DETECTION OF ORTHOPAEDIC IMPLANTS AND IN VITRO OBJECTS USING HAND HELD METAL DETECTOR

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DISCLAIMER

I declare that this dissertation records the results of the study performed by me and that it is of my own composition.

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LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

BMI	Body mass index
BOLD	Blood oxygen level dependent
DCP	Dynamic compression plate
FDA	Food and drug administration
FMDS	Ferromagnetic detector system
FRGS	Fundamental Research Grant Scheme
G	Gauss
HHMD	Hand held metal detector
HUSM	Hospital Universiti Sains Malaysia
K wire	Kirschner wire
LCP	Locking compression plate
MRI	Magnetic resonance imaging
RF	Radiofrequency
T	Tesla
THR	Total hip replacement
TKR	Total knee replacement
WHO	World Health Organization

ABSTRAK

Latar Belakang: Pengesan logam genggam (HHMD) digunakan di persekitaran MRI di kebanyakan hospital tidak sesuai untuk mencegah bahaya MRI. Objektif kajian ini adalah untuk menilai ketepatan diagnostik HHMD dalam mengesan objek dalam vitro dan faktor-faktor yang berkaitan dalam pengesanan implan ortopedik dalam pesakit.

Bahan dan Kaedah: Ini adalah kajian keratan rentas yang dilakukan di Jabatan Radiologi, HUSM dari Oktober 2018 hingga Jun 2019. Pada fasa pertama kajian, 180 pesakit ortopedik berumur 18 tahun ke atas, di bedah di HUSM yang datang ke klinik ortopedik untuk pemeriksaan lanjut, diimbas menggunakan HHMD dan hasil penemuan direkodkan. Pesakit dikategorikan sebagai obes dan tidak obes, menggunakan indeks jisim badan. Maklumat implan (dimensi dan tapak) diperoleh dari nota pembedahan pesakit. Pada fasa kedua, 164 objek in vitro (ferromagnetik dan bukan ferromagnetik) diimbas menggunakan HHMD dan penemuan direkodkan. Ujian Pearson chi-square digunakan untuk menentukan faktor (status kegemukan dan tapak implan) yang berkaitan dengan pengesanan implan ortopedik pada pesakit yang menggunakan HHMD (in vivo). Kepekaan, kekhususan dan ketepatan HHMD dalam pengesanan ferromagnetik dan bukan ferromagnetik (in vitro) dikira menggunakan formula standard.

Hasil: Seratus tujuh puluh lima (97.2%) daripada 180 implan dikesan oleh HHMD. Kadar pengesanan keseluruhan adalah 100% untuk implan arthroplasty dan 100% untuk plat. 94.1% skru dikesan. Hanya 60% wayar K dikesan. 100% titanium dan 95.5%

implan ortopedik keluli tahan karat dikesan. Dua implan dalam setiap julat <50 mm dan 51-100 mm serta satu implan dalam julat 101-150 mm tidak dikesan. Implan ortopedik lain dikesan tanpa mengira saiz. Obesiti dan tapak implan ortopedik tidak menunjukkan perkaitan dengan pengesanan implan ortopedik pada pesakit menggunakan HHMD (P = 1.000 dan P = 0.158). Kepekaan, kekhususan dan ketepatan pengesan logam genggam dalam mengesan objek ferromagnetik masing-masing adalah 96.3%, 73.2% dan 84.8%.

Kesimpulan: Semua prostesis sendi, paku, dan piring dikesan oleh HHMD. Beberapa skru dan wayar K tidak dikesan. Semua implan titanium dikesan dan sejumlah kecil implan keluli tahan karat tidak dikesan. Obesiti dan tapak implan ortopedik bukan faktor penting dalam pengesanan HHMD. HHMD tidak tepat dalam mengesan objek logam dan bukan logam.

Kata kunci: Implan ortopedik, Detektor ogam genggam, Pengimejan resonans magnetik, Kesan projektil, Hukum faraday, Arus eddy.

ABSTRACT

Background: Hand held metal detector (HHMD) is used in the MRI environment of many hospitals, which is not appropriate to prevent MRI hazards. The objective of this study is to assess the diagnostic accuracy of the HHMD in detecting in vitro objects and the associated factors involved in detection of orthopaedic implants within patients.

