Detection of Implants and Other Objects Using a Ferromagnetic Detection System: Implications for Patient Screening Before MRI

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OBJECTIVE. Ferromagnetic detection systems have been used to prevent accidents related to external ferromagnetic objects (e.g., pocket knives, hearing aids, and so on). If a ferromagnetic implant was missed during MRI screening, the ability to use a ferromagnetic detection system to discover the object in a patient before MRI could potentially avoid a serious injury, which has important implications for patient safety. Therefore, the purpose of this investigation was to use a ferromagnetic detection system to assess implants and other objects that may be encountered in patients referred for MRI procedures.

MATERIALS AND METHODS. A "pillar-type" ferromagnetic detection system was used to evaluate 67 different implants and other objects (pulse generators [*n* = 43], electronic devices [*n* = 5], stents [*n* = 6], CSF shunt valves [*n* =3], orthopedic implants [*n* =3], bullets [*n* =4], and others [*n* =3]) that were attached to a volunteer subject's body to approximate a realistic in situ location. The subject with the test item approached the ferromagnetic detection system, rotated in front of it four times, and withdrew while the alarms were monitored and recorded.

RESULTS. There were 58 true-positive, four true-negative, no false-positive, and five false-negative findings. Thus, the sensitivity was 92% and the specificity was 100%.

CONCLUSIONS. These results indicated that, besides being used to identify external ferromagnetic objects, this ferromagnetic detection system may be a useful tool to screen patients referred for MRI examinations who may have implanted or embedded items. Further investigation to determine the use of this ferromagnetic detection system to detect additional implants in the clinical setting is warranted.

Ferromagnetic detection systems have been used as part of the screening procedure for MRI with the primary intent of preventing accidents or other problems related to external ferromagnetic objects (e.g., pocket knives, cell phones, hearing aids, and so on) [1, 2]. Notably, the use of a ferromagnetic detection system is recommended as an additional means of evaluating patients and individuals before entry into the MRI system room but is not meant to replace a thorough and conscientious screening practice [1, 3].

Because of the serious risks associated with exposure of ferromagnetic implants or foreign bodies to the powerful magnetic fields of MRI systems, a critical component of screening involves using procedures to identify unsafe items that may be implanted or embedded in patients [1, 3, 4]. Unfortunately, MRI screening is not always able to determine the presence of implanted objects that are potentially hazardous. For example, the patient may be a poor historian and medical records may be inaccurate or incomplete. Furthermore, patients are frequently unaware of the material details related to their implants, devices, or foreign bodies. If a ferromagnetic implant or foreign body was missed during routine MRI screening, the ability to use a ferromagnetic detection system to discover the object in a patient before entry into the scanner room could potentially avoid a serious injury and therefore increase the usefulness of this detection system with respect to MRI screening procedures and have important implications for patient safety.

The magnetic field associated with a ferromagnetic object (e.g., an implant) located within the human body is unaffected by the surrounding tissue because the magnetic permeability of tissue is very low [5–7]. Therefore, because tissue is essentially a "transparent" carrier for a ferromagnetic object, a

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ferromagnetic detection system could be used to identify ferromagnetic implants or foreign bodies. To our knowledge, there has been no prior report of this specific use of a ferromagnetic detection system. Thus, the purpose of this investigation was to use a ferromagnetic detection system to assess a variety of implants and other objects that may be encountered in patients referred for MRI examinations.

Materials and Methods

Ferromagnetic Detection System

A vertically mounted, "pillar-type," ferromagnetic detection system (Ferroguard Screener, Model FGS1, Metrasens) was selected for use in this investigation because its configuration permits it to be used to effectively screen a patient in an overall manner (Fig. 1). This particular ferromagnetic detection system uses multiple fluxgate sensors. A fluxgate sensor is the most sensitive type of solid-state magnetometer that is practical for detecting ferromagnetic objects, and using multiple sensors in a pillar configuration provides head-to-toe coverage of the patient or individual [2]. The sensors are electronically designed to remove large unwanted magnetic signals, such as the Earth's geomagnetic field.

