Cervical External Immobilization Devices
Evaluation of Magnetic Resonance Imaging Issues at 3.0 Tesla

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**Study Design.** Laboratory investigation, *ex vivo.*

**Objective.** Currently, no studies have addressed the magnetic resonance imaging (MRI) issues for cervical external immobilization devices at 3-Tesla. Under certain conditions significant heating may occur, resulting in patient burns. Furthermore, artifacts can be substantial and prevent the diagnostic use of MRI. Therefore, the objective of this investigation was to evaluate MRI issues for 4 different cervical external immobilization devices at 3-Tesla.

**Summary of Background Data.** Excessive heating and substantial artifacts are 2 potential complications associated with performing MRI at 3-Tesla in patients with cervical external immobilization devices. Using *ex vivo* testing techniques, MRI-related heating and artifacts were evaluated for 4 different cervical devices during MRI at 3-Tesla.

**Methods.** Four cervical external immobilization devices (Generation 80, Resolve Ring and Superstructure, Resolve Ring and Jerome Vest/Jerome Superstructure, and the V1 Halo System; Ossur Americas, Aliso Viejo, CA) underwent MRI testing at 3-Tesla. All devices were made from nonmetallic or nonmagnetic materials. Heating was determined using a gelled-saline-filled skull phantom with fluoroptic thermometry probes attached to the skull pins. MRI was performed at 3-Tesla, using a high level of RF energy. Artifacts were assessed at 3-Tesla, using standard cervical imaging techniques.

**Results.** The Generation 80 and V1 Halo devices exhibited substantial temperature rises (11.6°C and 8.5°C, respectively), with “sparking” evident for the Generation 80 during the MRI procedure. Artifacts were problematic for these devices, as well. By comparison, the 2 Resolve Ring-based cervical external immobilization devices showed little or no heating (≤0.6°C) and the artifacts were acceptable for diagnostic MRI examinations.

**Conclusion.** The low degree of heating and minor artifacts associated with the Resolve-based cervical external immobilization devices indicated that these products are safe for patients undergoing MRI at 3-Tesla.

**Key words:** magnetic resonance imaging (MRI); magnetic resonance imaging, safety; cervical external immobilization devices; heating, MRI; artifacts, MRI.

**Spine** 2010;35:411–415

A halo-based, cervical external immobilization device is commonly used to manage a patient who sustains a traumatic injury to the cervical spine.1–3 Primarily indicated for cervical instability or postoperative cervical stabilization, this device serves to maintain and immobilize cervical alignment, thus, facilitating the healing process.1–3

A cervical external immobilization device has multiple metallic and nonmetallic components that include a halo ring, skull pins, the superstructure, and a vest.1–3 Because of the presence of metallic components, magnetic resonance imaging (MRI) issues exist that can pose serious problems for patients, including those related to magnetic field interactions, excessive heating, and artifacts.4–11

MRI procedures performed at 3-Tesla may be particularly problematic for implants and devices because of the higher field strength and frequency (128-MHz) compared to examinations conducted at 1.5-Tesla/64-MHz and lower levels.11,12–17 Notably, the use of 3-Tesla MR systems for clinical applications, especially with respect to imaging the cervical spine, is increasing worldwide.18–20 In fact, assessment of the cervical spine at 3-Tesla permits a better understanding of the injury mechanism and location, which is important clinically in selecting single- or multilevel fixation.19

To date, we are unaware of investigations performed to evaluate issues for cervical external immobilization devices related to the use of 3-Tesla MR systems. Accordingly, the findings would have substantial implications for patients with cervical external immobilization devices referred for 3-Tesla MRI examinations. Therefore, the purpose of this investigation was to determine heating and artifacts associated with 4 different cervical external immobilization devices in a 3-Tesla MRI environment, using *ex vivo* testing techniques (note that the cervical external immobilization devices that underwent evaluation were made from nonmagnetic and nonmetallic materials and, therefore, there are no concerns for magnetic field interactions for these products).

