Aneurysm Clip Testing for Ferromagnetic Properties: Clip Variability Issues

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To assess ferromagnetic properties of intracranial aneurysm clips reported to be nonferromagnetic, 1,765 Yasargil, 11 Sugita, and 15 Perneckzy aneurysm clips were studied for rotation or translation on plate glass in a 1.5-T MR imager. Sixty-three clips (52 Yasargil, 11 Perneckzy) weakly reoriented along the static magnetic resonance (MR) field. These results confirm the need for standardized testing for ferromagnetic properties for implantable metallic devices.

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Numerous articles have appeared testing the magnetic resonance (MR) compatibility and presence or absence of ferromagnetic properties of various types of metallic devices and implants (1-13). For most MR sites, these studies have been routinely used as the mainstay for assessing whether a patient with a given implant would be able to safely undergo an MR examination. Nevertheless, as recently as March 1993 the U.S. Food and Drug Administration (FDA) suggested that findings in these articles and studies not be relied on to attempt to determine the MR compatibility of any device (4,13). The FDA explains that there are no current consensus standards for assessing ferromagnetic properties or for determining MR compatibility in general. Further, the composition and design of implants may change without the need for the manufacturer to notify the FDA (7,13). Finally, there is yet no mandate that statements need to be made in package labeling in regard to MR compatibility in general or to ferromagnetic properties in particular for any implant or device.

To further assess these statements, we conducted a study to evaluate the ferromagnetic properties of multiple aneurysm clips from various manufacturers. These clips included models that have been claimed by their manufacturer to be nonferromagnetic and MR compatible. As static magnetic fields and their associated static gradients can cause rotational as well as translational motion of ferromagnetic objects, both types of motion were assessed.

Materials and Methods

A 28 x 36-cm sheet of plate glass was washed and dried. We tested 1,765 Yasargil FE intracranial aneurysm clips (Aesculap, San Francisco, Calif) of various sizes, shapes, and overall morphology that were obtained from the store-rooms of the University of Pittsburgh Medical Center. All of these clips had already been removed from the sterile packaging in which they had been initially distributed by the manufacturer. Many of these clips had been resterilized, perhaps on numerous occasions, in the past. Several clips at a time were placed onto the glass in such a way that no clip touched any other. Curved clips were manually positioned with the convex surface oriented downward on the glass to decrease the frictional coefficient with the glass, thus facilitating rotation. The clips were placed in a random orientation relative to the static magnetic field of the imaging system.

Some of the Yasargil FE clips were temporary clips. Although such clips are not designed to be permanently implanted, the similarity in the manufacturing and testing processes allowed a greater number of clips to be tested. Further, rare cases may exist (Yonas H, oral communication, 1995) in which a temporary clip may be left in place despite the fact that this is not recommended by the manufacturer.

We also tested 54 Yasargil FD clips (Aesculap) which, according to the manufacturer, were all distributed prior to 1983. All of these clips were presumed to have been handled extensively and perhaps resterilized on numerous occasions, although their precise handling history was not known.

We also tested 11 Sugita aneurysm clips (Mizuho Medical, Tokyo, Japan) in the same manner. All of these clips were freshly distributed from the manufacturer and removed from their sealed packages immediately prior to testing and were not handled in any other way prior to testing.

We also tested 15 Perneckzy (von Zeppelin Surgical Instruments, Pulchach, Germany) aneurysm clips. All 15 were nonsterilized: Nine had been extensively handled prior to testing, and six were received from the distributor unused and not previously handled (Paul J, oral communication, 1995).

The plate glass with the clips was manually inserted 30 cm into the bore of an unshielded 1.5-T MR imaging magnet (Signa; GE Medical Systems, Milwaukee, Wis) and kept constantly parallel to the floor.

The clips were observed for translational motion (sliding across the glass surface) and rotational motion (swiveling to orient along the magnetic lines of force of the static field of the MR imager). The plate glass was then turned a full 180° around the vertical axis, both clockwise and counterclockwise, and observed for motion of any of the clips (the "at-rest phase" of the test). The plate glass was then vibrated manually to and fro along the lateral (left-to-right), horizontal (front-to-back), and vertical (up-and-down) axes. Such motion induced the clips to slide a short distance over the glass. Further testing was performed by tapping or drumming the fingers on the surface of the glass ("in-motion phase"), which served to decrease the frictional coefficient of the clips against the glass. During the in-motion shaking phase, the clips were observed for only rotational and not translational motion. During the in-motion finger-drumming phase, the clips were observed for rotational and/or translational motion. The results were then recorded according to clip make, model, and type.