A

B

Fig. 1—Pillar-type ferromagnetic detection system used in this investigation.
A and **B,** Photographs show ferromagnetic detection system as it was used for evaluation of implants and other objects (**A**) and as it might be used in MRI environment (**B**).

Implants and Other Objects

Sixty-seven different implants and other objects were selected for testing and included items made from materials that have relatively low magnetic susceptibility values (e.g., an aneurysm clip made from Phynox and orthopedic implants made from titanium or cobalt-chromium) as well as many known to be contraindicated for MRI examinations (e.g., certain cardiac pacemaker pulse generators and a ferromagnetic armor-piercing bullet). The items included pulse generators (n = 43), electronic devices (n = 5), stents (n = 6), CSF shunt valves (n = 3), orthopedic implants (n = 3), bullets (n = 4), a device for vascular access (n = 1), hemostatic clip (n = 1), and aneurysm clip (n = 1) (Table 1). None of the electronically activated devices (e.g., pulse generators) were turned on during this evaluation. Importantly, these implants and objects were selected with an emphasis on ferromagnetic items and because they may be present in patients referred for MRI examinations [3, 4]. To our knowledge, none of these objects were previously exposed to magnetic fields. Notably, care was taken to avoid magnetizing the implants and other objects with strong magnetic fields prior to the tests, as this would have made them easier to detect, thus, impacting the results.

Protocol

As previously indicated, the magnetic susceptibility of human tissue is relatively low (i.e., below 10^{-5} SI [Systeme International], dimensionless) [5–7] and well below the level that a ferromagnetic detection system designed for the MRI environment can measure. Therefore, because tissue is transparent to a ferromagnetic detection system, it is essentially irrelevant to the magnetic aspect of an object whether it is located internally or externally to the test individual (or patient). In this investigation, a volunteer subject was used to conduct the testing of implants and other objects, with each item fixed to approximate an in situ location and orientation, albeit on the external surface of the subject's body. Although there may be a small positional discrepancy by having the implant or object external to the subject, this can be compensated for by slightly increasing the distance between the ferromagnetic detection system and the implant or object on the volunteer subject, as was done in this study.

The positions used for placement of each object were selected to approximate the in situ scenario as shown and explained in Figure 2. Table 1 summarizes the positions used for the implants and objects that underwent testing.

In accordance with the manufacturer's instructions, the ferromagnetic detection system was set up at a location where environmental factors did not cause false-positive alarms. The process recommended by the manufacturer when using the pillar-type, ferromagnetic detection system is for the patient or individual to walk up to the device, rotate 360°, and then walk away. The correct distance relative to the ferromagnetic detection system is accomplished by using a manufacturer-provided floor mat as a guide. However, in this investigation, the following procedure was followed to facilitate detection of a ferromagnetic item: First, the volunteer subject, known to have no implants or foreign body, was clothed to eliminate metallic materials. The lack of metallic materials was verified by having the volunteer subject screened verbally, visually, and using the ferromagnetic detection system. Second, each implant or other object was then attached to the volunteer subject to approximate an appropriate in situ position. Third, the volunteer subject approached the front of the ferromagnetic detection system to a distance of 5 cm, rotated four times (4 seconds per rotation with a 3-second delay between rotations) in front of the device, and then walked away from the ferromagnetic detection system. The normal starting position during general use of this detection system is for the subject's elbow, when standing sideways, to be within 2.5 cm of the pillar. An additional 2.5-cm was used to approximate the in vivo positioning of an implant or other object.

Data Analysis

For the purpose of analysis, the following criteria were applied to the results.

