.e., reprogramming was needed), the function of the programmable valve was not permanently affected. Therefore, this magnetically programmable CSF shunt valve is acceptable for a patient undergoing MRI at 3-Tesla or less when specific safety guidelines are followed, including resetting the valve, as needed.

Keywords: Magnetic resonance imaging; Safety; MRI; Implants; Specific absorption rate; Artifacts; Hydrocephalus; CSF; Programmable valve

1. Introduction

A hydrocephalus shunt valve is an implantable device that provides constant intraventricular pressure and drainage of the cerebrospinal fluid (CSF) for the management of hydrocephalus and other conditions of impaired CSF flow and absorption [1–4]. Programmable shunt valves allow surgeons to noninvasively optimize the opening pressure of a shunt system before and after implantation, permitting the implementation of specialized treatment regimes [1–4].

Programmable valves are typically adjusted using an externally applied programmer tool to magnetically couple to the adjustable components of these devices [5–14]. Accordingly, exposure to powerful magnetic fields can cause inadvertent changes in valve settings or permanently damage CSF shunt valves [3–14]. With regard to magnetic resonance imaging (MRI), various other issues exist for programmable valves, including the possibility of movement of the implant, extreme heating and the impact of substantial artifacts on diagnostic imaging [9–12,15,16]. The increasing clinical use of 3-T scanners necessitates the evaluation of implanted devices at this higher field strength [5–7,12,16]. Therefore, the objective of this investigation was to assess magnetic field interactions, heating, artifacts and functional changes for a commonly used [1] programmable valve (Codman Hakim Programmable Valve, Codman, a Johnson & Johnson Company, Raynham, MA) in relation to the use of a 3-T MR system.

2. Materials and methods

2.1. Programmable valve

The programmable valve (Codman Hakim Programmable Valve, Codman, a Johnson & Johnson Company) is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired (Fig. 1). Intraventricular pressure is controlled by a “ball and cone” valve that is under the control of a calibrated flat spring and can be noninvasively adjusted with the use of an external programmer with a magnetic mechanism. Hard magnets fixed within the base of a moveable cam react to the presence of the magnetic field by rotating the cam to achieve equilibrium. The adjustable valve accommodates 18 valve settings from 30 to 200 mm H₂O in 10-mm H₂O increments. Metallic
steels, within a casing with the following dimensions: 4.8 mm in diameter × 10 mm in length.

materials for the programmable CSF valve include 316L stainless steel, Vacoperm (Ni–Fe), Vacomax (Sm–Co) and unalloyed titanium.

2.2. MR system

A 3-T (Excite, Software G3.0-052B, General Electric Medical Systems, Milwaukee, WI) active-shielded, horizontal field scanner was utilized for all tests conducted on the programmable valve.

2.3. Magnetic field interactions

Magnetic field interactions were determined for the programmable valve in association with the 3-T MR system.

2.3.1. Translational attraction

Translational attraction was assessed for the programmable valve using the deflection angle technique [12,17–19]. The programmable valve was attached to a test fixture to measure the deflection angle. The test fixture has a protractor mounted to the top of the structure and included a bubble level to ensure proper orientation in the scanner. Measurements were obtained at the position in the 3-T MR system that produced the greatest magnetically induced deflection angle [12,17–19]. This point was determined using gauss line plots, magnetic field measurements and visual inspection to identify the location of the highest spatial gradient. The highest spatial gradient for the 3-T MR system occurs at a position that is 74 cm from the isocenter of the scanner [12,19]. 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, and an average value was calculated.