Materials and Methods: This is a cross-sectional study conducted in Radiology Department, HUSM from October 2018 to June 2019. In the first phase of the study, 180 orthopaedic patients of age 18 years and above, operated in HUSM who came to the orthopaedic clinic for follow-up, were scanned using HHMD, and findings were recorded. Patients were categorised into obese and non obese, using body mass index. Implants details (dimension and site) were obtained from the patient's operative notes. In the second phase, 164 in vitro objects (ferromagnetic and non ferromagnetic) were scanned using HHMD, and findings were recorded. Pearson chi-square test was used to determine the factors (obesity status and site of implant) associated with the detection of orthopaedic implants in patients using HHMD (in vivo). The sensitivity, specificity, and accuracy of the HHMD in the detection of ferromagnetic and non ferromagnetic objects (in vitro) were calculated using standard formulas.

Results: One hundred seventy five (97.2%) of the 180 implants were detected by the HHMD. The overall rate of detection was 100% for arthroplasty implants and 100% for plates. 94.1% of screws were detected. Only 60% of K wires were detected. 100% of titanium and 95.5% of stainless steel orthopaedic implants were detected. Two implants in each range <50 mm and 51-100 mm and one implant in the range 101-150 mm were not detected. Other orthopaedic implants were detected regardless of size. Obesity and site of orthopaedic implants did not show association with detection of orthopaedic implants in patients using HHMD (P = 1.000 and P = 0.158). Overall sensitivity, specificity, and accuracy of HHMD in detecting ferromagnetic objects were found to be 96.3%, 73.2%, and 84.8% respectively.

Conclusion: All joint prostheses, nails, and plates were detected by the HHMD. Few screws and K wires were not detected. All titanium implants were detected and a small number of stainless steel implants were not detected. Obesity and site of orthopaedic implants were not significant factors in HHMD detection. HHMD was not accurate in detecting ferromagnetic and non ferromagnetic objects.

Keywords: *Orthopaedic implants, Hand held metal detector, Magnetic resonance imaging, Projectile effect, Faraday's law, Eddy current*.

CHAPTER 1: BACKGROUND

1.1 Introduction / Problem Statement

Magnetic Resonance Imaging (MRI) is a non invasive imaging modality. It uses a radiofrequency electromagnetic field and magnetic field to produce detailed three dimensional anatomical images of the body. It is routinely used for disease diagnosis and treatment monitoring (National Institute of Health, 2019). Due to superior soft tissue contrast compared to other radiological imaging modalities, functional applications, guiding interventional procedures, and planning radiation therapy, there is tremendous growth in MRI imaging (Sammet, 2016). With the increasing use of MRI, MRI incidents are also increasing such as translational forces, torque forces, and thermal heating (Technical Advisory Bulletin, 2019). Potential risks for orthopaedic implants include loosening of implant, migration of implant, heating of metal with surrounding tissue causing thermal damage and artifactual distortion of MRI image compromising diagnostic value. MRI is a complex imaging modality with many components (including main magnet, radiofrequency coil, and imaging gradient coils) functioning in a co-ordinated manner to produce good quality images.

Based on magnetic susceptibility, generally, materials are categorised into three types including ferromagnetic, diamagnetic, and paramagnetic. These materials behave differently in the external magnetic field based on their different electronic configurations. Due to the interaction of different types of magnetic fields within the MRI environment and different types of materials as mentioned above, various types of

MRI hazards are noted. It includes the translation of objects, movement of implants, heating of implants, and artifacts in MRI images. These interactions can damage the MRI machine leading to monetary loss, injuring the patient, patient's death, and difficult medical management of patient due to difficult or improper diagnosis. Based on magnetic susceptibility objects are labeled as MRI safe, MRI conditional, and MRI unsafe. This categorisation of objects helps to prevent MRI hazards, however, in most hospitals orthopaedic implants do not have these labellings. Also, other objects used in hospitals in daily practice, do not have these labellings. Therefore, most of the patients with hazardous implants and other hazardous objects enter into MRI environment and cause numerous incidents (Delfino et al, 2019). To some extent, these incidents are prevented by routine screening (visually, verbally, and by MRI screening form). Other devices such as Hand held metal detector (HHMD) and Pillar ferromagnetic detector system (FMDS) are also used as additional screening methods.

Problem Statement

Medical implants are made from ferromagnetic, paramagnetic, and diamagnetic materials. If a patient with a medical implant comes for MRI scanning we have these options to know whether the medical implant is MRI safe, MRI conditional, or MRI unsafe: enquiring from the patient, patient’s medical records, and through screening with FMDS. But some patients do not know whether their medical implant is MRI safe or not. In addition, the medical records system in Malaysia is still poor (e.g in HUSM when we searched medical records of orthopaedic patients, most of the time orthopaedic implant stickers were not present, so it was difficult to know the size and material of orthopaedic implants). Even, it is very difficult to trace the patients' operative records if the operations are performed in other hospitals, and most of the time failed to get the information. To avoid hazards, pillar FMDS is used in the MRI setting. It can differentiate between ferromagnetic and non ferromagnetic objects. However, as pillar FMDS is costly, many hospitals use HHMD to screen patients before MRI scanning. A google survey which involved 31 hospitals in Malaysia (Government and private) was performed. With regards to HHMD usage, it was revealed that 2 (6.7%) hospitals were using HHMD as the only screening method in the MRI environment. Six (20%) hospitals were using HHMD with MRI screening form, and 9 (30%) hospitals were using a combination of MRI screening form, HHMD, and FMDS as a screening method in MRI environment. In this survey 5 (16.7%) hospitals mentioned previous MRI hazards. Most of the MRI hazards mentioned were of the projectile type including two incidents of projectile incidents of the oxygen tank.