Testing was performed by two individuals simultaneously, and grossly detectable motion in the magnetic field was decided by consensus. All clips that tested positive for any type of motion or alignment during either phase were re-tested by a third observer who independently confirmed the same results, with the clips all placed initially perpendicular to the orientation of the static magnetic field.

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Results

None of the Yasargil FE clips demonstrated gross translational motion on the plate glass (Table). In addition, 1,713 of them did not demonstrate any rotational motion and 52 (2.9%) did. Of these latter clips, six (three permanent clips, three temporary clips) demonstrated rotational motion even during the at-rest phase (0.3%), whereas 46 clips demonstrated rotational motion during only the in-motion phase (2.6%). Nineteen of the 52 were permanent and 33 were temporary. Some of the clips that demonstrated rotational motion were of the identical model, shape, and size as others that demonstrated no rotational motion.

All 54 of the Yasargil FD clips demonstrated alignment to the field, although the degree of attraction was extremely variable. One such clip demonstrated positive translational forces. It was sufficiently attracted that it jumped up to a hand-held magnet. Among the others, some aligned to the field even before the plate glass was brought into the bore of the magnet. Others aligned (and then only weakly) during only the in-motion phase.

None of the 11 Sugita clips responded in any way to the magnetic field. Among the 15 Perneczky clips, definite alignment was seen during the at-rest phase in one clip and during the in-motion phase in 10 clips, and four did not respond in any grossly detectable manner to the presence of the magnetic field. Further, among the six Perneczky clips that had not been previously distributed or handled, two did not respond in any way to the presence of the static magnetic field and four aligned during the in-motion phase.

Discussion

It is important to distinguish between grossly detectable weak ferromagnetism and patient safety. We are not making a statement herein that any of the tested clips (with the exception of the Yasargil FD clips) would necessarily have posed a risk or absolutely excluded a patient from undergoing an MR examination. It is in fact likely that the large majority of the non-Yasargil-FD clips would have posed a negligible ferromagnetic risk for patients—even those clips that exhibited the greatest ferromagnetic response. Since such variability was observed, however, and the mechanism by which it was produced is not yet clear, it does not seem possible to guarantee that a greater level of ferromagnetic attraction may not exist in any given untested clip. It is not the magnitude but rather the very existence of such variability in ferromagnetic response that is our main concern about our results. This finding undermines the practice of relying on the testing of any given clip to determine the safety of imaging in a patient with any other clip.

Aneurysm clips seem to hold a rather unique position in discussions of safety and MR environments for various reasons. Motion of these implants can have potentially catastrophic results, as documented in the report of a fatality associated with exposure of such a ferromagnetic aneurysm clip to the static field of an MR imager (14). The recent FDA warning (4,13) against attempting to assess ferromagnetic properties of any given aneurysm clip on the basis of published data and the lack of accepted testing procedures and standards with which to assess the ferromagnetic properties of such devices (7) further confounds this issue. Unfortunately, some suggested standardized tests for aneurysm clips (15) have taken translational forces in an MR imaging environment into account but have entirely ignored the potential for rotational, or torque-related, forces. Because numerous manufacturers produce many clip types, models, and designs, assurance of present and continued MR compatibility of metallic implants is a clinically crucial issue.

The ferromagnetic nature of aneurysm clips (and, indeed, of any surgical implant or device), even from the same manufacturer, may vary for many reasons, including changes in the manufacturing process or the composition of the clip, contamination by other metals, alterations in the magnetic nature of the clip by cold working, and changes in the process by which the clip is produced or handled. Differences in postdistribution handling, storage, and resterilization may result in modification of the ferromagnetic properties of the clip, although this has not been verified, to our knowledge. We attempted to evaluate the degree of variability of ferromagnetism among various clips to ascertain if the FDA recommendation was appropriate or was overly cautious. The implications of these results are as far reaching as they are serious. If specific aneurysm clips are able to develop or acquire ferromagnetic properties, the magnetic properties of any given clip cannot be relied on to predict the safety of MR imaging in a patient with a similar clip.

