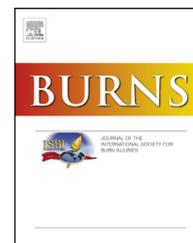


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MRI compatibility of silver based wound dressings



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ABSTRACT

As silver dressings gain more widespread use, it is more likely that patients with silver-based dressings will also undergo magnetic resonance imaging (MRI). In current practice, these dressings are removed prior to imaging due to concerns over heating and image distortion. As dressing changes can be painful, the need to remove dressings simply for MRI may increase pain and contribute to opioid dependency. To examine the need for dressing removal, American Society for Testing and Materials International standards for assessing device deflection and torque were performed on 5 silver containing and 3 non-silver control dressings. Magnetically induced heating and image distortion were examined in a porcine hind limb wound dressed with control and test dressings. The limb was scanned in a clinical high field 3T MRI scanner using a series of standard MRI sequences (Survey, T₁-weighted SE, T₁-weighted IR TSE, T₂-weighted TSE, DUAL TSE, and FLAIR). Deflection and torsion were not detected in control or silver-based dressings. For all combinations of dressings and MRI scans, average heating was between 0–0.2°C. Additionally, dressings, in dry and hydrated forms, caused no image distortion in any MRI scan performed. Evaluation of MRI safety and compatibility revealed no concerns for safety or image distortion in any of the silver-containing wound dressings tested thus it would be acceptable to leave these dressings intact during MRI. The ability to leave dressings in place during imaging will provide a significant benefit to patient care by reducing pain associated with dressing removal.

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1. Introduction

The use of dressings containing long-acting silver has become routine in the care of burns and wounds. Used in dressings to cover burns, donor sites, and skin grafts, this class of dressings offers a simplification of in- and out-patient care regimens with decreased frequency of wound care and potential cost savings [1,2]. Use of silver-containing dressings has expanded beyond burn care with increasing utilization for the management of dermal ulcers, surgical wounds, and wounds within skin folds [3–5]. As these dressings become more popular, it becomes progressively more likely that patients benefitting from this class of dressings will require magnetic resonance imaging (MRI).

As pain management during burn dressing changes and wound care can be painful with over 75% of burn centers using premedication with opioids for dressing changes [6], the need to remove dressings simply for MRI only adds to the patient's pain and can contribute to opioid dependency [7]. To determine if these wound dressings are safe for MRI and thus can remain on during scanning, standardized testing procedures for MRI safety and compatibility have been developed by the American Society for Testing and Materials International (ASTM) [8–10]. ASTM standards for assessing safety focus on the potential for deflection and torsion of the implant as well as the generation of heat [8–10] and are routinely utilized to examine medical devices such as vessel clips, electroencephalography electrodes, and dental implants [11–13]. In addition to the overriding concern regarding patient safety, there is also potential for interference with image acquisition with standards for image distortion evaluation established by the ASTM [14]. While dressings of this class have been tested and reported safe for MRI previously [15–17], this assertion cannot be applied to all silver dressings. If a given dressing has not been directly tested and reported safe for MRI, the dressing must be removed for the MRI procedure [17].

As silver dressings have been reported to improve bacterial clearance from burn wounds [18], reduce the frequency of burn wound sepsis [19], and reduce the need for frequent dressing changes [20], it seems unlikely that the use of dressings with long-acting silver will become less popular. In deference to safety, the default removal of dressings with unknown MR compatibility will continue. For that reason, we report the systematic evaluation of a series of silver-containing dressings from a single manufacturer. In addition to the standardized testing for torque and deflection described by the ASTM, an appropriate phantom consisting of a porcine limb was used to more closely mimic clinical conditions of MRI use on patients and also to evaluate possible tissue heating and/or image distortion in a myriad of different scenarios meant to mimic the wound environment.