Most orthopaedic implants are made of non ferromagnetic materials, therefore it is safe to do MRI scanning of patients with these orthopaedic implants. HHMD detects all types of metals. It cannot differentiate between ferromagnetic and non ferromagnetic objects. This situation may disturb the imaging procedure and create a disturbance particularly if the MRI investigation is urgent. Delay in confirmation will result in deferral of the appropriate management for the patient.

1.2 Objectives

1.2.1 General Objective

To assess the diagnostic accuracy of the HHMD in detecting in vitro objects.

1.2.2 Specific Objectives

1. To describe the detection status of orthopaedic implants in patients using HHMD (in vivo).
2. To describe the detection of orthopaedic implants using HHMD according to dimension of the implants (in vivo).
3. To determine the factors (obesity status and site of orthopaedic implant) associated with detection of orthopaedic implants in patients using HHMD (in vivo).
4. To determine the sensitivity, specificity, and accuracy of the HHMD in the detection of ferromagnetic and non ferromagnetic objects (in vitro).

1.3 Research Questions

1. Are there any significant factors (obesity status and site of implant) associated with the detection of orthopaedic implants using a HHMD?
2. What are the sensitivity, specificity, and accuracy of the HHMD in detecting

ferromagnetic and non ferromagnetic objects (in vitro)?

1.4 Hypothesis

1. There are significant factors (obesity status and site of orthopaedic implants) associated with the detection of orthopaedic implants using HHMD.
2. HHMD has low accuracy in detecting ferromagnetic and non ferromagnetic objects (in vitro).

CHAPTER 2: LITERATURE REVIEW

2.1 Literature Review

MRI is a complex imaging modality. It has three main components including the main magnet, radiofrequency coil, and imaging gradient coils. The main magnet produces a large static magnetic field, typically 1.5-3.0 T. Radiofrequency coil generates a radiofrequency electromagnetic field, and imaging gradient coils create spatial encoding magnetic fields (change in the strength of the magnetic field to distance). The spatial encoding gradient is a key parameter determining the force exerted on an object (Panych and Madore, 2017). MRI uses a strong magnetic field that aligns protons in a human body with the magnetic field. When the radiofrequency electromagnetic field is turned on, it stimulates protons and spins out of magnetic field alignment. Next, when the radiofrequency electromagnetic field is turned off, protons realign again with the magnetic field. Energy is released which is detected by radiofrequency coils of MRI and an MRI image is produced. Time taken for protons to realign with magnetic field and amount of energy released depends on the chemical nature of molecules and their environment. Thus different types of tissues on MRI images can be differentiated (National Institute of Health, 2019).

The magnetisation of material depends on the magnetic moments of its constituent atoms. The magnetic moment is produced by the spinning of electrons on its axis and the orbital motion of the electron around its nucleus (Figure 1). In a material, if there is more alignment of magnetic moments of atoms, a higher magnetisation of material will be noted (Sinatra, 2010).