**Materials and Methods**

**External Cervical Fixation Devices**

The following 4 cervical external immobilization devices (Ossur Americas, Aliso Viejo, CA) underwent evaluation for MRI issues at 3 Tesla:

1. Generation 80—aluminum halo ring, titanium skull pins, and aluminum superstructure;

2. Resolve Ring and Superstructure—compression-molded, glass composite halo ring, ceramic-tipped skull pins, and glass composite superstructure;
3. Resolve Ring and Jerome Vest/Jerome Superstructure—compression-molded, glass composite halo ring, ceramic-tipped pins, and aluminum superstructure; and


It should be noted that nonmagnetic and nonmetallic materials were used for the above products. Accordingly, there were no magnetic-field-interaction issues present for these products in association with exposure to the 3-Tesla MR system (Unpublished Data, F.G. Shellock, 2008). These devices were selected for evaluation because they represent typical, commercially available cervical external immobilization devices.

**MRI-Related Heating**

**Phantom and Temperature Measurements.** MRI-related heating was assessed for the cervical external immobilization devices in consideration of methodology described in previous reports. Thus, a plastic cylinder-shaped phantom (6.2' × 6.2') was used to properly assess MRI-related heating. This phantom had dimensions selected to approximate the human head/skull and facilitated the attachment of each cervical fixation device in a suitable manner (Figure 1). Holes were made to permit passage of 4 skull pins into the phantom. A small hole was used to pass 4 fiber-optic thermometry probes (attached to the tip of each pin) through a rubber stopper, from inside of the phantom to the outside. Importantly, the fluoroptic thermometry probes (Luxtron Model 3100 Fluoroptic Thermometry System, Lumasense, Santa Clara, CA) were placed in direct contact with the ends of the pins of each product since these positions are where the greatest amount of heating will occur based on prior work performed on similar devices (i.e., the only invasive component intended to directly contact the patient’s tissue for each product during an MRI procedure would be at the pin/tissue interface). Therefore, each cervical external immobilization device under evaluation had thermometry probes attached using porous paper tape (3-M Co., St. Paul, MN), which does not cause thermal or other insulation, as follows: (1) right anterior; (2) left anterior; (3) right posterior; and (4) left posterior.

The phantom was filled with 4 L of a semisolid, gelled-saline solution that was made to simulate human tissue. Because this phantom and experimental set-up lacked “blood flow,” it involved an extreme condition used to assess MRI-related heating for each cervical fixation device that underwent testing. The “neck/thorax” portion of the vest of each device was filled with 2 copper sulfate filled phantoms. This was done to ensure adequate loading of the transmit radiofrequency (RF) body coil of the 3-Tesla MR system (Figure 1).

**MRI Procedure.** MRI was performed on each cervical fixation device attached to the gelled-saline-filled phantom, using a 3-Tesla MR system (Excite, Software G3.0–052B, General Electric Healthcare, Milwaukie WI). The body RF coil was used to transmit and receive RF energy. MR imaging parameters were applied to generate a relatively high level of RF energy at 3-Tesla, as follows: fast spin echo pulse sequence; axial plane; repetition time, 425-millisecond; echo time, 14 milliseconds; echo train length, 4; flip angle, 90°; field of view, 30 cm; imaging matrix, 256 × 256; section thickness, 10 mm; number of section locations, 20; intersection gap, 10 mm; imaging time, 15 minute. The land-marking position (i.e., the center position or anatomic region for the MRI procedure) and section locations were selected to encompass the entire area of each device under evaluation and verified by obtaining MR images and reviewing this information. These imaging parameters produced an MR system reported, whole body averaged specific absorption rate (SAR) of 3.0-W/kg.

**Experimental Protocol.** Baseline (Pre-MRI) temperatures were recorded at 10-second intervals for 5-minutes MRI was then performed for 15 minutes with temperatures recorded at 10-second intervals. Post-MRI temperatures were recorded for 2-minutes with temperatures recorded at 10-second intervals. The temperature findings recorded from the thermometry probe are reported, herein, for the cervical external immobilization devices under evaluation during the MRI-related heating experiments. Additionally, each device was visually observed to detect any unusual occurrence during the MRI-related heating evaluations.

**MRI Artifacts**

With each cervical external immobilization device attached to the gelled-saline-filled phantom, MRI artifacts were assessed at 3-Tesla according to a previously described protocol. Because the same halo ring and skull pins are used for the Resolve Ring and Superstructure and Resolve Ring and Jerome Vest/Jerome Superstructure, only the former device underwent the artifact assessment (i.e., since the resulting MR images would be the same).