2. Materials and methods

2.1. Characterization of magnetically induced displacement force and torque

Assessment of magnetically induced displacement force and torque was carried out following ASTM Standards F2052-15 and

F2213-06, respectively [8,9]. To measure displacement force, silver containing wound dressings (TRITEC™ Silver, ULTRA Silver, ASSIST™ Silver, and ASSIST™ Silver Absorbent; Milliken Healthcare Products LLC, Spartanburg, SC; and Interdry® Ag; Coloplast Corporation, Minneapolis, MN) and non-silver containing control dressings (ULTRA and AFM® Absorbent Pad; Milliken Healthcare Products, LLC, Spartanburg, SC; and Kerlix™ gauze; Covidien Ltd., Minneapolis, MN) were rolled into a cylindrical shape, massed and held in suspension with a string from a non-magnetic test fixture (Fig. 1A). The total mass of the string was recorded to ensure that it was < 1 wt.% of the dressing. The apparatus was placed near the entrance and axis of the bore of a clinical high field 3T MRI scanner (Philips Healthcare, Best, The Netherlands) at The Ohio State University Wright Center of Innovation in Biomedical Imaging. The dressing was released and its angular deflection, α , recorded to the nearest degree. Each dressing type was assessed three times. Magnetically induced deflection force, F_m , for each dressing was calculated from the following equation, $F_m = mg \tan \alpha$, where m = mass of dressing, g = acceleration due to gravity and α = deflection angle. In addition, a positive control material (steel screw) was attached to the apparatus and assessed to confirm that the test fixture was functioning properly. Dressings with an angular deflection of less than 45° were deemed MRI safe according to ASTM F2052-15.

To measure magnetically induced torque, rolled wound dressings were measured, massed, and then placed on a holder suspended by a torsional spring with a known spring constant in a non-magnetic test fixture (Fig. 1B). The fixture was placed in the center of the bore of the high field 3T MRI scanner and slowly rotated 90°. The deflection of the device, θ , in response to the magnetic field was calculated with respect to the base at 0, 45 and 90°. These measurements were repeated a total of three times for each wound dressing. Magnetically induced torque, τ , was calculated from the following equation, $\tau = k\Delta\theta$, where $\Delta\theta$ is the deflection angle of the basket from its equilibrium position relative to the fixed base outside of the magnet and k is the spring constant. Average torque (Newton × meter, $N \times m$) + standard deviation were reported. A positive control, a rod of steel (7 cm × 0.5 cm diameter), was utilized to confirm that the test apparatus was functioning properly. Materials were considered MRI safe if the maximum measured torque was less than the longest dimension of the dressing multiplied by its weight according to ASTM F2213-06.

2.2. Characterization of magnetically induced heating and image distortion

To assess magnetically induced heating and image distortion, the hind limb of a euthanized Yorkshire pig was imaged in a clinical high field 3T MRI scanner (Philips Healthcare, Best, The Netherlands). The hind limb was harvested approximately 5 h prior to MR procedures and kept at room temperature (18–20°C) without light exposure during this time. To simulate a wound with full-thickness skin loss, a roughly circular (approximately 10 cm diameter), area of skin was sharply excised. Temperature probes (Luxtron 790 Fluoroptic Thermometer; Luxtron Corp., Santa Clara, CA) were placed at the periphery of the wound and within the subcutaneous fat in the center of the