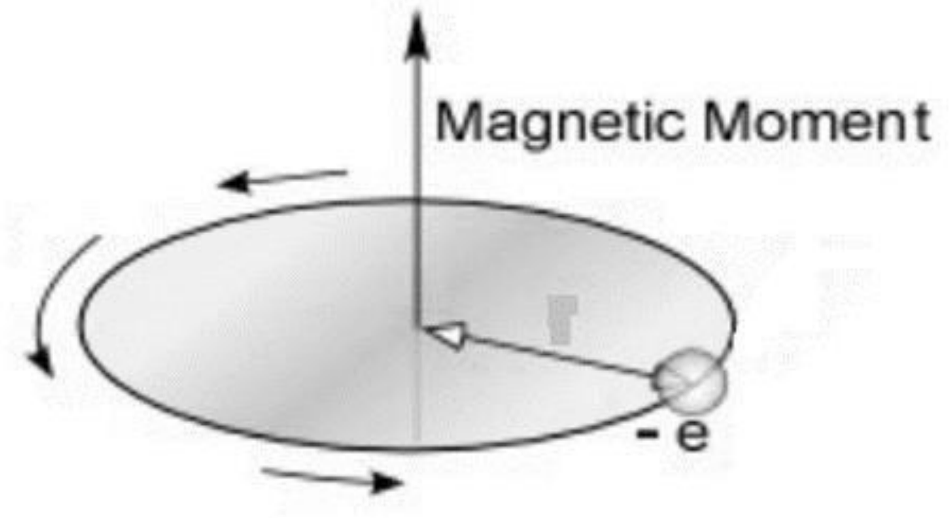

Figure 1: Orbital motion of electron and magnetic moment of atom (Adapted from Sinatra, 2010).

Material can be classified into three categories based on its magnetic properties that are ferromagnetic, diamagnetic, and paramagnetic (Figure 2). Ferromagnetic materials have some unpaired electrons. In absence of a magnetic field, magnetic moments of atoms in these materials are aligned in one direction. They have large and positive magnetic susceptibility. When placed in the external magnetic field, the magnetic moment of atoms in ferromagnetic materials permanently aligns parallel to the external magnetic field, creating the large magnetic field. When placed in the large static magnetic field of MRI, it is attracted towards MRI magnet and it is the only category that causes projectile incidents. Few elements such as iron, nickel, and cobalt exhibit ferromagnetic properties at room temperature. In diamagnetic materials, all electrons are paired. These materials have small and negative magnetic susceptibility. When these materials are exposed to the external magnetic field, magnetic moments of atoms align opposite to the applied magnetic field. These materials are repelled by the magnet, however, due to small magnetic susceptibility; they cannot be seen in daily life. Most of the everyday objects are included in this category such as water, wood, many types of plastics, and almost all biological tissues. Paramagnetic materials have some unpaired electrons. In absence of a magnetic field, magnetic moments of atoms in paramagnetic materials are randomly aligned. These materials have small and positive magnetic susceptibility. These materials when exposed to the external magnetic field, magnetic moments of atoms are temporarily aligned parallel to the external magnetic field. When the external magnetic field is removed, magnetic moments again become randomly aligned and lose magnetism. These materials are not common in everyday life and include chelated gadolinium (used in MRI contrast) and deoxyhemoglobin [used as BOLD (Blood Oxygen Level Dependent) contrast in functional MRI]. Titanium and stainless steel which were present in orthopaedic implants in our study were also paramagnetic materials (Panych and Madore, 2017).

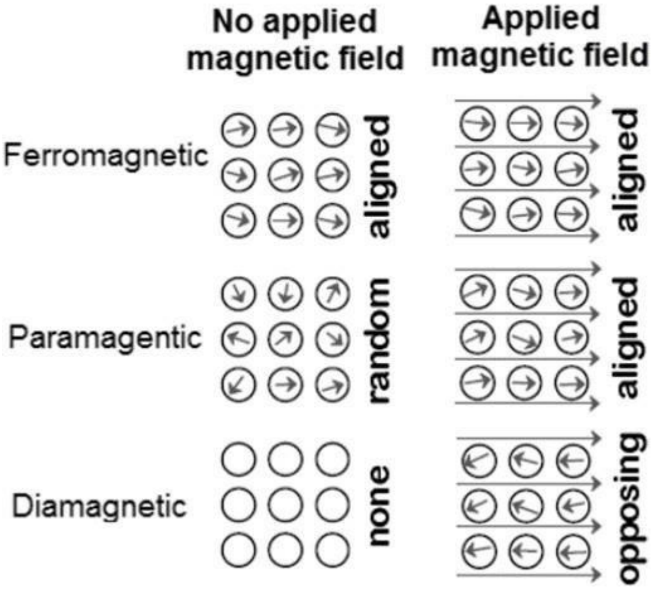

Figure 2: Illustration of alignment of magnetic moment of atoms in ferromagnetic, paramagnetic and diamagnetic materials (adapted from Panych and Madore, 2017)

Many hazards occur in MRI environments, including translational forces, torque, burn injury, and image artifacts. Translational forces depend on spatial gradient magnetic field. Maximal translational forces occur just outside the bore where spatial gradients are greatest. Inside the bore, as a ferromagnetic object reaches isocenter, the field becomes uniform, thus spatial gradient becomes zero and therefore translational forces also become zero there (Panych and Madore, 2017). Torque depends on strength of the static magnetic field, which is maximum within the bore, therefore maximum torque typically occurs inside the MRI bore. Diamagnetic and paramagnetic materials also experience torque and translational forces in the external magnetic field, however, they are too small to be of practical importance (Panych and Madore, 2017). Radiofrequency (RF) electromagnetic field used during MRI scan can lead to heating of medical implants and other conductive objects that enter the bore of the MRI system leading to burn injury to patients (Delfino et al, 2019). Magnetic field and metallic implant interaction can result in image artifacts leading to misinterpretation of MRI images (Krishnakumar et al, 2020).