Aesculap has independently tested two of the clips from our study and has confirmed by means of vibrating sample magnetometry that the clips are indeed weak ferromagnetic. Aesculap states that their aneurysm clips are all nonferromagnetic when they are distributed to hospitals. It is their opinion (Bush R, written communication, 1995) that the ferromagnetic properties might have been introduced after distribution. They distribute their clips prestereilized, in sealed, sterile packaging, and they recommend that the clips remain in their original packaging until implantation. This is not believed to be acceptable practice by some of the vascular neurosurgeons in our institutions, however, who request that dozens of clips of various sizes and configurations be readily available on trays in the operating room to facilitate rapid access should they be needed intraoperatively. Unused clips are then resterilized between cases. This, in fact, appears to be the standard procedure for many vascular neurosurgeons in this country. Indeed, the Sugita clips are distributed in nonsterile packaging, as Mizuho is aware that neurosurgeons will resterilize them (generally repeatedly) prior to implantation (Connolly BG, oral communication, 1995). Thus, although resterilization of unused Yasargil clips is specifically against recommendations on the package insert, the practice appears to be widely followed by vascular neurosurgeons in the United States (Friedman A, oral communication, 1995).

It was not the primary goal of our study to ascertain why the clips are ferromagnetic or how they came to possess some ferromagnetic properties, but rather to document such properties in order to alert all involved that some of
these clips are or have become—at the very least—weakly ferromagnetic. It is unclear whether these weakly ferromagnetic clips acquired these properties as a result of manufacturing differences (which seems most unlikely according to Aesculap) or as a result of postdistribution handling. Nevertheless, even if the clips were entirely nonferromagnetic at the time of distribution, as claimed, it is critical to realize that these clips can apparently become at least weakly ferromagnetic for reasons that have not yet been determined.

These results are probably not specific to only Yasargil FE clips, but rather are a potential problem for the industry as a whole. As recently as April 1995, Dujovny et al (16) reported no torque with Permecky clips tested by means of vibrating sample magnetometry, although we observed some positive rotational responses in our relatively small sample of Permecky clips. Further, earlier manufacturer claims (Burridge JL, written communications, 1992, 1993) and independent peer-reviewed studies (3,17) stated that Yasargil FD clips were all MR compatible (6), but since April 1993 the manufacturer has recommended that MR imaging not be performed in a patient with a Yasargil FD clip and that all such clips be discarded (Bush R, written communication, 1993). We observed substantial variability in these clips, and one jumped up to a handheld magnet. This variability may help explain why some authors—as well as the manufacturer—initially found these clips to be MR compatible, ferromagnetically, whereas we observed gross motion in the magnetic field. The degree of attraction or motion observed in some of the Yasargil FD clips (which are contraindicated for MR imaging in the new manufacturer guidelines) was sufficient for us to be concerned about serious patient risk and even potentially fatal outcomes if a patient with an implanted Yasargil FD clip were to be inadvertently exposed to an MR examination.

We found considerable variability in the degree of ferromagnetism in various aneurysm clips that were supposedly nonferromagnetic at distribution, and the cause is unclear. Regardless of the etiology, such variability is potentially problematic. There is no reason to assume that such variability would be restricted to clips from any particular manufacturer, although accessibility to large numbers of clips at our institutions permitted volume testing of clips from only one manufacturer to date. We currently recommend that patients with aneurysm clips not be generally accepted to undergo MR examinations regardless of the type of examination or the static and static-gradient magnetic field strengths. Exceptions could include patients in whom the specific clip had been tested on-site prior to implantation and was found to be nonferromagnetic, and the finding was recorded in the patient’s operative record. Another exception could include patients in whom MR imaging of the clip had already been performed and the results were available for review. If the artifact associated with that clip (eg, especially on moderate long-echo-time gradient-echo images) were quite limited, the evidence would be strong against the existence of substantial ferromagnetism in that clip. In any case, more investigations are needed to adequately understand why such variability exists and to help identify or prevent it prior to clip implantation and before patients with intracranial aneurysm clips are permitted into the environment of an MR imaging system.

In May 1994, as a result at least in part of the findings in our study (Munzener R, oral and written communications, 1994), the FDA sent a letter to all manufacturers of currently marketed aneurysm clips requesting that if any claimed MR compatibility for their clips, they must provide the FDA “all data and information pertaining to the testing of your device that assures it is safe and effective in MR imaging environments. Otherwise, we recommend that you revise your product labeling to clearly inform users that you have not tested your device for compatibility with MR imaging devices” (Callahan TJ, written communication, 1994). We believe this is an appropriate first step to ensure the safety of MR imaging examinations performed in patients with implanted intracranial aneurysm clips.

References