2.3.2. Torque

Magnetic-field-induced torque was assessed qualitatively for the programmable valve using previously described methodology [12,19]. This procedure utilized a flat plastic material with a millimeter grid. The programmable valve was placed on this test platform in an orientation that was 45° relative to the direction of the static magnetic field of the 3-T MR system. The test apparatus with the programmable valve was then positioned in the center of the scanner, where the effect of torque is the greatest (based on the known characteristics for the 3-T MR system), and observed for alignment or rotation [12,19]. The programmable valve was then moved 45° relative to its previous position and again observed for alignment or rotation. This procedure was repeated to encompass a 360° rotation of positions for the programmable valve in the scanner. A qualitative scale was applied to the results to characterize torque [12,19]: 0, no torque; +1, mild or low torque, the implant slightly changed 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. Of note is that one of the investigators (F.G.S.) has more than 20 years of experience applying this qualitative scale to the characterization of torque.

2.4. MRI-related heating

An in vitro experiment was performed at 3-Tesla/128-MHz to determine MRI-related heating for the programmable valve according to a previously described protocol [12,17,19–21]. The programmable valve was placed to approximate its intended in vivo use position in a plastic head/torso phantom (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 in an aqueous solution (i.e., 0.8 g/L NaCl plus 5.85 g/L polyacrylic acid in distilled water) [12,17,19–21].

Temperatures were recorded using a fluoroptic thermometry system (Model 3100, Luxtron, Santa Clara, CA) with fluoroptic thermometry probes (Model SFF, 0.5 mm in diameter) positioned on the programmable valve to record temperatures associated with the greatest heating during MRI, as follows [12]: Probe 1, sensor portion of the probe placed in direct contact with one end of the programmable valve; Probe 2, sensor portion of the probe placed in direct contact with the other end of the programmable valve; Probe 3, sensor portion of the probe placed in direct contact with the middle portion of the programmable valve. The positions of the fluoroptic thermometry probes were verified immediately before and after the heating experiment. The accuracy of the fluoroptic thermometry equipment used to record temperatures in this study is ±0.1°C.

MRI was performed at 3-Tesla/128-MHz on the gelled, saline-filled phantom with the programmable valve using a transmit radio frequency (RF) body coil to produce a relatively high level of RF energy, as follows: fast spin-echo pulse sequence; axial plane; multislice; 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

![Fig. 1. The programmable valve that underwent testing at 3-Tesla. The programmable valve is housed in a 3.7×5.2×10.8 mm rigid plastic casing. The antisiphon device contains two springs composed of 316L stainless steel, within a casing with the following dimensions: 4.8 mm in diameter × 10 mm in length.](image-url)
section locations, 20. The landmarking position (i.e., the center position or anatomic region for the MRI procedure) and section locations were selected to encompass the entire area of the programmable valve. The imaging parameters produced an MR-system-reported value for the whole-body averaged specific absorption rate (SAR) of 3.0 W/kg. The room temperature and scanner’s bore temperature were at a constant level throughout the heating experiment. After recording baseline temperatures (5 min), MRI was performed for 15 min, with temperatures recorded at 10-s intervals [12,17,19–21].

2.5. MRI artifacts

Artifacts were evaluated at 3-Tesla with the programmable valve placed inside of a gadolinium-doped, saline-filled phantom [12,17,19]. MRI was performed using a send–receive RF head coil and the following pulse sequence parameters [12,17,19]: for the T1-weighted, spin-echo pulse sequence: repetition time, 500 ms; echo time, 20 ms; matrix size, 256×256; section thickness, 5 mm; field of view, 24 cm; number of excitations, 2; for the gradient-echo pulse sequence: repetition time, 100 ms; echo time, 15 ms; flip angle, 30°; matrix size, 256×256; section thickness, 5 mm; field of view, 24 cm; number of excitations, 2. The imaging planes were oriented to encompass the long axis and short axis of the programmable valve. The frequency encoding direction was parallel to the plane of imaging. Section locations were selected through the programmable valve from multiple “scout” MR images to represent the largest artifacts for this implant. Image display parameters (i.e., window and level settings, magnification) were used in a consistent manner to facilitate valid measurements of artifact size. Cross-sectional artifact areas were measured for each MRI condition using planimetry software provided with the MR system (accuracy, ±10%) [12,17,20].

