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Implementation of a ferromagnetic detection system in a clinical MRI setting

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ABSTRACT

Purpose: To evaluate the implementation of a ferromagnetic detection system (FMDS) into a clinical MRI setting.
Materials and methods: One thousand patients were considered for MRI safety screening using an FMDS. Equipment used was a Ferroguard® Screener (Metrasens Ltd, Malvern, Worcestershire, UK). Fully gowned patients rotated 360° in front of the FMDS in a standardized manner following traditional MRI screening methods (the use of a written questionnaire (Fig. B.1) and verbal interview.
Results: Final results included 1032 individual screening events performed in 977 patients. There were 922 (94%) initial passes using the FMDS; 34 (4%) failed initial screens but passed a subsequent screen; 21 (2%) failed the initial and subsequent screens. Thus, including all screening events (n = 1032), there were 956 (93%) true negatives (TN); 21 (2%) false positives (FP) and 55 (5%) true positives (TP). No false negatives (FN) were recorded. Therefore, sensitivity was 100% and specificity was 98%.
Conclusion: Implementation and correct usage of an FMDS proved to increase safety within a clinical MRI environment by alerting staff to ferromagnetic items or implants not identified using traditional MRI screening methods. An FMDS should be used as an adjunct to these methods. The information in this study pertains to the specific equipment used in this investigation.

Introduction

Safety is an integral part of undertaking magnetic resonance imaging (MRI), whether it be in a research or clinical environment and all staff, including "management and individuals must be fully aware, at all times, of the need for safety and the consequences that may arise if vigilance is relaxed."[1]

Although studies have been performed to assess the safety aspects of MRI, various issues still persist.[2] There have been many adverse incidents reported including damage to MR systems; injuries to patients and staff; and unfortunately even some fatalities that have been attributed to projectiles as well as scanning of patients with aneurysm clips or cardiac pacemakers *in situ*. However, the true extent of MRI incidents and accidents is unknown due to underreporting, as discussed by Chaljub et al.,[3] who also stressed the importance of adhering to MRI safety policies and procedures. MRI safety incidents or near misses are currently underreported due to the fact that there is no obligation to do so and the knowledge of some incidents are based on anecdotal evidence; however the Joint Commission[4] refers to a study by Jason Launders in 2005 indicating that there were 389 MRI safety incidents within the previous ten year period, 10% of which were projectile related.

Safety issues in the MRI environment include both direct and indirect hazards. Direct hazards are "those arising directly from exposure of the human body to EMF (the static magnetic field, time-varying magnetic fields and radiofrequency radiation)"[5] which include peripheral nerve stimulation, MRI-related heating, and acoustic noise. Indirect hazards involve the interaction between the electromagnetic fields and objects or implants, such as projectile effects or malfunction of cardiac pacemakers.

The hazards that are associated with MRI include those already mentioned as well as risks associated with cryogens in superconducting magnets. These hazards are not often realized or understood by referring or attending clinicians or patients.

One of the most infamous MRI safety incidents occurred in 2001 which led to the death of a six year old boy from a head injury caused by the projectile effect of an oxygen cylinder.[6] This caused various societies to introduce guidelines to reduce the risks in MRI environments and promote education in MR safety.[1,7–9]

In the presence of continuing medical advancement and more complex procedures being undertaken, it is important to determine the safety of any implants that may be present in patients referred for MRI, because not all may have been tested, and to identify

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external ferromagnetic objects that may pose a hazard in the MRI environment. The implementation of comprehensive pre-MRI screening procedures, including using forms and verbal interviews, is vital to ensure a safe MRI environment.

Recently, ferromagnetic detection systems (FMDS) have been proposed as a useful tool to facilitate MRI screening.[10,11] To date, there have been no investigations reporting the benefits of an FMDS in the clinical MRI setting.

Therefore, the rationale for undertaking this research project lies in the view that MRI safety procedures can be improved by the implementation of an FMDS to reduce the risk of ferromagnetic objects or implants being allowed, or inadvertently taken, into the MR system room. It is important to note, however, that this is not to replace existing screening procedures, rather to be used as an adjunct to thoroughly screen those patients and individuals prior to entering the MR system area.

Materials and methods

Study population

One thousand consecutive patients were selected for the sample population, with 23 of these being dismissed due to mobility issues and therefore inability to follow the screening methods used in this study. These included patients attending from a hospital ward or elsewhere on a gurney; infants; patients undergoing general anesthesia and patients unable to weight bear for other reasons not mentioned.