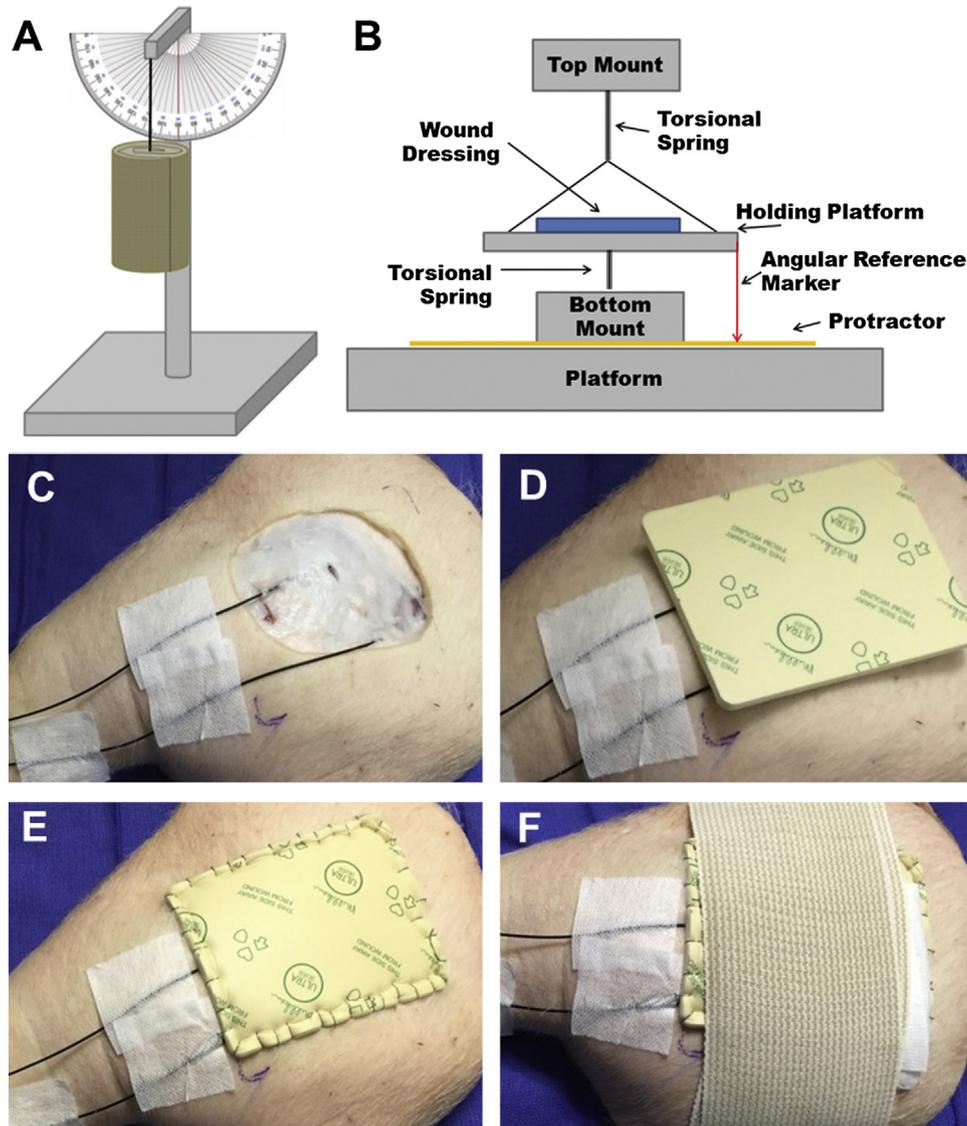


Fig. 1 – Schematic of the non-magnetic test fixtures to examine deflection (A) and torsion (B). Photographs of the porcine hind limb model used to examine heating and image distortion beneath wound dressings. (C) Temperature probes were placed at the periphery of the wound and at the center of the wound beneath the thin layer of remaining dermal tissue. (D) Dressings were placed over the wound in a dry or hydrated state for MR imaging. To mimic the complete assembly of dressings often used, wound dressings were also stapled to the periphery of the wound (E) and covered by absorbent gauze followed by elastic bandaging (F).

wound (Fig. 1C). All experimental and control dressings were applied to the limb and sequentially scanned using a series of six standard MRI sequences (Survey, T_1 -weighted SE, T_1 -weighted IR TSE, T_2 -weighted TSE, DUAL TSE, FLAIR and DWI) with both dry and moistened applications (soaked in saline with 5 wt.% bovine serum albumin) with no additional fixation or dressings. The images for each set of scans were graded individually on a 0–4 scale, in which a 0 rating corresponded to an image without any distortion present and a 4 signified that the image was unusable. An image receiving a 0–3 grade was considered clinically useful. The overall grade given to a series of images was based on the worst graded image of that series. If any image of a series showed a distortion of greater than 3 then the entire series was considered unusable. Additionally, to more closely mimic wound dressings in clinical use, a hydrated wound dressing was secured to the wound using

surgical staples (Appose ULC 35W Skin Stapler, Covidien Ltd., Minneapolis MN) (Fig. 1E), covered with absorbent gauze (Curity, Covidien Ltd., Minneapolis, MN) followed by Ace bandages (Fig. 1F) and scanned as above. Temperature during all scans was recorded at 30s intervals throughout the scan and average change in temperature+standard deviation reported for each dressing type and MRI sequence.

