



Original contribution

Assessment of metallic patient support devices and other items at 7-Tesla: Findings applied to 46 additional devices[☆]



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ABSTRACT

Objective: Recently, the first 7-Tesla MR system was approved for clinical use in Europe and the United States. Unfortunately, few metallic objects have undergone testing in association with this high-field-strength scanner, including essential equipment such as patient support devices and other items. Therefore, the objective of this investigation was to assess metallic patient support devices and other items for translational attraction at 7-Tesla.

Methods: Thirteen different metallic items (e.g., gurney, Mayo stand, step stool, utility table, wheelchair, etc.) underwent testing for translational attraction using a previously described methodology in association with a clinical 7-T MR system. The findings were categorized as pass (no translational attraction) or fail (the item was attracted by the scanner).

Results: Every metallic item tested exhibited a lack of magnetism while in a worst-case use position and, thus, passed the test for translational attraction in associated with the 7-Tesla MR system.

Conclusions: The different thirteen different metallic patient support devices and other items can be designated as MR Conditional at 7-T or less. Furthermore, because each item represented a worst-case with respect to its mass and the type of metallic material used for its fabrication, the results can be applied to 46 additional smaller items made from the same material or material with a lower magnetic susceptibility. This expanded list of essential patient support devices and other items will facilitate the clinical use of a comparable 7-Tesla scanner, or another UHF scanner with similar fringe field characteristics.

1. Introduction

The unique research and clinical applications afforded by 7-Tesla (T) magnetic resonance imaging (MRI) are predominantly due to the associated increase in the signal-to-noise ratio that can be exploited to achieve higher resolution images [1–4]. In addition, imaging at this ultra-high-field (UHF) enables the improved detection of functional and metabolic (i.e., using MR spectroscopy) abnormalities compared with lower-field-strength MR systems [1–3]. Recently, the first 7-T MR system was approved for clinical use in Europe and the United States [5] and, accordingly, there is considerable anticipation regarding the impact that the utilization of this scanner will have on clinical outcomes [1–4].

At the present time, a limitation of using 7-T in research and clinical

settings relates to the scarcity of safety information that exists for biomedical implants, as well as the lack of essential patient support devices and other items that are commonly needed to ensure patient safety and the operational aspects of the facility [3,6–12]. While studies have begun to address the basic issues for implants (i.e., magnetic field interactions, MRI-related heating, and artifacts) [3,6–11], there has been relatively little effort directed towards evaluating metallic items that are used external to the MR system (e.g., gurneys, step stools, wheelchairs, utility tables, etc.). With respect to externally-used, patient support devices and other items, the main concern is static magnetic field-related, translational attraction, particularly because serious injuries and fatalities have occurred in patients and staff members due to the missile effect [6]. Therefore, prior to being used in the scanner room, all external devices must undergo proper testing to ensure that

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they can be safely used in that area [6]. In consideration of the above, the purpose of this investigation was to assess metallic patient support devices and other items for translational attraction at 7-Tesla.

2. Materials and methods

2.1. Patient support devices and other items

Table 1 presents 13 different, metallic patient support devices and other items that were selected for assessment because they are essential for patients, staff members, and/or the operational aspects of the MRI facility. Each item represented the largest version of a particular item with respect to its mass and the type of metallic material used for its fabrication. These particular metallic items, most of which are relatively large, may pose a serious projectile-related hazard to research subjects, patients, and staff members if they are made from ferromagnetic materials. According to the manufacturer (MRIequip, Nisswa, MN), every item was made from grade 304 stainless steel with the exception of the walker, which was made from aluminum.

2.2. Assessment of translational attraction

A 7-T MR system (MAGNETOM, Terra, Siemens, Siemens Medical Solutions) was used in this investigation. A previously described method was used to assess translational attraction for each item [12]. First, a powerful handheld magnet (approximately 1200-gauss) was used to methodically assess each part of each item prior to taking the item into the MR system room. If that procedure identified a relatively large part or surface area of the item made from ferromagnetic material, the item was not permitted near the scanner. Next, a nylon rope was securely tied around each sample and the other end of the rope was fastened to the doorframe leading into the MR system room (fringe field, < 50-gauss, documented by the field plot provided for this particular MR system, Siemens, Siemens Medical Solutions). This procedure was performed in order to prevent the metallic item from becoming a potential projectile during the evaluation.