True-positive (TP)—The ferromagnetic detection system gave a positive alarm during all of the

TABLE 1: Summary of Findings for 67 Different Implants and Other Objects Evaluated Using a Ferromagnetic Detection System

Type	Implant or Object Information	Manufacturer	Position	Positive Alarm	Outcome
B	0.223 Armor-piercing round	Western Cartridge	P3	Yes	TP
B	0.308 Winchester	Winchester	P3	No	TN
B	Armor-piercing bullet	Norinco	P3	Yes	TP
B	Armor-piercing, full metal jacket bullet	Norinco	P3	Yes	TP
NS	ActivaPC	Medtronic	P3	No	FN
NS	ActivaSC	Medtronic	P3	Yes	TP
NS	Demipulse 103	Cyberonics	P3	Yes	TP
NS	Interstim2	Medtronic	P1	No	FN
NS	Itrel 3, Interstim 1	Medtronic	P1	Yes	TP
NS	NCP VNS, model 101	Cyberonics	P3	Yes	TP
NS	Pulse, VNS, model 102	Cyberonics	P3	Yes	TP
NS	Restore or RestoreAdvanced	Medtronic	P1	Yes	TP
NS	RestoreSensor	Medtronic	P1	Yes	TP
NS	Soletra	Medtronic	P3	Yes	TP
NS	Synergy or Kinetra	Medtronic	P1	Yes	TP
NS	Ultra or ActivaRC1	Medtronic	P1	Yes	TP
NS	Versitrel	Medtronic	P1	Yes	TP
OR	Fixator Z Arm	OrthoFix	P2	Yes	TP
OR	Fixator Z Knee	OrthoFix	P6	Yes	TP
OR	Hip Screw, S&N	Smith and Nephew	P5	No	TN
OT	Port-a-Cath	Deltec	P2	Yes	TP
OT	Resolution clip	Boston Scientific	P2	Yes	TP
OT	Yasargil aneurysm clip, FE856 K	B. Braun	P4	No	TN
PG	Accent DR, PM2112	St. Jude Medical	P2 and P3	Yes	TP
PG	Accent DR, radiofrequency PM2212	St. Jude Medical	P2 and P3	Yes	TP
PG	Accent MRI, PM2124	St. Jude Medical	P2 and P3	Yes	TP
PG	Accent SR, radiofrequency PM1210	St. Jude Medical	P2 and P3	Yes	TP
PG	Atlas II+, V-268	St. Jude Medical	P2 and P3	Yes	TP
PG	Auricle, 3107–36P	St. Jude Medical	P2 and P3	Yes	TP
PG	Cosmos, 238–01	Intermedics	P2 and P3	Yes	TP
PG	Cosmos II, 238–03	Intermedics	P2 and P3	Yes	TP
PG	Cosmos II, 238–05	Intermedics	P2 and P3	Yes	TP
PG	Current DR, radiofrequency 2207–36	St. Jude Medical	P2 and P3	Yes	TP
PG	Delta Type DDD 0937	Cardiac Pacemakers, Inc.	P2 and P3	Yes	TP
PG	Epic II+, V-258	St. Jude Medical	P2 and P3	Yes	TP
PG	Fortify DR, CD2231–40	St. Jude Medical	P2 and P3	Yes	TP
PG	Integrity SR, 5142	St. Jude Medical	P2 and P3	Yes	TP
PG	Microny II SR, 2525 T	St. Jude Medical	P2 and P3	Yes	TP
PG	Nova, 281–01	Intermedics	P2 and P3	Yes	TP
PG	Nova II, 281–05	Intermedics	P2 and P3	No	FN
PG	Nova II, 282–04	Intermedics	P2 and P3	Yes	TP
PG	Protecta XT VR	Medtronic	P2 and P3	Yes	TP
PG	Quantum, 253–19	Intermedics	P2 and P3	Yes	TP

(Table 1 continues on next page)

TABLE 1: Summary of Findings for 67 Different Implants and Other Objects Evaluated Using a Ferromagnetic Detection System (continued)