Usually, three types of objects are encountered in MRI setting daily. They can be MRI safe, MRI conditional, and MRI unsafe. MRI safe objects are non ferromagnetic and do not cause any hazard in all MRI environments. MR safe items are composed of materials that are electrically non conductive, non metallic, and non magnetic. MRI conditional objects do not cause any hazard in a specified MRI environment. Specified MRI environment includes magnetic field strength, spatial gradient magnetic field, radiofrequency field, and specific absorption rate. MRI unsafe objects cause hazards in all MRI environments. It includes ferromagnetic material. Two types of metal detectors are used for screening the patient before entering the MRI suite: HHMD and pillar FMDS. HHMD is a hand held unit that is swept over the patient for screening. When a piece of metallic object comes near this device, it gives the audio and visual signal. It will give the signal for both ferromagnetic and non ferromagnetic objects, thus it cannot differentiate whether metallic object is ferromagnetic or non ferromagnetic. While pillar FMDS are usually fixed near the door of the magnet room. When ferromagnetic object passes through this detector, it gives the audio and visual signal. It gives a signal only when ferromagnetic object passes through it.

To date, few studies have been performed on the detection of orthopaedic implants using the metallic detector.

Evans and Ferris, (1993), scanned 8 subjects with orthopaedic implants using HHMD. HHMD alarmed over larger superficial implants but deep implants were shielded. A substantial tissue screening was noted. 8 holes tibial plate, intramedullary tibial nail, and TKR (Total Knee Replacement) were detected. Screw in tibia and THR (Total Hip Replacement) were not detected.

Asch et al, (1997), scanned in vitro, a variety of commonly placed radiologic and orthopaedic implants using HHMD. Subcutaneous metallic ports, rush rods, Moore’s prosthesis, and pacemaker caused activation of HHMD at an anatomical distance. Inferior vena cava filters, oesophageal stents, biliary stents, embolisation coils, K wire, staple, dynamic hip screw, THR, TKR, buttress plate, and screws were not detected.

Kamineni et al, (2002), scanned 12 patients with orthopaedic implants in vivo using HHMD. HHMD detected almost all implants including shoulder hemiarthroplasty, hip screws, THR, and TKR.

Bluman et al, (2006), scanned 55 foot and ankle orthopaedic implants. Without sheathing 33 orthopaedic implants were detected and with sheathing 31 orthopaedic implants were detected.

Obremskey et al, (2007), scanned 96 regularly scheduled trauma clinic patients with orthopaedic implants with HHMD. The HHMD detected all metal implants including femoral nail, tibial nail, dynamic hip screw, 4 holes plate, 8 holes plate, 16 holes plate, proximal tibial plate 9 holes, and THR. However, isolated acetabular or sacroiliac screws in the patients cannot be detected. Two plates and 4 screws at the symphysis pubis were detected.

Ismail et al, (2013), scanned prosthetic metal implants passing under an HHMD. Implants such as expandable breast prostheses, screws, K wires, auto suture ligation clips, staples, plates used in wrist and hand surgery were included in the study. Expandable implants and wrist plates were only implants detected by passing HHMD directly over them. No implant was detected when it was under cover of axillary soft tissue. Screws, K wires, auto suture clips, and staples were not detected in both conditions.

Kuczmarksi et al, (2018), conducted a review of available literature on HHMD using Pub Med. He concluded HHMD is highly sensitive in detecting orthopaedic implants with exceptions of isolated screws and upper extremity implants including shoulder arthroplasty.

Kunasuntiwarakul and Poopitaya, (2020), scanned two hundred and sixty one volunteers with orthopaedic implants (in vivo) using HHMD. Most of the orthopaedic implants were detected. Total joint prostheses, nails, and plates will routinely detected, whereas screws and wires are rarely detected.

2.2 Rationale of Study

Although there have been several recent publications on HHMD, there was no previous research and documentation on sensitivity, specificity, and accuracy of HHMD in the detection of a ferromagnetic object in patients going for MRI scanning. The objective of this study is to calculate the sensitivity, specificity, and accuracy of HHMD in the detection of a ferromagnetic object with patients going for MRI scanning.

