Aneurysm Clips: Evaluation of Magnetic Field Interactions With an 8.0 T MR System

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This study was conducted to evaluate magnetic field interactions for aneurysm clips exposed to an 8.0 T magnetic resonance (MR) system. Twenty-six different aneurysm clips were tested for magnetic field translational attraction (deflection angle test) and torque (qualitative assessment method) using previously described techniques. Six of the specific aneurysm clips (ie, type, model, blade length) made from stainless steel alloy (Perneczky) and Phynox (Yasargil, models FE 748 and FE 750) displayed deflection angles above 45° and torque measurements of +4, indicating that these aneurysm clips may be unsafe for patients or individuals in an 8.0 T MR environment. The specific aneurysm clips (ie, type, model, blade length) made from commercially pure titanium (Spetzler), Elgiloy (Sugita), titanium alloy (Yasargil, model FE 750T), and MP35N (Sundt) displayed deflection angles less than 45° and torque that ranged from +1 to +4. Accordingly, these aneurysm clips are likely to be safe for patients or individuals exposed to an 8.0 T MR system. Depending on the actual dimensions and mass, an aneurysm clip made from Elgiloy may or may not be acceptable for a patient or individual in the 8.0 T MR environment. J. Magn. Reson. Imaging 2000;12:107-111. © 2000 Wiley-Liss, Inc.

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THE PRESENCE of an intracranial aneurysm clip in a patient or individual in the MR environment represents a potentially hazardous situation (1–10). For example, aneurysm clips made from martensitic stainless steels are an absolute contraindication to the use of MR procedures because excessive, magnet-related forces can displace them, causing serious injury or death (1,3–10). By comparison, aneurysm clips classified as "nonferromagnetic" or "weakly ferromagnetic" (eg, those made from Phynox, Elgiloy, austentitic stainless steels, titanium alloy, or commercially pure titanium) are considered safe for patients undergoing MR procedures using MR systems with static magnetic fields of 1.5 T or less (3–10).

For this discussion, the term "weakly ferromag-

netism" refers to metal that demonstrates extremely low ferromagnetic qualities using extremely sensitive measurements techniques [eg, vibrating sample magnetometer, superconducting quantum interference (SQUID) magnetometer, etc.]. As such, the material may not be technically referred to as "nonferromagnetic" (4). Furthermore, it is recognized that all metals possess some degree of magnetism, such that no metal is considered to be totally "nonferromagnetic" (4).

Many current MR systems have static magnetic fields that exceed 1.5 T. Most ex vivo tests performed to determine MR safety for bioimplants, materials, and devices involved the use of MR systems with static magnetic fields of 1.5 T or lower (8,9). It is conceivable that an object that exhibits "nonferromagnetism" or weak ferromagnetic qualities in association with a 1.5 T MR system is attracted with sufficient force to pose a hazard to a patient or individual in an MR environment that has an MR system operating at 2.0 T or higher.

The most powerful, whole-body MR system currently in existence operates at a static magnetic field strength of 8.0 T (11,12). Obviously, it is necessary to conduct ex vivo testing to identify potentially hazardous bioimplants, materials, and devices prior to subjecting patients or individuals with these objects to an ultra-high-field MR environment. To date, there has been no evaluation of MR safety with regard to bioimplants and the 8.0 T MR system. Therefore, this investigation was performed to assess magnetic field interactions for aneurysm clips exposed to an 8.0 T MR system.

MATERIALS AND METHODS

8.0 T MR System

An $8.0\,\mathrm{T}$, whole-body (bore diameter, $80\,\mathrm{cm}$) MR system was used in this investigation. Details pertaining to the construction and design of this ultra-high-field MR system have been previously described (11,12).

The static magnetic field of the 8.0 T MR system was surveyed using a Hall-effect magnetometer to determine the magnitude and location of the highest gradient along the central axis. This procedure was performed to identify the appropriate position for the evaluation of translational attraction for the aneurysm clips. The highest magnetic field gradient was determined to be 7.915 T/m and occurred at a distance of 134 cm from the center of the magnet (28 cm from the opening of the bore or the end-plate).

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Aneurysm Clips

Twenty-six different aneurysm clips obtained directly from manufacturers were tested for magnetic field interactions associated with the 8.0 T MR system (Table 1). These clips were specifically selected for this investigation because they represent various types of clips made from nonferromagnetic or weakly ferromagnetic materials that are used in patients for temporary or permanent treatment of aneurysms or arteriovenous malformations. Additionally, these aneurysm clips have been reported to be safe for patients undergoing MR procedures using MR systems with static magnetic field strengths of 1.5 T or less (3–10).