Ferromagnetic detection system

The ferromagnetic detection system used for the study was the Ferroguard® Screener (Metrasens Ltd, Malvern, Worcestershire, UK) which was installed in the patient changing room (Fig. B.2). In the United Kingdom, there is currently no mandate to standardize screening methods that must be employed in a clinical MRI setting, however, in terms of best practice and following Medicines and Healthcare Products Regulatory Agency (MHRA) recommendations,[1] routine pre-MRI screening procedures including written and verbal questioning and gowning of all patients, were undertaken as is standard practice in the MRI unit performing the examination. Additionally, following manufacturer instructions, the Ferroguard® Screener was activated via a push button and the individual patient was positioned in a standing position on a fixed floor mat to ensure optimum distance from the Screener. The patient was then requested to rotate 360° at a comfortable speed, equating to approximately 3–4 s for an entire rotation, using the floor mat as a guide without coming into contact with the FMDS.

This procedure was carried out by trained MRI radiographers who visualized the lights and alarms of the Ferroguard® Screener to determine the final safety status of the patient, with any amber or red lights being investigated. Notably, all staff members undertaking the screening procedure were instructed to be ferrous free as set out by the local MRI dress code.

The FMDS used for this study uses fluxgate sensor technology, this being the most sensitive method for detection of ferromagnetic objects for the purpose of MRI safety screening, with multiple sensors allowing for full body coverage during a single rotation.[10,12] The system detects moving ferromagnetic items only, and is therefore not affected by the static magnetic field. The necessity for rotation of the patients causes this required movement and also brings any objects nearer to the FMDS sensors where sensitivity is greatest.

The sensitivity of the system was adjusted on installation to allow for the local environment so that extraneous magnetic field interference, and therefore false positives, was minimized.

Results of the study were dependent on correct set up of the device, training of staff, and an appropriate protocol being utilized.

Results were documented on a proforma to include any known objects or implants and whether the screener alerted to the presence of ferromagnetic material. For all positive alerts, further questioning and investigation was performed on the patient, with any identifiable and removable external ferromagnetic objects being removed prior to repeating the process. Any implants that were identified were checked for MRI safety using available resources such as identification cards, safety reference manual[13] and manufacturer's websites.

In the event of two consecutive positive screening events, these cases were dealt with on an individual basis, with discussion with the supervising radiologist in order to make a decision on whether to proceed directly to MRI, refer for alternate imaging, or to have the MRI examination postponed or canceled. If the decision was made to proceed as an “approved fail”, informed consent was gained from the patient with an explanation to utilize the provided emergency alarm in case of any untoward event.

Screening procedure

Included with patient appointment letters was the MRI safety questionnaire (Fig. B.1) which patients were requested to complete prior to arrival for the appointment. Instruction was given to telephone the MRI department if the answer to any of the pertinent questions was positive, with any necessary investigations occurring before patient arrival. Short notice appointment patients completed this questionnaire on arrival.

All patients were accompanied by an MRI trained member of staff to a confidential area in order to undergo verbal questioning, with any queries or safety concerns being addressed prior to gowning of the patients.

All FMDS screening was undertaken by an MRI trained radiographer immediately prior to escorting the patient into the MR system room due to the responsibility of this person for final confirmation of MR safety status.

Data analysis

For the purpose of this study the following criteria were used to determine sensitivity and specificity[10]:

True negative (TN): on screening an individual patient, there was no alert on the FMDS as to the presence of ferrous materials. This corresponded with information gained from written and verbal questioning and available patient records.

True positive (TP): there was a positive alert by the FMDS as to the presence of ferrous material. Written and verbal questioning was reviewed to corroborate the presence of implants or removable objects which were subsequently discovered by inspection. TP was recorded in the presence of ferromagnetic material whether declaration was made prior to screening and also if discovered subsequently after an initial positive alert.

False positive (FP): a positive alert was given by the FMDS indicating the presence of ferromagnetic material, however on reviewing written and verbal questioning and available patient records no cause was identified.

False negative (FN): no alert was given by the FMDS, however ferromagnetic material was found *in situ* on or in the patient.

Results

Of 1000 patients selected for the sample population, 977 were included in the results of the study. The remaining 23 were dismissed due to issues relating to mobility. For the purpose of the study patients were required to be weight bearing and able to

rotate 360° unaided. In everyday practice these patients are screened using traditional methods (verbal and written questioning), and also pass through an entryway control system (Ferroguard®, Metrasens, Malvern, UK) prior to entering the MRI scan room. If patient transport is required, then a ferrous free gurney or wheelchair is utilized so as not to cause a false positive alert. This entryway control system is used as a final safety measure to eliminate ferromagnetic items from entering the MR system room, but was not included in the results for this study.