With the tethering rope in place, each item was slowly positioned in 30-cm increments towards the scanner until it either displayed translational attraction or it could be placed as close as possible to the opening of the bore of the scanner without actually contacting it. The maximum magnetic fringe field at this point was 5100-gauss, measured using a gauss meter (Extech Model 480823, Electromagnetic Field Meter; Extech, Nashua, NH). That particular position was considered worst-case for an item intended to be used externally to an MR system.

Table 1

Summary of the metallic patient support equipment and medical devices that underwent testing at 7-T. Each item represented the largest version of a particular item with respect to its mass and the type of metallic material used for its fabrication. Every other item was made from 304 stainless steel, with the exception of the walker which was made from aluminum (Product name and number).

1. Gurney, Fixed Height (ST-2000)
2. Hamper with Lid and Foot Pedal (HA-2002)
3. I.V. Pole for Gurney (ST-2006)
4. Ladder, Double-sided, 6-foot (LA-1002)
5. Mayo Stand (TA-1000)
6. Oxygen Cart on Wheels for D and E Cylinders (OX-1000)
7. Oxygen Tank and I.V. Holder for Wheelchair (WC-1101)
8. Oxygen Tank Holder for Gurney (ST-2009)
9. Step Stool with Handrail (SS-1001)
10. Stool on Casters with Back and Arms (CH-8038)
11. Utility Table with Top Shelf and Rails, 18" × 24" (TA-5001)
12. Walker, Bariatric, Folding, Adjustable Height, 550 lb. Weight Capacity (WA-1002)
13. Wheelchair, 22" Wide with Detachable Footrests and Removable Armrests (WC-1002)

Note that as each item was moved towards the scanner, there was no "slack" left in the rope until it was ascertained that there was no magnetic field interaction. If magnetic field attraction was detected for the item, the distance at which that occurred would be recorded and documented by obtaining a digital photograph. If there was no magnetic attraction, a small amount of slack would be intentionally left in the rope and a digital photograph would be obtained to record the results with the item positioned as close as possible to the opening of the scanner's bore.

The following qualitative scale was applied to the results [12]: 0, no translational attraction; +1, mild translational attraction, the item slowly changed orientation or moved relative to the scanner; +2, moderate translational attraction, the item moved gradually relative to the scanner; +3, high translational attraction, the item showed rapid and forceful movement towards the scanner; and +4, very high translational attraction, the item showed very rapid and very forceful movement relative to scanner. The findings for the samples that underwent testing were categorized as either pass (0, no translational attraction, the item was not attracted by the scanner) or fail (+1 or higher, the item was attracted by the scanner).

3. Results

Using the handheld magnet, there was no evidence that any item exhibited a part or area that was magnetic to warrant prevention of further testing associated with the MR system. Using the rope-tethering technique, there was no translational attraction exhibited by the 13 different metallic items when each item was positioned in a worst-case position relative to the 7-T scanner (i.e., as close as physically possible to the MR system without contacting the scanner). Therefore, these particular patient support devices and other items may be used safely in association with a 7-T or less MR system. Fig. 1 shows an example of the procedure used to test each metallic item using the previously-described, rope-tethering procedure.

4. Discussion

The further implementation of 7-T MRI for both research and clinical applications requires proper testing of implants, devices, and other equipment in order to ensure safety for volunteer subjects, patients and healthcare workers in this UHF setting [3,6]. Currently, only a limited number of metallic objects have undergone testing in association with UHF scanners [6–13]. Of note is that metallic items used external to the scanner, especially those with a large metallic mass, can pose substantial projectile-related hazards if they are made from ferromagnetic materials and result in serious injuries or fatalities [6].

In the present investigation, several metallic patient support devices and other items were selected for testing with the intent of establishing if they could be used safely in a 7-T setting. While the materials used to make these items (i.e., grade 304 stainless steel and aluminum) are presumably nonmagnetic or weakly magnetic, there is a possibility that ferromagnetic qualities may have been imparted into these materials during the manufacturing process (e.g., due to mechanically-induced changes or impurities that may have been introduced). Therefore, it was critical to conduct appropriate testing to verify that there would be no issues related to the utilization of these metallic items in the immediate area of the 7-T MR system.