3. Results

3.1. Magnetically induced displacement torque and force

For all wound dressings, non-silver based and silver based, the angle of deflection, measured by two independent observers, when the test fixture was placed at the entrance of the bore

Table 1 – Average deflection and torque of non-silver and silver-based wound dressings. A material with a deflection angle less than 45° was considered MRI safe. A torque less than the material’s longest axis multiplied by its mass was considered MRI safe.

Material/test	Deflection (degrees)	Torque (N*m)
AFM [®] absorbent	0±0	0±0
AFM [®] Ag absorbent	0±0	0±0
ASSIST [™] Silver	0±0	0±0
Interdry Ag	0±0	0±0
TRITEC [™] Silver	0±0	0±0
ULTRA	0±0	0±0
ULTRA Silver	0±0	0±0
Kerlix [™]	0±0	0±0
Metal control	90±0	0.47±0.01

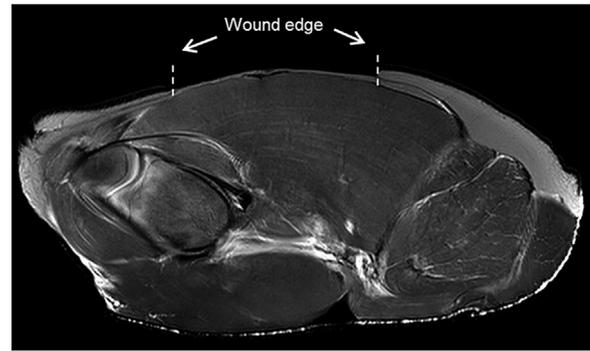


Fig. 3 – A T₂-weighted TSE MRI of a porcine hind limb with a full-thickness cutaneous injury (wound borders indicated with white dashed line).

was zero (Table 1). When a small, steel screw was attached to the fixture, it was strongly and immediately deflected towards the bore. In addition, all tested wound dressings generated no torque within the MRI scanner (Table 1).

3.2. Magnetically induced heating and image distortion

A series of seven, standard clinical MRI sequences were performed on the wound dressings, in both dry and hydrated conditions, and the limb alone (Blank) to assess RF-induced