Type	Implant or Object Information	Manufacturer	Position	Positive Alarm	Outcome
PG	Relay, 294–03	Intermedics	P2 and P3	No	FN
PG	Res-Q ACE, 101–01	Intermedics	P2 and P3	Yes	TP
PG	REVO MRI Surescan	Medtronic	P2 and P3	Yes	TP
PG	Unify (DF4), CD3231–40Q	St. Jude Medical	P2 and P3	Yes	TP
PG	Unify SS CD3235–40	St. Jude Medical	P2 and P3	Yes	TP
PG	Verity ADx, XL DR 5357	St. Jude Medical	P2 and P3	Yes	TP
PG	Victory DR, 5820	St. Jude Medical	P2 and P3	Yes	TP
PG	Viva Quad C, CRT-D	Medtronic	P2 and P3	Yes	TP
PU	Synchromed II, 20 mL	Medtronic	P2	Yes	TP
PU	Synchromed II, 40 mL	Medtronic	P2	Yes	TP
R	Reveal 9526, loop recorder	Medtronic	P3	Yes	TP
R	Reveal Plus, loop recorder	Medtronic	P3	Yes	TP
R	SJM Confirm, DM2100	St. Jude Medical	P2 and P3	Yes	TP
S	Luminexx stent	Bard	P6	No	TN
S	Zenith Endo stent	Cook Medical	P6	Yes	TP
S	Zenith Endo stent, combined	Cook Medical	P6	Yes	TP
S	Zenith P-branch stent	Cook Medical	P6	Yes	TP
S	Zenith T-branch stent	Cook Medical	P6	Yes	TP
S	Zenith Universal stent	Cook Medical	P6	Yes	TP
SC	Precision Plus	Boston Scientific	P3	Yes	TP
ST	SpF100	Biomet	P1	Yes	TP
V	Certas CSF shunt valve	Codman	P4	Yes	TP
V	proGAV CSF shunt valve	Miethke	P4	Yes	TP
V	proSA CSF shunt valve	Miethke	P4	No	FN

Note—B = bullet, NS = neurostimulation system pulse generator, OR = orthopedic implant, OT = other, PG = pulse generator for cardiac pacemaker or implantable cardioverter defibrillator, PU = implantable infusion pump, R = cardiac recorder, S = stent, SC = spinal cord stimulator, ST = bone fusion stimulator, V = CSF shunt valve, P1 = posterior superior gluteal area, P2 = abdominal/hip area, P3 = subclavicular area, P4 = head area, P5 = knee area, P6 = abdominal aorta area, TP = true-positive, FP = false-positive, TN = true-negative, FN = false-negative.

volunteer subject's rotations with the ferromagnetic implant or object. Note that the implant or object was known to be ferromagnetic on the basis of one or more of the following: the materials used for the item were provided by the manufacturer, information from prior testing, or MRI labeling information indicating that it was MR unsafe [8].

True-negative (TN)—The ferromagnetic detection system gave no alarm during all of the volunteer subject's rotations with the nonferromagnetic or weakly magnetic implant or object. Note that the implant or object was known to be nonferromagnetic on the basis of one or more of the following: the materials used for the item were provided by the manufacturer, information from prior testing, or MRI labeling information indicating that it was MR conditional [8].

False-positive (FP)—The ferromagnetic detection system gave a positive alarm during one or more of the volunteer subject's rotations with the nonferromagnetic or weakly magnetic implant or object.

False-negative (FN)—The ferromagnetic detection system gave no alarm during one or more of the volunteer subject's rotations with the ferromagnetic implant or object.

The data were analyzed, as follows: sensitivity = *no. of TP* / *no. of TP* + *no. of FN*, and specificity as *no. of TN* / *no. of TN* + *no. of FP*.

Results

Table 1 displays a summary of the results of the evaluation of the pillar-type ferromagnetic detection system as it was used to evaluate a volunteer subject with 67 implants and other objects. There were 58 true-positive, four true-negative, no false-positive, and five false-negative findings. Thus, the sensitivity was 92% and the specificity was 100%.