Additionally, with specific reference to grade 304 stainless steel, this austenitic stainless steel alloy is commonly used for a wide variety of applications in the medical field because of its excellent mechanical properties and resistance to corrosion [14–16]. It is well known that any process that mechanically deforms an austenitic stainless steel alloy including cold working, drawing, bending, and welding can cause the austenitic form to be converted into the ferromagnetic, martensitic form [14–16]. The reason for this is that the metallic atoms in an austenitic stainless steel alloy, which are normally arranged on a face-



Fig. 1. Example of the rope-tethering procedure used to test each metallic item in association with a 7-T MR system. A nylon rope was securely tied around the wheelchair (22" wide) and the other end was fastened to the entry doorframe of the room. This figure shows the position that the wheelchair would be in in a worst-case situation with respect to its intended use (i.e., as close as possible without contacting the opening of the bore of the scanner). Note the slack intentionally placed in the rope, thus, illustrating the lack of translational attraction. The slack in the rope was introduced after it was ascertained that there was no magnetic field interaction.

centered cubic (fcc) lattice (Note, the unit cell of an fcc crystal consists of a cube with an atom at each of the cube's eight corners and an atom at the center of each of the cube's six faces. This arrangement of atoms prevents the molecules in the austenitic stainless steel from aligning in a unified direction, preventing it from developing magnetism.) convert by mechanical deformation into a martensitic stainless steel alloy, which is magnetic (i.e., because it has a body-centered (bcc) lattice, with one atom at each of the eight corners and a single atom at the geometric center of the cube).

Because of the aforementioned information as well as in consideration of the processes that are commonly applied when manufacturing patient support devices and other items as they are configured into the necessary shapes [16], we were compelled to test the items in this study for translational attraction, despite knowing the material compositions of the test samples. The previously described technique by Dula, et al. [12], which involved the assessment of a power injection system, was applied to the large items in this investigation because it was not physically possible to use the technique from the American Society for Testing and Materials (ASTM) International, which is only intended and suitable for relatively small items such as medical implants [17]. Of further note is that the determination of translational attraction determined by ASTM International F2052-15 is only relevant to a medical implant that would be present in a patient passing through

the higher spatial gradient magnetic fields of the scanner while entering the MR system versus the level of the magnetic fringe field that would impact an externally used patient support device or other item that is never intended to be used inside of the bore of the scanner.

Thus, utilizing what was deemed to be an appropriate technique of assessing translational attraction, the findings indicated that each metallic item is acceptable according to its intended use in a 7-T or less MRI environment. Because the characteristics of the magnetic fringe field associated with a given MR system is specific to the scanner, the information in this investigation applies to the particular clinical 7-Tesla MR system that was used to test the items (i.e., to date, the only 7-T scanner approved for clinical use is the MAGNETOM, Terra, Siemens, Siemens Medical Solutions) or another UHF scanner with similar fringe field characteristics.

5. Conclusions

Because there was no translational attraction (i.e., a lack of magnetism) exhibited by each metallic item that underwent testing while in a worst-case use position, each one can be categorized as "MR Conditional at 7-T or less" (i.e., using current labeling terminology, an item that poses no hazard or risk under specified MRI conditions) [18]. Furthermore, because each item (Table 1) represented a worst-case with respect to its mass and the type of metallic material used for its fabrication, the results can be applied to 46 additional smaller items made from the same material or material with a lower magnetic susceptibility (i.e., aluminum versus 304 stainless steel) (Appendix I). Importantly, as a precaution, the manufacturer of these items has a standard, quality assurance/quality control procedure whereby each metallic item listed in Appendix I is tested with a powerful (1200 gauss) handheld magnet prior to being shipped to the purchaser.

The strategy of testing the worst-case size and material for an item with respect to MRI issues and then applying the findings to other metallic objects has been used previously for various implants and devices including aneurysm clips, hemostatic clips, orthopedic implants, ossicular implants, and other metallic objects [6,19–21]. Notably, this approach to testing worst-case, representative samples has been accepted by the U.S. Food and Drug Administration with respect to labeling those various metallic objects with the term, MR Conditional. The expanded list of essential patient support devices and other items will hopefully facilitate the research and clinical uses of 7-Tesla MRI.