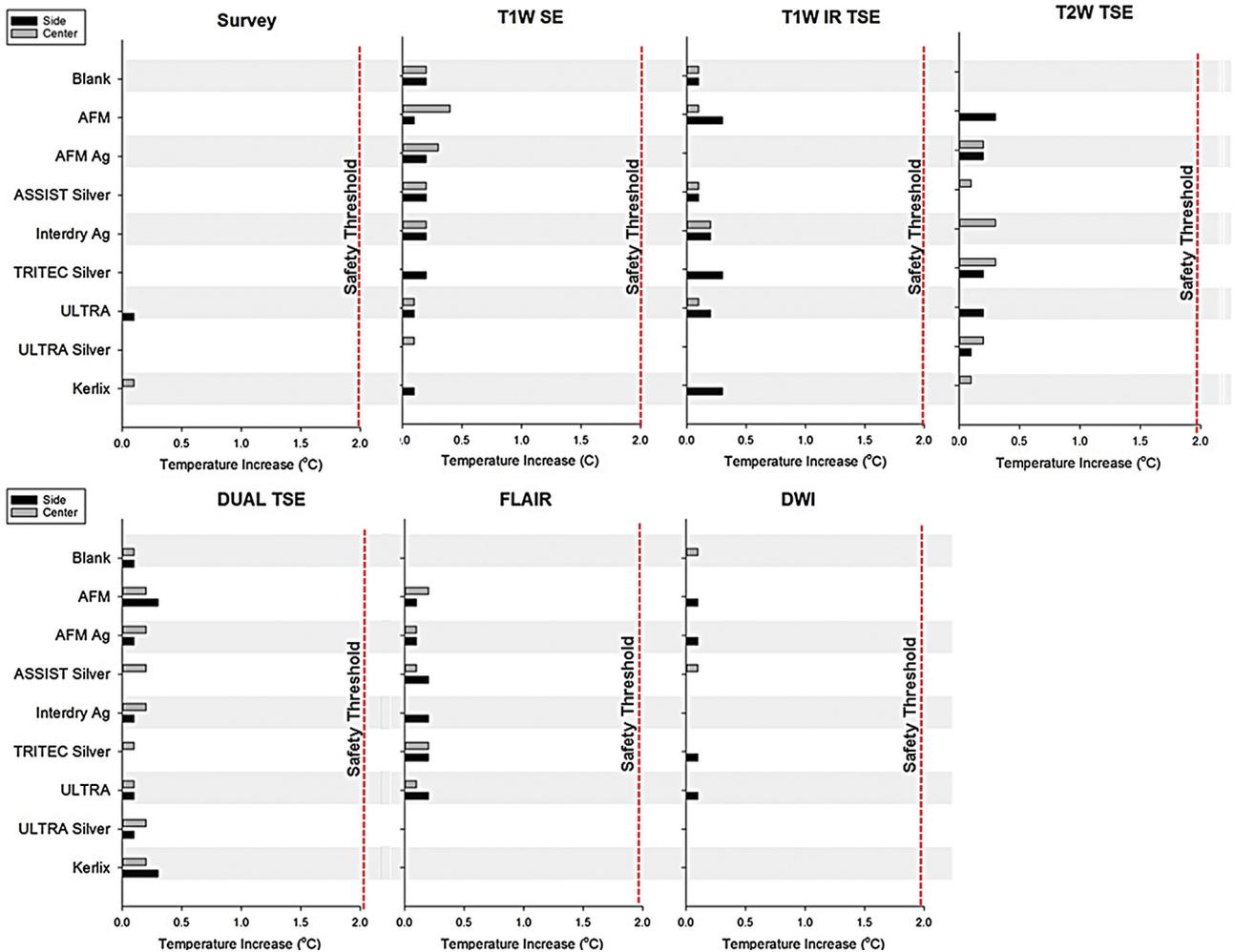


Fig. 2 – Magnetically induced heating of porcine tissue under dry wound dressings after MR scanning using a series of 7 standard clinical MRI sequences. A wound dressing was considered MRI safe if the increase in temperature was less than 2 °C.

heating of the underlying tissue. As expected, the more rapid gradient echo scans (Survey and DWI) resulted in no heating to very little heating (<0.1°C). For all scans and all wound dressings, either in their dry or hydrated state, increases in temperature were equal to or below 0.4°C with the majority <0.2°C (Fig. 2).

All images in each MR sequence were scored on an ordinal scale ranging from 0 to 4 with 0 representing no distortion and 4 representing an unusable image. All images scored in the 0 category (*data not shown*) and thus the wound dressing was not observed to cause any image distortion (Figs. 3 and 4). In