The implants for the five false-negative findings were known to have low magnetic content and therefore would generally not pose a hazard to a patient with respect to magnetic field interactions; however, two of the pulse generators (Nova II, 281–05 and Relay, 294–03, Intermedics) are associated with contraindicated cardiac pacemakers. Furthermore, two of the five implants were pulse generators (ActivaPC and Interstim2, Medtronic) associated devices that have approved labeling designating them as, "MR conditional" [8] and thus acceptable for patients referred for MRI examinations when specific conditions are followed in association with 1.5-T MR systems.

Discussion

MRI issues that exist for implanted or embedded biomedical implants and other objects include magnetic field interactions, heating, and artifacts [1, 2, 4]. With respect to magnetic field interactions, if the item is weakly magnetic or sufficient counter-forces exist (i.e., provided by tissue in-growth, scarring,

sutures, cement, screws, or another mechanism that will prevent displacement), it is safe to perform an MRI examination on the patient without concerns of movement of dislodgement of the item [1, 3, 4, 8, 9]. Examples of weakly magnetic implants that are acceptable as well as those that have higher magnetic content include those that are labeled "MR conditional," such as certain aneurysm clips, pulse generators, vascular stents, filters, embolization coils, programmable (i.e., using a magnetic programmer) CSF shunt valves, and others [3, 4, 8, 10].

The aforementioned information is important to understand when using a ferromagnetic detection system to screen a patient with an implant or other object because a positive alarm signifies that the item is either MR unsafe (i.e., highly magnetic with the possibility of displacement) or MR conditional (i.e., deemed acceptable for the patient under highly specific MR conditions) [3, 4, 8]. Accordingly, when a positive alarm occurs, the health care professional needs to further investigate the implant or object to ensure that there will be no risks posed to the patient under the particular MRI conditions (e.g., 1.5 T, 3 T, type of transmit radiofrequency coil, etc.) that are planned for the MRI examination. Therefore, it is important that MR conditional implants be identified in addition to MR unsafe objects. An MR conditional implant could be unsafe for the patient if the conditions are not fully met [4]. Importantly, further attention by the MRI health care professional with regard to the particular ferromagnetic object that was identified by the ferromagnetic detection system is critical when using this device for screening. This should involve reexamination of the patient's history and further questioning plus performing the additional research necessary to fully resolve the situation.

The overall findings (sensitivity, 92%; specificity, 100%) of this study indicated that the ferromagnetic detection system might be useful for determining the presence of a ferromagnetic item in a patient as part of the screening procedure. The implants involved in the five false-negative findings had low magnetic content and would not pose a hazard to a patient with respect to magnetic field interactions. Furthermore, two of the five implants were pulse generators associated with MR conditional devices [8]. Importantly, there were no false-positive findings. Thus, the nuisance associated with false alarms is unlikely to be problematic.

Some of the highest-risk implants are those that are electronically activated and include cardiac pacemakers, implantable cardioverter defibrillators, and neurostimulation systems [1, 3, 4]. For these implants, hazards may be associated with movement of the pulse generator, damage to the pulse generator, excessive heating of the associated leads and electrodes and other factors [3, 4]. It should be noted, however, that there are several electronically activated cardiac devices and neurostimulation systems that are MR conditional, permitting MRI examinations in accordance with the approved MRI-specific labeling.

The ferromagnetic detection system identified 39 of 43 (91%) of the pulse generators that are used for electronically activated devices, which is a relatively high percentage. As previously stated, two of the four unidentified pulse generators, the ActivaPC and Interstim2, are MR conditional [8]. Therefore, the ferromagnetic detection system could be particularly beneficial in screening patients with electronically activated implants that incorporate pulse generators. However, when a positive alarm occurs, additional attention must be given to the patient to determine whether the alarm was associated with an MR conditional device.

Another interesting finding was that the ferromagnetic detection system gave a positive alarm for the two armor-piercing bullets and thus identified small objects that may pose serious injuries to patients referred for MRI examinations. These are relatively small highly magnetic items. A ferromagnetic bullet may pose hazards depending on its location in the patient [4]. Interestingly, although previously indicated as a contraindication for MRI due to high magnetic content, the Resolution clip, which was detected by the FMDS, is now labeled MR conditional at 1.5 T and 3 T.