MRI was performed at 3-Tesla MR system using the following imaging parameters: gradient echo pulse sequence; sagittal plane; repetition time, 100-millisecond; echo time, 15 milliseconds; flip angle, 30°; matrix size, 256 × 256; section thickness, 10 mm; field of view, 30 cm; number of excitations, 2. A qualitative assessment was conducted to characterize the artifacts associated with each cervical fixation device, as follows: (a) +1 Small, artifact area the same size and shape of the metallic components of the medical device, no distortion or other irregularities; (b) +2, Moderate, artifact area 25% to 75% larger than the size and shape of the metallic components of the medical device, minor distortion or other irregularities;...
Table 1. Summary of MRI-Related Heating at 3-Tesla for the Cervical External Immobilization Devices: Highest Temperature Changes Measured on the Skull Pins

<table>
<thead>
<tr>
<th>Device</th>
<th>Probe 1</th>
<th>Probe 2</th>
<th>Probe 3</th>
<th>Probe 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generation 80</td>
<td>+11.6°C</td>
<td>+0.5°C</td>
<td>+2.0°C</td>
<td>+1.3°C</td>
</tr>
<tr>
<td>Resolve ring and superstructure</td>
<td>+0.3°C</td>
<td>+0.3°C</td>
<td>+0.4°C</td>
<td>+0.4°C</td>
</tr>
<tr>
<td>Resolve ring and Jerome Vest/ Superstructure</td>
<td>+0.4°C</td>
<td>+0.8°C</td>
<td>+0.5°C</td>
<td>+0.6°C</td>
</tr>
<tr>
<td>V1 Halo system</td>
<td>+0.7°C</td>
<td>+8.5°C</td>
<td>+2.9°C</td>
<td>+2.9°C</td>
</tr>
</tbody>
</table>

(c) +3, Large, artifact area 76% to 100% larger than the size and shape of the metallic components of the medical device, moderate distortion or other irregularities; or (d) +4, Very Large, artifact area greater than 101% the size and shape of the metallic components of the medical device, large distortion, or other irregularities.

Discussion

External cervical external immobilization devices are vital products used as a nonsurgical means of treating cervical spine trauma. Because of the increasing use of 3-Tesla MR systems for diagnostic imaging, especially with respect to evaluating the cervical spine, a patient with a cervical fixation device may be referred for an MRI examination in order to assess and/or monitor the degree and extent of injury and the healing process, to evaluate a pre-existing health problem, or to determine if a new condition develops. Accordingly, it is important to determine the MRI-related issues for these devices to ensure patient safety. To date, investigations have only assessed potential MRI problems for cervical external immobilization devices using MR systems operating at 1.5-Tesla or less. At 3-Tesla, there is a potential for greater risks and larger artifacts due to the higher static magnetic field and frequency (128 MHz).

In the present study, 4 different cervical external immobilization devices underwent MRI testing. These devices are made from nonmagnetic and nonmetallic materials and, therefore, there were no concerns for magnetic field interactions for these products. However, since metals are generally good conductors and known to create artifacts on MR images, testing was necessary to identify potential issues related to excessive heating and image quality at 3-Tesla.

MRI-Related Heating

Substantial MRI-related heating may occur in an implant and device made from metallic material but this only occurs for an item that has a certain length or that has a closed loop of a relatively large diameter. For cervical external immobilization devices, substantial MRI-related heating can occur at the skull pin-scalp interface. In the brief report by Kim et al., a patient sustained severe scalp burns from halo pins associated with a titanium fixation device as a complication of MR imaging performed at 1.5-Tesla MR system. This case

Figure 2. MRI artifact assessment performed on the cervical external immobilization devices: Comparison between the Generation 80 (A) and Resolve Ring and Superstructure (B) devices. Sagittal plane MR image obtained through the phantoms, using gradient echo pulse sequence. Note the problematic image quality observed for the Generation 80 with respect to the multiple sites of image distortion.
illustrates the critical importance of studying MRI-related heating for cervical external immobilization devices, using ex vivo techniques.