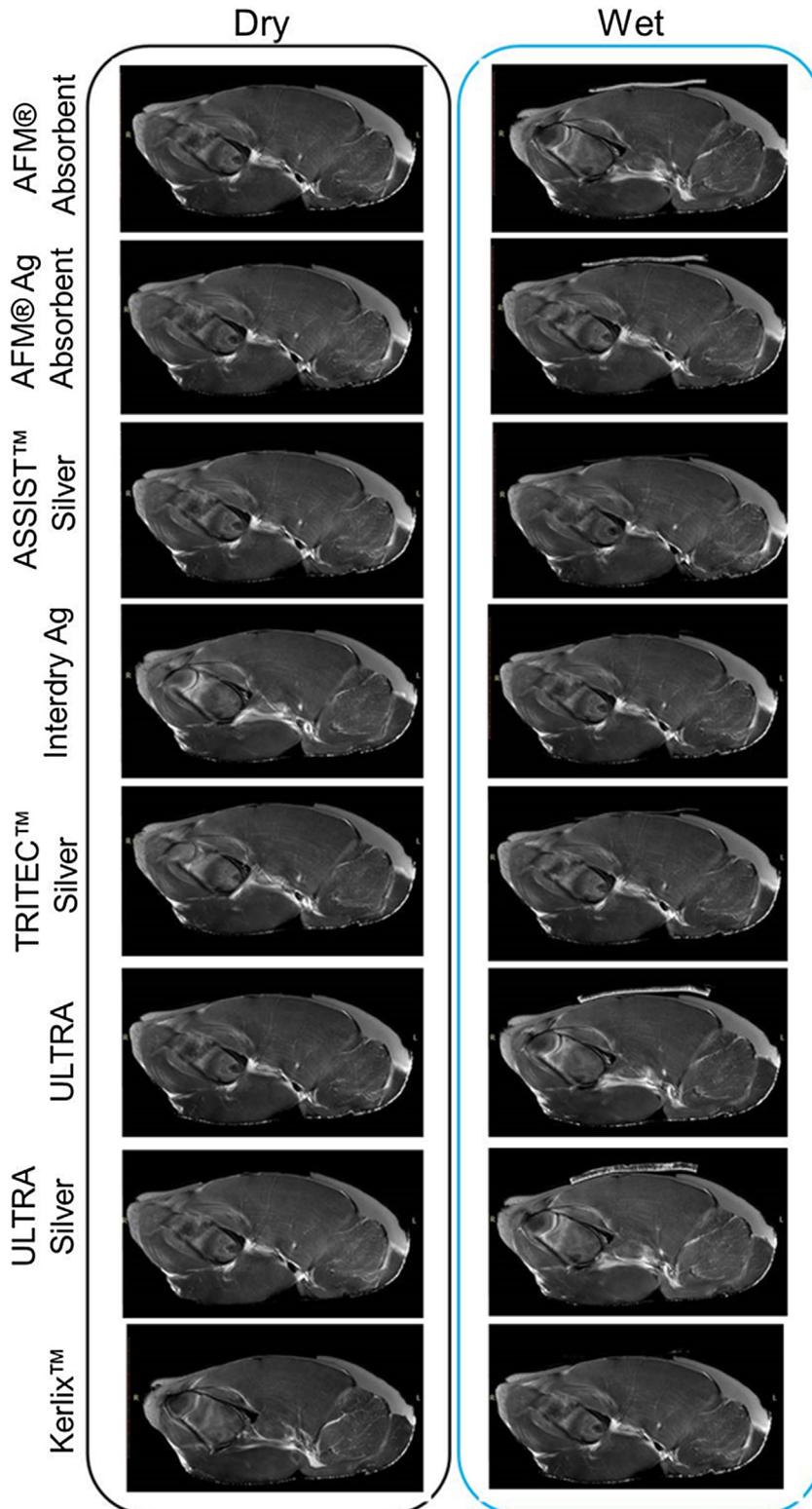


Fig. 4 – MR images of a porcine hind limb with wound dressings covering a full-thickness cutaneous injury. Wound dressings were imaged in their dry and hydrated forms using seven standard, clinical MRI sequences (T₂-weighted TSE MRI sequence shown as examples). No image distortion was observed in this study.

addition, when the wound dressing was affixed to the wound using skin staples followed by the application of absorbent gauze and elastic bandaging, no image distortion (Fig. 5) or additional heating was observed.

4. Discussion

With the growing popularity of silver-based dressings, there is a need to assess the compatibility and safety of the metallic component with MRI use. Depending on the type of material, the magnetic field lines within an object in the MR unit can be concentrated, as in the case of ferromagnetic, paramagnetic, and superparamagnetic materials, or dispersed, as in the case of diamagnetic materials like silver and silver ions. The extent to which a material becomes magnetized when placed in an external magnetic field is described as magnetic susceptibility (χ). A material is expected to produce negligible force and torque along with little to no image distortion if difference in magnetic susceptibility between the material and water is less than 10^{-5} [21]. As the magnetic susceptibility of water and silver ions is -9.05×10^{-6} and -27×10^{-6} [21,22], respectively, the potential image distortion for silver-based dressings is anticipated to be quite low. In addition, the inclusion of electrically conductive components to medical devices can create eddy current within these materials leading to heating. The temperature increases resulting from these materials are related to the material properties, including heat capacity, electrical conductivity and implant dimensions [23]. As the silver utilized in these wound dressings is in the form silver ions encased in zirconium phosphate ceramics which are then within a non-conductive polymer, electrical conductivity would be extremely low and subsequently the possibility for significant dressing-related heating would be minimal. While we did not anticipate any heating or image distortion, pain and heating during MRI scanning was previously reported in a patient who had been wearing a different anti-microbial dressing containing silver thus providing evidence of MRI safety and compatibility is desired [24]. In current practice, unless the packaging directly asserts MRI safety and compatibility, all silver-containing

wound dressings must be removed prior to MRI. As dressing changes are associated with increased anxiety, pain and analgesia for the patient, it is critical to determine if safety concerns in fact exist for these materials.