There were 956 (93%) true negatives; 21 (2%) false positives; 55 (5%) true positives, and no false negatives (Fig. B.3).

Including all screening events, due to some patients requiring subsequent screening rotations following identification of objects or implants (n = 1032), sensitivity was therefore determined as follows:

Sensitivity = number of TP/(number of TP + number of FN)

Sensitivity = 55/(55 + 0) = 100%

Again, including all screening events, specificity was:

Specificity = number of TN/(number of TN + number of FP)

Specificity = 956/(956 + 21) = 98%

Of the 956 TN screening events, 191 patients had declared implants or objects prior during routine screening methods.

Of the 55 patients that required second screening 34 (62%) were true positives. 18 (53%) of these were found to have removable objects and were true negative on a second screen, whereas 16 (47%) had non-removable objects or implants and screened as true positive a second time. There were 21 false positives (38%), of which 16 (76%) passed on a second screen and 5 (24%) that required a radiologist decision to proceed with an approved fail.

Added time of the extra step to the entire screening procedure was not formally recorded, however it was noted that the majority of cases took less than 1 min additional time.

Discussion

General discussion

Previous studies have been undertaken in a non-clinical setting to evaluate the effectiveness of FMDS of identifying implants and objects. Shellock, et al.[10] recommended further research in the clinical MRI environment, an area in which some studies have been made, however are yet unpublished.

The results of the current study demonstrated that, although conventional screening procedures on gowned patients were reliable in the majority of cases, the FMDS identified ferromagnetic objects that may otherwise have been missed using traditional screening procedures alone. These included loose items that may have been a projectile safety concern, such as patient locker keys (n = 3), as well as items that had a potential of heating, movement or artifact, such as hair bands (n = 1), hearing aids (n = 1), underwear (bras) (n = 4), jewelry (n = 2), safety pins (n = 1). Some items were identified by the FMDS as being a potential ferromagnetic source, such as conditional stapes implants, dental implants, orthopedic implants, and foreign bodies. Even with general good practice in terms of screening procedures, there is scope for continuous improvement and there will undoubtedly be patients who will fail to follow verbal and written instructions and who may provide communication challenges.

The MRI safety status of identified implants was checked against current MRI labeling of the American Society for Testing and Materials (ASTM) International.[14] These labels are as follows:

MR Safe – items that are non-conducting, non-metallic and non-magnetic. These have no known hazards in any MR environment.

MR conditional – items that pose no known hazard in a specified MR environment if specified conditions of use are followed.

MR Unsafe – items that are known to pose hazards in any MR environment.

Of the true negative screening events, the majority of patients had no known ferromagnetic objects or implants. Implants or objects that were declared during routine screening methods were investigated, and if considered MRI safe or conditional, were not expected to be identified by the Ferroguard® Screener. The majority of these were orthopedic implants, with the remainder comprising mainly other surgical implants (Table A.1). Some patients declared multiple implants and/or objects.

The screening events that were true positive followed by true negative on the second pass were investigated. The majority of these were due to patient error which was remedied after removal of forgotten items or reinforcing screening technique. These items and reasons are listed in Table A.2.

Other reasons included staff errors, however, there were some instances where no apparent cause was identified. Where staff error was a factor, this was due to non-compliance of following the correct screening procedure. For example, patients were screened while wearing a robe as well as a patient gown (n = 2). On occasion these were found to have items in pockets or have safety pins present. Patient locker keys were not always taken from the patient prior to screening which were found to cause a positive screening alert. On two occasions there were radiographers present who were not ferrous free. This may have been due to staffing issues, for example covering sickness absence, or non-MRI radiographers in the area due to the changing area being shared with the computerized tomography (CT) department. These results show that staff training and compliance is important in implementing proper screening procedures using an FMDS and will decrease the number of false positives. Policies and procedures should be written, and followed by all MRI staff members. Recalibration may be required if false positives continue to be caused by extraneous interference, for example the air handling units.

Cases that resulted in two consecutive positive screening events were investigated. Of these, 12 patients had a history of implants or objects, with some patients having multiple known items that were potentially ferromagnetic (Table A.3).

Of the implants that were identified, none were classed as MR unsafe, likely due to appropriate screening methods identifying these prior to patient arrival. Conditional cardiovascular implants included coronary stents and sternal wires and ENT implants included MR conditional stapes implants. Although not MR unsafe, it is important to identify any conditions required for MR scanning to ensure safety. A reason for discrepancy of conditional implants being picked up or not by the FMDS between patients could be due to strength of magnetism of individual implants. This may be an area for further research.