As HHMD does not differentiate between ferromagnetic and non ferromagnetic object, therefore it is not recommended for screening. FMDS has various advantages over HHMD allowing non ferromagnetic metal objects to pass through without alarming. Thus, FMDS may additionally be used for screening apart from traditional MRI screening. Therefore, this study will help in the proper screening of patients with mferromagnetic objects before MRI scanning.

CHAPTER 3: METHODOLOGY

3.1 Study Design

Cross-sectional study

3.2 Study location and Duration

The study was conducted in Radiology Department, HUSM. Data was collected from October 2018 to June 2019.

3.3 Study Population and Sample

1. Reference population: Patients who underwent MRI procedure in HUSM.
2. Source population: Patients who attended orthopaedic clinics in HUSM.
3. Target population: Patients with orthopaedic implant insertion performed in HUSM.
4. Sampling frame: List of the eligible patients who fulfill the inclusion and exclusion criteria of the study.

3.4 Sampling Technique

A simple random sampling method was applied during data collection.

3.5 Inclusion Criteria

Orthopaedic patients

1. Patients 18 years old and above.
2. Orthopaedic implanted patient.
3. Operation performed in HUSM.
4. Patients able to stand with or without aid.

In vitro other objects

1. Common ferromagnetic and non ferromagnetic objects accidentally encountered during MRI safety screening in HUSM.

3.6 Exclusion Criteria

Orthopaedic patients

1. Inadequate information from the post-operative report.
2. Patients with non orthopaedic implants.

3.7 Sample Size Calculation

Objective 1 and 2

Sample size calculation for these objectives is not necessary because they are descriptive.

Objective 3

There is a lack of supportive articles on associated factors (obesity status and site of implant) to provide necessary parameters. Thus, the sample size was unable to be calculated.

Objective 4

Sample size calculation for sensitivity, specificity, and accuracy analysis of HHMD in the detection of ferromagnetic and non ferromagnetic objects was done using Microsoft Excel software (Lin Naing, 2002), extrapolation of the pilot results can be seen in Table 1.

Table 1: Pilot study results, showing the summary of detection status of other ferromagnetic and non ferromagnetic objects.

Detection by HHMD	**Type of other objects**		TOTAL
	Ferromagnetic objects	Non ferromagnetic objects	
Detected	10	3	13
Not detected	0	7	7
TOTAL	10	10	20

Based on the pilot results,

- Expected sensitivity of HHMD vs. ferromagnetic objects = 1.0 (100%)
- Expected specificity of HHMD vs. ferromagnetic objects = 0.7 (70%)
- Prevalence / proportion of ferromagnetic objects = 0.5 (50%).
- Precision = 0.10
- Confidence interval = 95%

  Sample size = 163

The total calculated sample size was n=163. Thus, a total of 82 ferromagnetic objects and 82 non ferromagnetic objects were included. In conclusion, the final sample size for this study is n=163, obtained from Objective 4 which yielded the largest sample size.

3.8 Research Tools

3.8 Research Tool

Handheld Metal Detector (Garrett Super Scanner V, USA): A ligh weight instrument and easy to operate. This detector gives the audio and visual signal when a metallic object comes nearby. It is a battery operated instrument. Its battery needs to be charged after certain duration of use. It has an interference elimination button, to eliminate the signal from the floor containing rebar. For detailed specifications of this tool please refer to Appendix 6.3.

3.9 Operational Definition

Magnetic field interactions: When a ferromagnetic object comes within MRI magnetic field, torque and translational forces will act on the object, resulting in an uncomfortable sensation for the patient, injury, or even fatality. When implants having magnetic components such as cochlear implants, programmable cerebral spinal fluid shunt valves come within MRI magnetic field, their functions will be disrupted (Shellock Hardbound Book, 2014).

Torque: When a ferromagnetic object is brought into the MRI magnetic field, the force will act on the object to rotate and align in direction of the magnetic field. Torque will oppose any attempt to align the object in another direction (Home Studies Educational Seminars, 2015).

Translational Force: It is the attraction of a ferromagnetic object towards the magnet of the MR system. This leads to a projectile effect. When a ferromagnetic object comes within MRI magnetic field, it will become magnetised. Then, the object will encounter torque followed by translational force (Home Studies Educational Seminars, 2015).

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Projectile effect: In this effect, ferromagnetic objects are pulled towards the main static magnetic field (Delfino et al, 2019).

MRI Zones: There are four zones in the MRI suite. Zone I: It includes all areas that are freely accessible to the general public. Zone II: This zone restricts general public access. In this zone, MRI staff screen all patients (includes a medical history and MRI screening form), and patients are gowned. It includes a reception and waiting area. Zone III: This zone includes the MRI control room and technologist station. Only screened MRI patients and MRI personnel have access to this zone. This zone also includes a metal detector and a 1000 G handheld magnet to screen metallic Zone IV: This zone has an MRI system. Screened MRI patients under the direct supervision of trained MRI personnel only have access to this zone (Kanal et al, 2013).