A number of antimicrobial wound dressings containing silver have been previously evaluated for their MRI safety and compatibility. Nyenhuis and Duan evaluated a silver dressing using standardized measures of radiofrequency-induced heating, image distortion, and magnetic force [16]. An increase in temperature within their silver-dressing containing phantom gel was 0.5-0.7°C above baseline when scanned in a 3T unit with no discernable image distortion or material deflection [16]. Similarly, Chaudhry et al. used a porcine hind limb to serve as the phantom to examine temperature changes and potential image distortion with the application of three silver-based dressings; however, no significant heating and only low levels of image distortion were observed [17]. In the current study using a porcine hind limb as a phantom, no combination of wound dressing and MRI sequence resulted in image distortion or an increase in temperature over 0.4°C. The dressings tested in this study did not lead to heating of tissue nor image distortion in the MRI environment. One possible explanation for the lack of image distortion with the current dressings is the form of the silver used. The silver within these dressings consists of water soluble ionic silver molecules encapsulated within zirconium phosphate ceramic particles. If kept dry, the ionic silver remains in a stable, bound state within the ceramic particles; however, in the presence of moisture containing sodium ions, the bioactive ionic silver molecules are released into solution by exchanging with the sodium ions.

The current study confirms that no significant magnetic deflection or torsion was exerted on the tested dressings — both in their dry and moistened state. Similarly, there was no appreciable heat generated. As a result, there is no reason for concern regarding safety. In an effort to assess the potential for image distortion, we used a clinically relevant model (composite dressing over porcine hind quarter). Similar to all previous reports no appreciable image distortion was observed even when dressings were applied with staples and additional absorbent dressings were present. Other silver-containing wound dressings have been reported to be MRI safe and compatible; however, all studies have cautioned that their findings should not be generalized to all silver-based dressings [15-17]. Because of the different nature of each silver-containing dressing (dressing material and silver technology) and the strength of magnetic field used, we echo the need for evaluation of any silver-containing dressing prior to assuming compatibility with MRI. It also seems prudent for burn and wound centers to pro-actively provide these evaluations to their imaging departments to prevent patients from being subjected to unnecessary dressing changes or imaging delays.

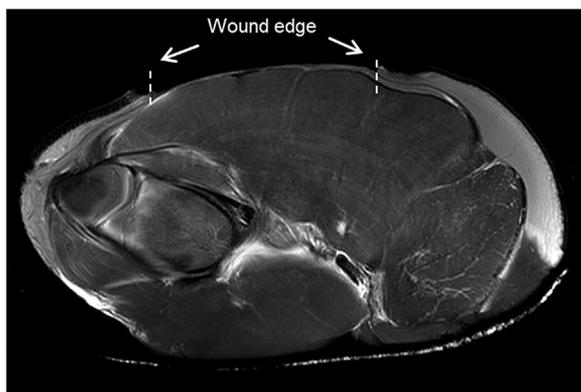


Fig. 5 – A T₂-weighted TSE image of a porcine hind limb with the wound dressings secured to the injury site (wound borders indicated with white dashed line) with non-ferromagnetic metallic staples, followed by absorbent gauze and elastic bandaging. No significant image distortion was noted.

5. Conclusion

Evaluation of MRI safety and compatibility following ASTM guidelines revealed no concerns for safety or issues with image distortion in any of the silver-containing wound dressings tested thus it would be acceptable to leave these dressings intact during MRI. The ability to leave dressings in place during

imaging will provide a significant benefit to patient care by reducing pain when removing the dressings and subsequently will lead to a decreased use of narcotics for treatment of anxiety and pain. Additionally, it will reduce the cost burden associated with the need for dressing replacements after imaging.

Conflict of interest

None.

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