Evaluation of Magnetic Field Interactions

For the assessment of translational attraction, each aneurysm clip was suspended by a 30 cm long piece of thread and attached to a plastic protractor so that the angle of deflection from the vertical could be measured (2–4,6,7). This test was conducted at the position in the 8.0 T MR system where the spatial gradient of the magnetic field was determined to be at a maximum. This procedure was done to determine the magnetic field translational attraction with regard to an extreme condition for the 8.0 T MR system. As previously indicated, the highest magnetic field gradient was determined to be 7.915 T/m at a distance of 134 cm from the center of the magnet. By comparison, the highest spatial gradient for a shielded 1.5 T MR system is approximately 450 g/cm (3,4,6).

The next assessment of magnetic field interactions was conducted to determine the presence of magnetic field-related torque for the aneurysm clips. This procedure involved a qualitative test that used a 30×30 cm, flat plastic plate with a millimeter etching on the bottom (4,6,13). Each aneurysm clip was placed on this test apparatus in an orientation that was perpendicular to the static magnetic field of the 8.0 T MR system. The test apparatus with the aneurysm clip was then positioned in the MR system at the position where the effect of torque from the 8.0 T static magnetic field would be the greatest, based on the survey using the Hall-effect magnetometer.

Each aneurysm clip was directly observed for any type of movement with respect to alignment, rotation, or change in position relative to the magnetic field of the 8.0 T MR system. The observation process was facilitated by having the investigator inside the bore of the magnet during the test procedure. This process was repeated to encompass a full 360° rotation of positions for each aneurysm clip (6,13).

The following previously described subjective scale was used to characterize the torque for each aneurysm clip (6,13): 0, no torque; +1, mild torque (the aneurysm clip slightly changed orientation but did not align to the magnetic field); +2, moderate torque (the aneurysm clip aligned gradually to the magnetic field); +3, strong torque (the aneurysm clip showed rapid and forceful alignment to the magnetic field); +4, very strong torque (the aneurysm clip showed very rapid and very forceful alignment to the magnetic field).

RESULTS

Table 1 shows a summary of the test results for the aneurysm clips evaluated for magnetic field interactions associated with the 8.0 T MR system. Every aneurysm clip showed a deflection angle and torque above 0° and 0, respectively. Deflection angles for the aneurysm clips made from commercially pure (CP) titanium and titanium alloy ranged from 5° to 6° and the torque was +1. Deflection angles for aneurysm clips made from Elgiloy ranged from 36° to 42° and the torque was +4. Deflection angles for aneurysm clips made from stainless steel alloy ranged from 50° to 53° and the torque was +4. Deflection angles for aneurysm clips made from Phynox ranged from 47° to 48° and the torque was +4. Deflection angles for aneurysm clips made from MP35N ranged from 17° to 22° and the torque ranged from +2 to +3. The torque data correlated well with the deflection angle data (ie, the higher the deflection angle, the greater the qualitative value was for torque).

Aneurysm clips made from commercially pure titanium (Spetzler), Elgiloy (Sugita), titanium alloy (Yasargil), and MP35N (Sundt) displayed deflection angles less than 45° and torque that ranged from +1 to +4.

Six of the 26 aneurysm clips displayed deflection angles above 45° and a torque of +4. These aneurysm clips were as follows:

- Perneczky, straight, 2 mm, stainless steel alloy, deflection angle 50°, torque +4
- 2. Perneczky, straight, 6 mm, stainless steel alloy, deflection angle 52° , torque +4
- 3. Perneczky, straight, 7 mm, stainless steel alloy, deflection angle 53° , torque +4
- 4. Yasargil, straight, 15 mm, Phynox, deflection angle 48° , torque +4
- 5. Yasargil, straight, 9 mm Phynox, deflection angle, 48° , torque +4
- 6. Yasargil, straight, 9 mm Phynox, deflection angle 48° , torque +4.

DISCUSSION

Translational attraction and torque are two magnetrelated mechanisms present in the MR environment that may produce an injury to a patient as a result of movement or dislodgment or a ferromagnetic object (7– 9). Translational attraction is proportional to the strength of the static magnetic field, the strength of the spatial gradient, the mass of the object, the shape of the object, and magnetic susceptibility of the object (4,6,7– 9). The deflection angle test, originally described by New et al (7), is commonly used to determine magnetic fieldrelated translational attraction for bioimplants, materials, and devices (3–10).