2.6. Effects of MRI on the function of the programmable valve

Experiments were conducted to determine the effects of exposing the programmable valve to the 3-T MRI environment (i.e., the static magnetic field, alone) and to various MRI conditions selected to be representative of techniques used for 3-T scanning (Tables 1 and 2) [12].

2.6.1. Conditions for 3-T static magnetic field exposures

Nine samples of the programmable valve were attached in different orientations to the outside of a plastic head/torso phantom that allowed consistent orthogonal positioning within the 3-T MR system. The samples were oriented in axial, sagittal and coronal planes in an “up” or “down” valve orientation:

<table>
<thead>
<tr>
<th>Valve Setting</th>
<th>Orientation and direction</th>
<th>Results</th>
<th>Adjustable</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) PCT 747</td>
<td>Cor, U–D</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>(2) PCU 524</td>
<td>Cor, U–D</td>
<td>120</td>
<td>200</td>
</tr>
<tr>
<td>(3) PCU 522</td>
<td>Cor, D–U</td>
<td>110</td>
<td>200</td>
</tr>
<tr>
<td>(4) PCT 746</td>
<td>Sag, D–U</td>
<td>120</td>
<td>200</td>
</tr>
<tr>
<td>(5) PCU 520</td>
<td>Sag, U–D</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>(6) PCU 523</td>
<td>Sag, D–U</td>
<td>120</td>
<td>200</td>
</tr>
<tr>
<td>(7) PCT 754</td>
<td>Axial, D–U</td>
<td>120</td>
<td>200</td>
</tr>
<tr>
<td>(8) PCU 521</td>
<td>Axial, U–D</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>(9) PCT 750</td>
<td>Axial, D–U</td>
<td>80</td>
<td>200</td>
</tr>
<tr>
<td>(10) PCT 753</td>
<td>Control</td>
<td>70</td>
<td>100</td>
</tr>
<tr>
<td>(11) PTI 105</td>
<td>Control</td>
<td>30</td>
<td>100</td>
</tr>
</tbody>
</table>

Valve orientation: Cor, coronal; Sag, sagittal; valve direction: U, up; D, down.
direction (Table 1). All valves were adjusted to a setting of 100 mm H2O. Two valves were used as control, unexposed devices. For the exposure test, the samples were attached to the phantom, placed on the patient table of the MR system and inserted in (i.e., pass isocenter and out the back of the scanner to the farthest point) and out (i.e., approximately 0.5 m past the opening of the bore of the MR system) of the scanner 10 times. Immediately before and after these exposures, the programmable valves underwent functional testing for valve setting adjustment.

2.6.2. Conditions for MRI exposures

The nine programmable valves were placed on the outside of a head/torso phantom similar to the manner used for the static magnetic field exposure test (Table 2). All valves were adjusted to a setting of 100 mm H2O. MRI was performed at 3-Tesla on the phantom with the programmable valves using a transmit/receive body RF coil and eight different pulse sequences, running sequentially for 1 min per pulse sequence, with a 10-s delay between sequences [12,17] (Table 3). The landmarking position and multiple section locations were selected to encompass all valve samples to ensure thorough exposure to the MRI conditions [12,17]. Immediately before and after the MRI exposure, the programmable valves underwent functional testing.

3. Results

The average deflection angle was 16° and the qualitative torque value was +2 for the programmable valve. Findings for the MRI-related heating experiment indicated that the highest temperature changes measured by Probes 1, 2 and 3 were 0.3°C, 0.4°C and 0.3°C, respectively. The temperature values did not appear to rise in association with time during the 15 min of MRI performed at a relatively high MR-system-reported whole-body averaged SAR value. The artifacts were seen as signal intensity voids that were substantially larger than the size and shape of the programmable valve, with the gradient-echo pulse sequence showing larger artifact areas than the T1-weighted, spin-echo pulse sequence (T1-weighted spin echo: long axis, 1590 mm²; short axis, 1022 mm²; gradient-echo: long axis, 2439 mm²; short axis, 2404 mm²) (Fig. 2). The data that compare the pre-MRI to the post-MRI functional assessment of the programmable valves indicated that five of the nine valves changed settings in relation to multiple exposures to the 3-T static magnetic field (Table 1) and that six of the nine valves changed settings (Table 2) in association with the MRI procedures. All programmable valves could be adjusted to other settings, indicating that the functional aspects of these devices were unaffected by these conditions.