The MRI-related heating experiments performed at 3 Tesla, using a transmit/receive RF body coil and a relatively high RF exposure level (i.e., 3.0-W/kg) for the 2 cervical external immobilization devices that incorporated titanium skull pins and aluminum superstructures (Generation 80 and V1 Halo System) indicated that the highest temperature changes were 11.6°C and 8.5°C, respectively. Importantly, “sparking” was observed for the Generation 80, which obviously is an undesirable event for a patient undergoing MRI. Because of these excessive heating levels, it is inadvisable to perform a 3-Tesla MRI procedure in a patient with these cervical fixation systems (note: the manufacturer, Ossur, does not recommend or label these devices for use in the MRI).

For the cervical external immobilization devices that used both compression-molded, glass composite halo rings, and ceramic-tipped skull pins (Resolve Ring and Superstructure and Resolve Ring and Jerome Vest/Jerome Superstructure) the highest temperature change was less than or equal to 0.6°C. Importantly, this temperature level is not considered to be physiologically consequential for a human subject. It is not surprising that these 2 devices exhibited only minor temperature perturbations considering that the materials used to construct these fixation systems are relatively nonconductive at all clinically relative MRI-related frequencies.

Artifacts
In addition to safety concerns, artifacts associated with implants and devices can substantially compromise the diagnostic aspects of 3-Tesla MRI procedures.11,12–16,21,22 For external cervical external immobilization devices, artifacts may impair the evaluation of the cervical spine and surrounding soft tissues.4–7,9 For cervical external immobilization devices, artifacts are predominantly caused by the magnetic susceptibility of the materials used in the skull pins, halo rings, as well as the braces and uprights of the superstructure. Though nonferromagnetic materials do not result in artifacts that are as severe as those associated with are ferromagnetic materials,11,22 the presence of any artifact has the capability of hindering accurate diagnosis, especially if the skull pins are adjacent to the area of clinical concern (e.g., for MRI of the brain examinations).

In the present study, larger artifacts were observed for the cervical external immobilization devices that used higher magnetic susceptibility materials (e.g., Generation 80 using aluminum halo ring, titanium skull pins, and aluminum superstructure; V1 Halo System using titanium skull pins and aluminum superstructure) compared to those seen for the other devices (Resolve Ring and Superstructure and Resolve Ring and Jerome Vest/Jerome Superstructure). The smaller artifact found for these later 2 cervical external immobilization devices was also likely due to the low conductive qualities of the materials used for the halo rings and the skull pins.10,11,22 Notably, the use of the Resolve Ring and Superstructure or the Resolve Ring and Jerome Vest/Jerome Superstructure will permit diagnostically acceptable MRI examinations to be performed at 3 Tesla.

Conclusion
Using ex vivo testing techniques, MRI-related heating and artifacts were evaluated for 4 different cervical external immobilization devices during MRI at 3-Tesla. The Generation 80 and V1 Halo devices exhibited substantial temperature rises (11.6°C and 8.5°C, respectively), with “sparking” evident for the Generation 80 during the MRI procedure. Artifacts were problematic for these devices, as well. By comparison, the 2 Resolve Ring-based cervical external immobilization devices showed little or no heating (<0.6°C) and the artifacts were acceptable for diagnostic MRI examinations. The low degree of heating and minor artifacts associated with the Resolve-based cervical external immobilization devices indicated that these products are safe for patients undergoing MRI at 3 Tesla. These cervical external immobilization devices used ceramic-tipped pins and compression-molded, glass composite halos. To date, these are the only acceptable cervical fixation systems reported to be safe at the static magnetic field strength of 3-Tesla.

Key Points
- Cervical external immobilization devices may pose unwanted complications and risks for patients undergoing MRI examinations at 3 Tesla.
- Excessive heating (including scalp burns) and substantial artifacts are 2 potential problems associated with performing MRI at 3 Tesla in patients with cervical external immobilization devices.
- Four different cervical external immobilization devices underwent ex vivo testing to characterize heating and artifacts associated with 3-Tesla MRI procedures.
- Two devices exhibited substantial temperature rises (11.6°C and 8.5°C, respectively), with “sparking” evident for the one of them during the MRI procedure. Artifacts were also problematic for these devices.
- Two devices showed minor heating and artifacts, indicating they would be were acceptable for patients undergoing 3-Tesla MRI examinations.

References
4. Ballock RT, Haged PC, Byrne TP, et al. The quality of magnetic resonance