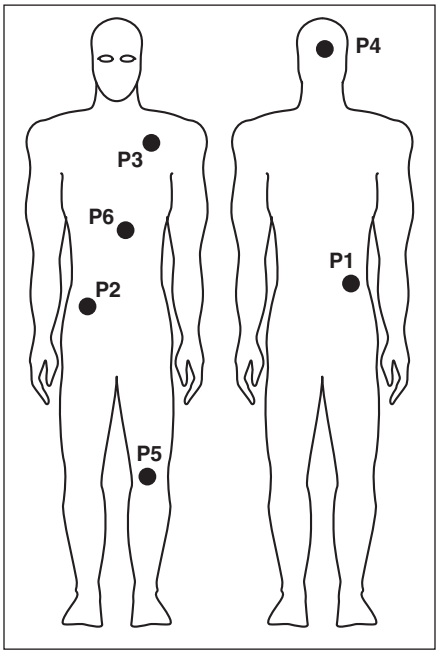

Fig. 2—Schematic drawing shows positions used to attach implants and objects that underwent testing using ferromagnetic detection system. P1 = posterior superior gluteal area, P2 = abdominal/hip area, P3 = subclavicular area, P4 = head area, P5 = knee area, P6 = abdominal aorta area.

Importantly, the possible future use of this ferromagnetic detection system for the identification of implanted or embedded objects will require that the users fully understand that this is an additional means that facilitates the typical MRI screening processes. However, the use of this system would not reduce the requirements for the questioning and discussions with patients or the care with which their history is examined.

Our study has some possible limitations. Because the results do not reflect the relative numbers of the varieties of implants and foreign bodies that may be present in the population of patients referred for MRI examinations, these results do not strictly pertain to the clinical effectiveness of the use of this ferromagnetic detection system for screening. However, these findings are very encouraging and suggest that a high proportion of ferromagnetic implants and objects, particularly electronically activated devices, can be identified during screening by following the protocol presented in this investigation.

This study was conducted with one type of ferromagnetic detection system that was selected on the basis of having fluxgate sensors that are known to be highly sensitive. Alternative detection systems based on other types of sensors are also commercially available, although comparative studies have yet to be performed using these systems. Notably, the detection performance for implants and other objects will presumably vary between different devices. Handheld ferromagnetic detection devices are unlikely to be suitable for identification of certain implants, such as pacemakers, because they contain powerful magnets.

Investigation of the use of the ferromagnetic detection system to screen nonambulatory patients was excluded from this study. Therefore, the ability to identify implanted or embedded ferromagnetic objects is currently unknown. This procedure would obviously necessitate using entirely nonferromagnetic wheelchairs and gurneys and performing a two-way "pass-by," which inevitably increases the range between the object and the sensors, potentially resulting in a lower detection performance.

The particular method of screening by patient rotation is recommended by the manufacturer for whole-body screening of external objects. It may not necessarily be an optimized motion for implant detection, and possibly other patient motions may be manageable that enhance the detectability of ferromagnetic objects, thus, increasing the sensitivity of the technique. Further research on improving the detection rate of this ferromagnetic detection system is warranted.

Conclusions

Sixty-seven different implants and other objects were evaluated to determine whether a pillar-type ferromagnetic detection system would be capable of identifying these items. The results indicated that, besides use to identify external ferromagnetic objects, this ferromagnetic detection system may be a useful tool to screen patients referred for MRI examinations who may have implanted or embedded items. Thus, this information represents a potentially important means of preventing serious injuries in the MRI environment. Further investigation to determine the use of this ferromagnetic detection system to detect implants in the clinical MRI setting is warranted. Notably, these findings are highly specific to this particular ferromagnetic detection system along with the protocol used in this investigation.

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