Torque, which rotates or aligns the object parallel to the magnetic field, is dependent on the strength of the magnetic field, the dimensions of the object, and the initial angulation of the object relative to the static magnetic field (4,6,7–9). Various techniques have been used to determine magnetic field-related torque qualitatively or quantitatively for bioimplants, materials, and devices (4,6,7–9). The actual amount of torque necessary

Table 1
Aneurysm Clips: Summary of Test Results for Evaluation of Magnetic Field Interactions With an 8.0 Tesla MR System

No.	Description	Deflection angle (°)	Torque ¹
А	Spetzler Titanium Aneurysm Clip, straight, 13 mm C.P. titanium Elekta Instruments, Atlanta, GA	5	+1
В	Spetzler Titanium Aneurysm Clip, straight, 9 mm C.P. titanium	5	+1
С	Elekta Instruments, Atlanta, GA Spetzler Titanium Aneurysm Clip, straight, 13 mm C.P. titanium	5	+1
D	Elekta Instruments, Atlanta GA Sugita, straight, 5 mm Elgiloy	36	+4
Е	Mizuho America, Inc., Beverly, MA Sugita, curved, 6 mm Elgiloy	38	+4
F	Mizuho America, Inc., Beverly, MA Sugita, bent, 7.5 mm Elgiloy	42	+4
G	Mizuho America, Inc., Beverly, MA Sugita, straight, temporary, 5 mm Elgiloy	37	+4
Н	Mizuho America, Inc., Beverly, MA Perneczky, straight, 2 mm Stainless steel alloy	50	+4
I	Zeppelin Chirugishe Instrumente, Pullach, Germany Perneczky, straight, 6 mm Stainless steel alloy	52	+4
J	Zeppelin Chirugishe Instrumente, Pullach, Germany Perneczky, straight, 7 mm Stainless steel alloy	53	+4
K	Zeppelin Chirugishe Instrumente, Pullach, Germany Yasargil, Model FE 750, straight, 15 mm Phynox	48	+4
L	Áesculap, Inc., South San Francisco, CA Yasargil, Model FE 750T, straight, 9 mm Titanium alloy	6	+1
М	Aesculap, İnc., South San Francisco, CA Yasargil, Model FE 748, straight, 9 mm Phynox	47	+4
N	Áesculap, Inc., South San Francisco, CA Yasargil, Model FE 750, straight, 9 mm Phynox	47	+4
0	Áesculap, Inc., South San Francisco, CA Sundt Slimline, fenestrated, 24 mm, 4 mm open MP35N	18	+2
Р	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, fenestrated, 24 mm, 6 mm open MP35N	18	+2
Q	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, fenestrated, 15 mm, 6 mm open MP35N	17	+2
R	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, reinforcing, 19 mm blade MP35N	18	+2
S	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, reinforcing, 18 mm blade, 30° angle MP35N	18	+2
Т	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, reinforcing, 18 mm blade, 60° angle MP35N	18	+2
U	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, Graft Clip, 7 mm diam., 7 mm barrel MP35N	22	+3
V	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, fenestrated, bayonet, 12 mm blade, 6 mm open MP35N	17	+2
W	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, curved, 11.5 mm MP35N	21	+2
X	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, straight, 25 mm MP35N	22	+3
Υ	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, fenestrated, straight, 24 mm MP35N	20	+3
Z	Codman, Johnson & Johnson Professional, Inc., Raynham, MA Sundt Slimline, Super Bayonet, 25 mm	22	+3

¹Deflection angle indicated in degrees. The following scale was used to characterize torque: 0, no torque; +1, mild torque, the aneurysm clip slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the aneurysm clip aligned gradually to the magnetic field; +3, strong torque, the aneurysm clip showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the aneurysm clip showed very rapid and very forceful alignment to the magnetic field.

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to displace an aneurysm clip or other implant has not been determined.

In 1994, the American Society for Testing and Materials (ASTM) issued a standard for the requirements and disclosure of aneurysm clips indicating that the deflection angle test should be used to evaluate aneurysm clips specifically (2). The ASTM report stated that the operational definition of a nonferromagnetic aneurysm clip is met only if the clip passes the following test (2): "The clip is suspended at the end of a string and held stationary in the vertical direction (that is, perpendicular to the ground) while it is placed in position at the portal of the imaging magnet. Following release of the clip, the deflection of the string from the vertical is then observed. The magnetic force is less than the gravitational force (that is, the clip's weight) if the deflection of the string with respect to the vertical is less than 45 degrees. The clip is then judged to be non-ferromagnetic and suitable for implantation." Notably, the ASTM document did not recommend an evaluation for torque with respect to testing aneurysm clips.

According to the ASTM, the deflection angle test as described above must be conducted such that the procedure is performed on a "finished" aneurysm clip using a 1.5 T MR system (ie, the most common, high-field strength MR system in 1994) at the point where the highest spatial gradient field exists for that specific MR system (2). Results from the deflection angle test allow aneurysm clips made from nonferromagnetic or weakly ferromagnetic materials (ie, those aneurysm clips that display deflection angles between 0° and 44°) to be present in patients undergoing MR procedures (2–6).