MRI personnel: Based on training level, there are two levels of MRI personnel.

MRI personnel level I: They must have minimal training for their own safety in zones III and IV. Their task includes taking the patient’s medical history and patient screening. MRI personnel level II: They are involved in patient’s safety in zones III and IV (Technical Advisory Bulletin, 2019).

Orthopaedic implant: It is a device used to support bone that has been fractured due to trauma and bone pathology. They are most commonly made of either stainless steel or titanium (Stainless Steel and Titanium in Surgical Implants, 2013).

HHMD: It works on Faraday's Law of electromagnetic induction. HHMD has a transmitter wire coil. As an electric current is passed through the coil, it creates a magnetic field perpendicular to the coil. When a metal object passes through this magnetic field, a small eddy current is created in the metal object, which in a result, creates its own magnetic field. The receiver coil records the magnetic field from the transmitter coil as well as from metal object and this will generate an electrical current in the receiver coil. If the metal object is ferromagnetic, the amplitude of the electrical current in the receiver coil will increase. If metal object is diamagnetic, the amplitude of the electrical current in the receiver coil will decrease. The receiver coil will detect differences in amplitude of electrical current and if the predetermined threshold is surpassed, it will give audio and visual signal (Obremskey et al, 2007).

Eddy current: When a conductive object is placed in a time varying magnetic field, charge flows within the object. This will create an induced current in the object, known as eddy current. The magnitude of eddy current induced in the object depends on the electrical conductivity of the object. A poor conductor will support a small eddy current, while a good conductor will support a large eddy current (National Institute of Justice; 2001).

Hand held magnet: It is used to test external items for MRI safety. It is not safe to test an implant in a patient's body. The approximately magnetic strength of 1000 G of the hand held magnet is used (Medicines and Healthcare Products Regulatory Agency, 2021).

Stainless steel and titanium implants:

Stainless steel implants: In our study are made of 316L stainless steel. It is paramagnetic. It is an alloy of metals. It contains approximately 60% iron, 16% of chromium, and 14% nickel. Carbon and nickel stabilise stainless steel. Chromium makes it resistant to corrosion. Molybdenum is added to protect from the acidic environment

Titanium implants: It is more corrosion resistant as compared to stainless steel thus generating less immune reaction. It has high tensile strength and lighter in weight as compared to stainless steel. It has a low modulus of elasticity as compared to stainless steel, making it less rigid thus limits the amount of stress on bones (Stainless Steel and Titanium in Surgical Implants, 2013).

Site of implant:

Superficial orthopaedic implants: Implants that require less traversing of the muscles and bones during implantation. Examples are any implant within the hand, any implant within the foot, ulnar plate, fibula plate, tibial plates, tibial screws, TKR, around olecranon, humeral plates, humeral epicondyle (condylar insertion, elbow joint replacement), clavicle, distal radius, and K wire.

Deep orthopaedic implants: Implants that require more traversing of the muscle and bone during implantation, which include all implants other than those classified under the superficial implant group.

Dimension of implant: The dimension of the orthopaedic implant is categorised into: Up to 50 mm, 51-100 mm, 101-150 mm, 151-200 mm, 201-250 mm, 251-300 mm, 301-350 mm, 351-400 mm, 401-450 mm, 451-500 mm and >500 mm.

MRI environment: It is the three dimensional volume surrounding the MRI system. It includes Faraday shielded volume and 5 gauss line. In this volume, an object exposes to an electromagnetic field produced by an MRI system and causes a hazard.

5 Gauss line: It is a border to an area surrounding the MRI system in which implanted devices can be affected by the magnetic field (Sammet, 2016).

3.10. Data Collection

For orthopaedic implants, patients' records were obtained from the orthopaedic clinic. Patients who fulfilled the inclusion and exclusion criteria were invited to be included in the research. MRI Checklist Form was used for screening to ensure patients fulfilled inclusion (orthopaedic implanted patients who were 18 years old and above, the operation performed in HUSM and who can stand with or without aid) and exclusion criteria (patients with non orthopaedic implants and inadequate information from post operative reports). Then informed consent was taken. Detailed information on dimension, exact site, and manufacturer of the orthopaedic implants and duration of surgery was documented based on the postoperative report. Data collection was conducted prospectively in the Department of Radiology. All readily removable metallic personal belongings such as jewellry, watches, cell phones, and clothing containing metallic fasteners, hooks, and zippers were removed. All the patients changed to the supplied gown with no metal fasteners as outlined in the ACR on MRI safe practices (Kanal et al, 2013). All personal belongings of the principal investigator were also removed and changed in clothes without metallic fasteners. The principal investigator scanned himself with HHMD to ensure that he is metal free. Patient was then scanned by HHMD. The principal investigator scanned over the surface of the body at close range within 5 cm of body surface (Home Studies Educational Seminars, 2015). Scanning was done three times and documented the presence or absence of signal alarms. Whether an orthopaedic implant is made of stainless steel or titanium was confirmed by our co-investigator from the orthopaedic department as most of the operative notes do not have the implants stickers. Retrospective, radiographs were used for the measurement of dimensions of implants which do not have details in the post operative report.