4. Discussion

4.1. Magnetic field interactions

During tests conducted at 3-Tesla, the programmable valve showed relatively minor magnetic field interactions (16° deflection angle and +2 torque). Of further note is that, besides the empirical findings for magnetic field interactions, the intended in vivo use of this implant must be considered [16]. In vivo counterforces (i.e., encapsulation, stabilization provided by attached catheters and sutures) exist for certain implants that will prevent these objects from presenting a hazard to patients in association with the MRI environment [16,17]. Accordingly, there is no concern with regard to movement or migration of this programmable valve.

4.2. MRI-related heating

The highest temperature change measured for the programmable valve during 3-T MRI performed at an MR system reported whole-body averaged SAR of 3 W/kg was 0.4°C. This is a trivial temperature increase that will not have a physiological impact on a patient examined using MRI under the conditions used for this evaluation. Of note is that we used a relatively high level of RF power (whole-body averaged SAR, 3 W/kg) for our MRI-related heating assessment of this programmable valve. While it may be possible to use imaging parameters to reach a whole-body...
averaged SAR of 4 W/kg, it is unlikely that this SAR level would be associated with a procedure performed as an MRI of the brain/head region, where this valve is implanted. Notably, even at 3 W/kg, the highest temperature change (i.e., 0.4°C) was only 0.1°C above the reference temperature (0.3°C).

4.3. Artifacts

Artifacts associated with the programmable valve were relatively large in relation to its size and shape. This was likely due to the presence of the magnetic components, which are known to create extensive signal loss on MR images [12,16]. A similar finding was observed in a previous study of another magnetically activated, programmable CSF shunt valve (proGAV, Aesculap, Inc., Center Valley, PA) [12]. In consideration of the extent of the artifact associated with the programmable valve, if the area of interest is close to this implant, the diagnostic use of MRI may be substantially impaired (Fig. 2). Optimization of imaging parameters to diminish susceptibility artifacts is recommended.

4.4. Function

Subjecting the programmable valve placed in various orientations to multiple exposures to the 3-T static magnetic field and MRI performed using eight different pulse sequences altered the valve setting for 56% and 67% of the devices, respectively. Magnetically activated CSF shunt valves have been reported to have unintentional changes in settings after exposure to magnetic fields [1,5,6,8–11,13,14]. As a result of this particular phenomenon, a magnetically adjustable valve is designated with the ASTM F 2503 “MR Conditional” classification, and accompanying instructions for use direct the user to take action to ensure that the valve setting is corrected if an MRI procedure has been associated with a changed setting. Importantly, an inappropriate valve setting can produce excessive increases in intracranial pressure or overdrainage with serious clinical consequences.

Zemack and Romner [1] reported the resetting of the Codman Hakim Programmable Valve due to exposure to the MRI environment, with both increases and decreases in settings occurring as much as 50 mm H2O in magnitude. Because subjecting the programmable valve to strong magnetic fields may change its setting and in consideration of the functional assessment results of this study, it is advisable to check and reset the valve immediately after the MRI exam.

5. Recommendations

The following guidelines are recommended for scanning a patient with the magnetically programmable valve:

1. A patient with the Codman Hakim Programmable Valve (Codman, a Johnson & Johnson Company) may undergo MRI at 3-Tesla or less immediately after implantation.
2. The exposure to RF energy should be limited to an MR-system-reported whole-body averaged SAR of 3 W/kg for 15 min.
3. After MRI, the programmable valve setting should be determined and reset, as needed.

Acknowledgment

This study was supported by a research grant from Codman, a Johnson & Johnson Company, Raynham, MA.
References