Of the remaining patients, three had not disclosed the presence of objects or implants on original questioning (both verbal and written) and these were discovered on further investigation. One had undergone hernia repair surgery; one had an orthopedic implant (i.e. a screw in the finger), and the other had not realized that he had a metallic foreign body located in the soft tissues of his knee. This was picked up only on subsequent X-ray examination.

Six remaining patients screened as positive on two consecutive screening events, with no evidence of ferromagnetic materials present. Reasons for these were not found at the time of investigation but possible causes may have included non-compliance of staff, for example not being ferrous free; external factors such as CT staff or patients (not ferrous free) in the vicinity; or movement of doors or other items during the screening procedure.

Time constraints were a consideration when incorporating an additional step into the screening process. Although time was not formally recorded, the majority of patients screened as true negative on first pass screening, therefore additional time was significantly less than one minute per patient. Those patients screening positive on first pass and negative following removal of items took slightly longer, however the equivalent time or longer may have

been required if patients had entered the MR system room and undergone initial imaging. Obviously, artifact on MR images, discomfort of patients, or projectile effects may have been a greater and more time consuming issue.

One rotation was performed for initial screening to minimize additional time required for the extra screening step in the clinical setting. This protocol may be improved for future studies by increasing the number of rotations, however throughput in a busy clinical department also needs to be considered.

A second screen was performed for any positive alert of the FMDS. This was done after verbal and visual checking of the patient to eliminate any obvious and removable cause.

FMDS results of two consecutive positive screening events that led to further investigation and discussion with the supervising radiologist took the longest in terms of screening process, however, this was typically no longer than 5–10 min. The radiologist was efficient in making a decision to proceed to scanning or not.

Possible limitations

Limitations of this investigation include the cases where no cause for a positive screen could be found, but the supervising radiologist authorized to proceed to MRI. These decisions can be questioned and were subjective on behalf of the radiologist on the day of examination. Is it likely that other radiologists in the same and other centers would make those same decisions?

Although there was a high percentage of true negatives on first pass screening with routine methods combined with Ferroguard® Screener, these results were assumed to be correct. For example, unless there was an untoward incident, or artifact on the area of scanning from an undisclosed item or implant, it was assumed that no ferromagnetic material was present. Similarly, in cases of known safe or conditional items or implants that were thought to be the cause of a positive screen, the absence of any additional items was assumed.

One FMDS only was used for the purposes of the study. Additional investigation may be warranted to assess any potential differences between other similar devices.

It should be noted that it is highly recommended that all patients undergoing MR examination are fully gowned,[1,7] however, this is not standard practice in all MRI facilities. In order to improve detection of ferromagnetic materials, optimization of general screening protocols is important. Additionally, the screening protocol utilizing an FMDS can be further improved from that of this study by increasing the number of rotations per patient. Although detection rate may be increased and additional time for screening has been shown to be negligible, this would need to be offset by any time constraints within a busy department.

Conclusions

At least one ferromagnetic detection system has been demonstrated to identify ferromagnetic items and other objects[10,15,16] and one preliminary study identified items that were not revealed by traditional screening procedures and that may have posed dangers, or at the very least would have caused artifacts on MR images. The time taken to employ the additional step in the screening process to use an FMDS is acceptable when one considers the time and inconvenience associated with the risks that can be prevented.

Although the FMDS in this study did not identify any unsafe implants after traditional MR screening methods, some previously undisclosed ferromagnetic items could have proved hazardous as projectiles e.g keys, some could have been damaged by the magnetic fields e.g. hearing aids, or caused inconvenience in the form of artifacts e.g. bras. The fact that these smaller items were identified by the FMDS after traditional screening methods can give confidence that it would identify larger and potentially more hazardous items if present. However thorough a facility is at following traditional MR screening procedures, there is no guarantee that patients will remember or realize the presence of potentially hazardous objects or implants.

Correct technique as well as compliance of patients and staff is important in making the most efficient use of an FMDS in a clinical MR setting and vigilance in undertaking traditional screening methods must remain, without sole reliance on an FMDS. Importantly, the findings of this study are specific to the particular type of FMDS and protocol used in this investigation.

Conflict of interest statement

None.

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Appendix A. Tables

Table A.1
Objects/implants declared by patients, or identified by MRI staff, prior to true negative FMDS screen.