In consideration of the above, the evaluation of aneurysm clips for safety in the MR environment routinely involved the use of the deflection angle test along with some form of assessment of torque to determine the relative degree of ferromagnetism for these metallic objects (2–9). Accordingly, this information was used to identify which aneurysm clips presented a possible hazard to a patient or individual in the MR environment (2–9). Basically, a deflection angle test would be performed to identify aneurysm clips that exceeded a deflection angle of 45°, which were deemed unsafe for patients or individuals in the MR environment (2–9). Test results specifically for torque measurements that were considered to be unacceptable have not been reported previously.

Similar to previously published reports (3–7), this study assessed magnetic field interactions for aneurysm clips exposed to an MR system. However, to our knowledge, this investigation is the first to acquire data for metallic objects in association with an 8.0 T MR system. Notably, we studied aneurysm clips that were previously determined to be safe for patients and individuals in MR environments of 1.5 T or less (3–10).

At 1.5 T, aneurysm clips that are considered to be acceptable for patients or others in the MR environment include those made from commercially pure titanium, titanium alloy, Elgiloy, Phynox, and austentic stainless steel (eg, MP35N) (3–10). These aneurysm clips were reported to be safe because none of the clips tested in

association with a 1.5 T MR system displayed greater than a 2° deflection angle (3–10).

By comparison, findings from the present study indicated that deflection angles for the aneurysm clips made from CP titanium and titanium alloy ranged from 5° to 6° , suggesting that these aneurysm clips would be safe for patients or individuals in the 8.0 T MR environment. However, deflection angles for aneurysm clips made from Elgiloy ranged from 36° to 42° , such that consideration must be given to the specific type of Elgiloy clip that is present. For example, an Elgiloy clip that has a greater mass than those tested in this study may exceed a deflection angle of 45° in association with an 8.0 T MR system.

Deflection angles for aneurysm clips made from stainless steel alloy ranged from 50° to 53° , indicating that these clips are unacceptable for patients or individuals in the 8.0 T MR environment. Notably, one of the smallest types of stainless steel alloy aneurysm clips (ie, blade length, 2 mm) that underwent testing exceeded a deflection angle of 45° .

Deflection angles for aneurysm clips made from Phynox ranged from 47° to 48° . Thus, these clips are deemed unsafe. Deflection angles for aneurysm clips made from MP35N ranged from 17° to 22° . Since some of the largest types of aneurysm clips made from MP35N underwent testing at $8.0\,\mathrm{T}$ (eg, blade length, $25\,\mathrm{mm}$), it is likely that all clips made from this material would be safe for patients or individuals in the $8.0\,\mathrm{T}\,\mathrm{MR}$ environment.

In conclusion, the findings of this investigation indicated that the specific aneurysm clips (ie, type, model, blade length) made from stainless steel alloy (Perneczky) and Phynox (Yasargil, models FE 748 and FE 750) may be unsafe for patients or individuals in an 8.0 T MR environment. Depending on the actual dimensions and mass, an aneurysm clip made from Elgiloy may or may not be acceptable for a patient or individual in the 8.0 T MR environment. The specific aneurysm clips (ie, type, model, blade length) made from commercially pure titanium (Spetzler), Elgiloy (Sugita), titanium alloy (Yasargil, model FE 750T), and MP35N (Sundt) are likely to be safe for patients or individuals exposed to an 8.0 T MR system.

Before allowing a patient or other individual with an aneurysm clip into the 8.0 T MR environment, MR users should follow previously published, recommended guidelines (4,9) that have been modified in consideration of the data from the present study, as follows:

- 1. Specific information (ie, manufacturer, type or model, material, lot and serial numbers, blade length) pertaining to the aneurysm clip must be known, especially with respect to the material used to make the aneurysm clip.
- 2. The only aneurysm clip allowed in a patient or individual in the MR environment is one made from material that is nonferromagnetic or weakly ferromagnetic and that passed the deflection angle test (ie, deflection angle between 0° and 44°).
- An aneurysm clip that is in its original package and made from titanium alloy or commercially pure titanium does not need to be specifically eval-

- uated for ferromagnetic qualities because the manufacturers ensure the pertinent MR safety aspects of these clips.
- 4. If the aneurysm clip is not in its original package and properly labeled, it should undergo testing for magnetic field interactions associated with the 8.0 T MR environment.
- 5. Testing for magnetic field interactions should first involve a qualitative procedure to assess torque. If a positive test result is noted, then the deflection angle test should be conducted following the guidelines of the ASTM (2).
- 6. The radiologist and implanting surgeon should be responsible for evaluating all available information pertaining to the aneurysm clip, verifying its accuracy, obtaining written documentation, and deciding to perform the MR procedure after considering the risk vs. benefit aspects for a given patient.

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