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Appendix I

A list of 46 additional items (product name and number) that the findings of this investigation can be applied to because one is smaller and/or is made from the same material or a material with a lower magnetic susceptibility.

1. Gurney, Flip Down Side Rails, Aluminum (ST-5000)
2. Gurney, Locking Casters with Crank Assembly, Stainless Steel (ST-2000)
3. Gurney, Swivel Locking Casters, Stainless Steel (ST-2001)
4. Gurney, Wrap Around Rails, Aluminum (ST-5300)
5. Hamper with Lid and Foot Pedal, Aluminum (HA-2301)
6. Hamper with Lid, Stainless Steel (HA-2001)
7. Hamper without Lid, Stainless Steel (HA-2000)
8. I.V. Pole for Gurney, Aluminum (ST-5100)
9. I.V. Pole and Oxygen Tank Holder, Aluminum (ST-2009)
10. I.V. Pole for Wheelchair, Aluminum (WC-2100)

11. Ladder, Double-sided, 4-foot, Aluminum (LA-1012)
12. Ladder, Double-sided, 5-foot, Aluminum (LA-1000)
13. Ladder, Double-sided, 7-foot, Aluminum (LA-1001)
14. Ladder, Double-sided, 8-foot, Aluminum (LA-1013)
15. Ladder, Double-sided Step Stool, Non-folding, 16", Stainless Steel (LA-1005)
16. Ladder, Double-sided Step Stool, Non-folding, 24", Stainless Steel (LA-1006)
17. Ladder, Double-sided Step Stool, Folding, 18", Stainless Steel (LA-1003)
18. Ladder, Double-sided Step Stool, Folding, 24", Stainless Steel (LA-1004)
19. Ladder, Step Stool, Non-folding, 16", Stainless Steel (LA-1007)
20. Oxygen Tank Holder for Gurney, Aluminum (ST-5101)
21. Oxygen Tank Holder for Wheelchair, Aluminum (WC-2102)
22. Step Stool with Handrail, Aluminum (SS-5001)
23. Step Stool without Handrail, Aluminum (SS-5000)
24. Step Stool without Handrail, Stainless Steel (SS-1000)
25. Step Stool, Narrow with Handrails, Stainless Steel (SS-1008)
26. Step Stool, Narrow without Handrails, Stainless Steel (SS-1007)
27. Stool, Adjustable 15" to 21", Stainless Steel (CH-8030)
28. Stool, Adjustable 16" to 22", with Back and Arms on Casters, Stainless Steel (CH-9038)
29. Stool, Adjustable 21" to 27" Stainless Steel (CH-8033)
30. Stool, Adjustable 21" to 27", with Back and Arms on Casters, Stainless Steel (CH-9035)
31. Stool, Adjustable 22" to 28", with Back and Arms on Casters, Stainless Steel (CH-8041)
32. Utility Table with Top Shelf and No Rails, 18" × 24", Stainless Steel (TA-5007)
33. Walker, Adult, 32" to 36" Adjustable Height, Aluminum (WA-1000)
34. Walker, Adult, Aluminum (WA-1050)
35. Walker, Bariatric, Aluminum (WA-1052)
36. Walker, Adult, 32" to 36" Adjustable Height, Stainless Steel (WA-1000)
37. Walker, Junior, 28" to 32" Adjustable Height, Aluminum (WA-1051)
38. Walker, Junior, Aluminum (WA-1051)
39. Wheelchair, 20" Wide, Aluminum (WC-1027)
40. Wheelchair, 22" Wide, Aluminum (WC-1002)
41. Wheelchair, 18" Wide with Fixed Footrests and Detachable Armrests, Stainless Steel (WC1000)
42. Wheelchair, 18" Wide with Detachable Footrests and Flip Up Armrests, Stainless Steel (WC-1001)
43. Wheelchair, 18" Wide with Detachable Legrests and Flip Up Armrests, Stainless Steel (WC-1021)
44. Wheelchair, 20" Wide with Detachable Footrests and Removable Armrests, Stainless Steel (WC-1004)
45. Wheelchair, 20" Wide with Detachable Legrests and Removable Armrests, Stainless Steel (WC-1022)
46. Wheelchair, 22" Wide with Detachable Footrests and Removable Armrests, Stainless Steel (WC-5002)

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