Object/implant	Number
Orthopedic	118
Ear Nose Throat (ENT) e.g stapes	4
Cardiovascular implants e.g stents	16
Dental items/implants	25
Body piercing jewelry	4
Contraceptive/sterilization implant	9
History of metal intraorbital foreign body	7
Ophthalmic items eg lens replacement	2
Breast implants	2
Neurological items/implants	4
Hernia mesh repair	3
Surgical clips	1
Urinary catheter	1
Vascular implant e.g. stent	1
Total no. implants	197

Table A.2
Positive alarm on FMDS screening mainly related to removable external ferromagnetic items identified following initial positive screen.

Object/reason for alarm	Number
Hearing aid	1
Denture	3
Bra (underwire/clips)	4
Jewelry items	2
Hair band	1
Safety pin in underwear	1
Possible movement of FMDS during screening	1
Total	13

Table A.3
Implants and objects identified after two positive screening events using the FMDS.

Object/Implant	Number
Orthopedic implant	8
Cardiovascular implants e.g stents	3
Dental items	2
ENT e.g. stapes implant	1
Foreign body	1
Total	15

Appendix B. Figures

Please complete this form before attending your MRI appointment

Patient Name _____Daytime Tele. No. _____

Date of birth_____Weight _____ Occupation _____

Please indicate if you have or have had any of the following	Yes	No
1. Cerebral Aneurysm Clips or any other brain surgery	☐	☐
2. Cardiac Pacemaker, heart valves, stents or other heart surgery	☐	☐
3. Electronically/magnetically activated or mechanical implant	☐	☐
4. Any metallic fragments **into your eyes** for which you have sought medical attention	☐	☐
5. Any surgery in the past 6 weeks	☐	☐
6. Brain / Spinal Neuro-Stimulators	☐	☐
7. Cochlear or Stapes Implants	☐	☐

If you answer **YES** to any of the above, telephone the MRI department on **xxxxxx**

Please answer the remaining questions and bring this form with you on the day of your appointment.

Indicate if you have or had any of the following	Yes	No
Artificial / prosthetic limbs, plates, screws, wires or nails	☐	☐
Shunts (Spinal/Intra ventricular (***especially programmable***))	☐	☐
Any previous experience of MRI	☐	☐
Any Tattoos / Body piercing	☐	☐

Please ensure you **remove all body piercing** prior to your arrival at the MRI department.

If you require a **hearing aid**, this will need to be removed before entering the MRI scanning room.

Contrast Safety

Do you (have you ever) suffer from and Kidney problems	☐	☐
Female patients only		
Could you be pregnant	☐	☐
Are you breast feeding	☐	☐

You will be asked to change into a hospital gown ensuring any metallic items are removed. Please remove all medication patches. All personal belongings (including handbags, purses, wallets, keys, watches, jewellery, hair fastenings and mobile phones etc.) must either be placed in a secure locker or left on the ward. Immediately prior to the procedure any other loose metallic objects, including glasses, hearing aids and dentures with metallic plates must be removed. For your own safety you will be given ear protection.

You may be offered music. Please select your music preference

No Music □ Classical □ Chillout □ 80's □ 70's □ 60's □ Modern □ Jazz □

Signature of person completing form _____ ***Date*** _____

Office Use Only:

Ferroguard Check PASS ☐ FAIL ☐ Object/s Found_____ MRI Safe☐ MRI not safe☐

MRI Staff signature _____ *Date*_____

Figure B.1. MR safety questionnaire.

Figure B.2. Installation of the FMDS with floormat in the patient dressing room.

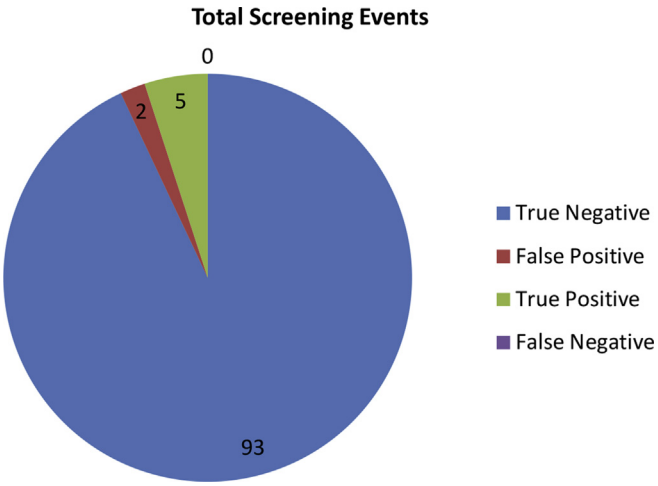

Figure B.3. Graphical representation of total screening event results.

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