For other ferromagnetic and non ferromagnetic objects, volunteer changed to a hospital gown and all readily removable personal belongings of subjects were removed as mentioned above. Subject changed to clothes without metallic fasteners and worn white laboratory coat over it (as this contains pockets which were used to place objects). Objects that needed to be tested were placed at usual locations and different pockets of laboratory coat. Scanning was done with HHMD as described earlier. Manual measurements of the size of objects were taken and documented.

In a previous study, they mention that no statistically significant difference in HHMD scanning by experience versus inexperienced investigators. In that study, before the scanning, the principal investigator participated in a limited self-taught session to learn the basic functions of HHMD. In that study, they mentioned that during scanning with HHMD, all patients have positioned away from possible interfering objects such as cabinets, tables, or chairs containing metallic parts (Seikel et al, 1999). Previous studies have shown that short-term training is adequate to accurately perform HHMD examination (James et al, 2018). In our study also, the principal investigator was involved in limited self taught sessions to learn the basic functions of HHMD through referring to the manufacturer manual. Scanning was performed in the center of the room in Zone III, away from metallic objects within the room. According to a previous study, thorough scanning with HHMD can be performed in less than 2 minutes (James et al, 2018). In our study, thorough HHMD scanning took approximately 3-5 minutes. We used a sensitivity setting for HHMD as set by the manufacturer. For persons who cannot stand without support, we used wooden made walking aids without any metallic object within them. These walking aids were made by a local carpenter for this study only. We followed the scanning method described in the user manual (Figure 3).

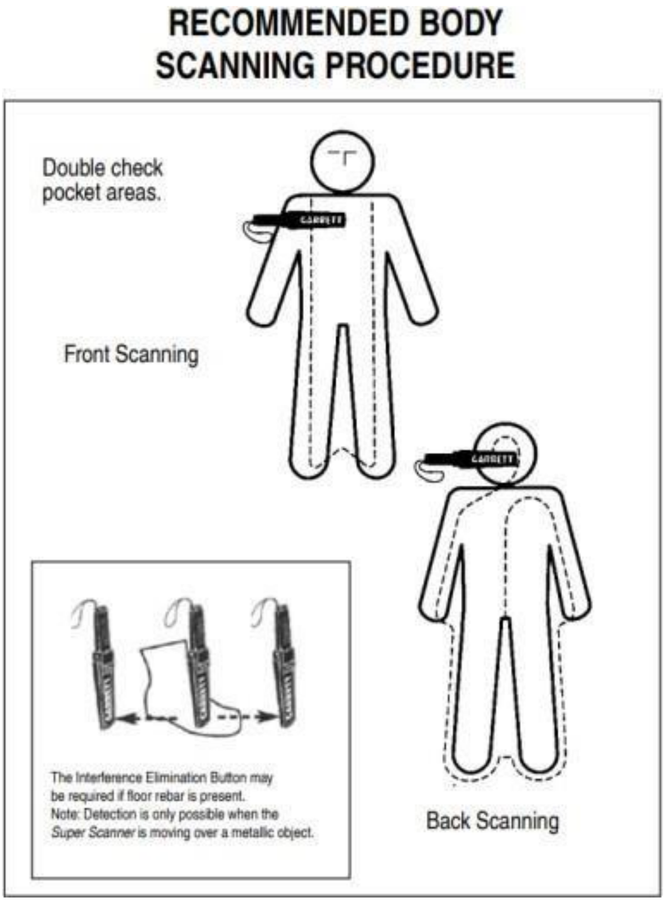

Figure 3: Scanning method through HHMD, provided in user's manual.

As mentioned in the previous study, there should be a strong hand held magnet (1000 G) in Zone III. This will help to detect external ferromagnetic devices or objects (Kanal et al, 2013). In the Radiology department in HUSM, there is also the presence of a hand held magnet in Zone III for testing of external devices, implants, and objects. We used this magnet as a gold standard to test other objects in the second phase of our study.