Hearing protection for paediatric patient undergoing MRI for radiotherapy planning

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Background. For paediatric oncology patients requiring MRI scans, regular earplugs used for hearing protection are typically too large to fit into the ear canal. Alternatives, such as headphones or mini-muffs are not an option in the radiotherapy treatment position with a thermoplastic shell covering patient's head as they could affect the shape of the shell. In this work we tested alternative hearing protection methods that can be used together with a thermoplastic shell.

Methods. All acoustic noise measurements were performed in a 1.5T scanner (Philips Ambition) using an OptiSLM 100 sound meter with an Optimic 1150 microphone positioned in the stem of a silicone funnel to mimic the ear canal and enable fitting hearing protection at the opposite opening (see figure 1). Three different hearing protection types were tested: silicone ear plugs (Boots Soft Silicone), otological putty (Oto-soft) and standard foam ear plugs (Acro Essentials). Sound Pressure Levels (SPL) were recorded during scanning of the same sequence and a Single Number Rating (SNR) was calculated as a difference between the mean Sound Pressure Level (A-weighted) without and with protection. Acoustic noise at ear was calculated using HSE noise calculator [1], manufacturer-quoted SNR values where available and highest SPL value (C-weighted) recorded at the scanner centre without the funnel.

Results. Table 1 shows the SPL measured with and without hearing protection along with the calculated SNR and manufacturer-quoted SNR. Foam ear plugs showed the most attenuation. Silicone earplugs and putty had similar performance with SNR of 24 and 25 respectively. The highest recorded SPL value without the funnel was 106dB(C).

Figure 1. Microphone in the funnel set up

Setting	Average SPL (dBA)	Mean calculated SNR (dB)	Quoted SNR (dB)	At ear* (dB)
No protection	113	-	-	-
Foam ear plug	77	36	37	73
Silicone ear plug	89	24	23	87
Putty	88	25	N/A	85

Table 1. Measured SPL, calculated SNR and noise reduction at ear drum

Discussion. The recorded acoustic noise levels of the scanner exceed 80dB, therefore hearing protection must be worn in order to reduce the SPL at the ear drum to 85dB(A) [2]. The different types of hearing protection tested closely matched SNR values quoted by the manufacturers for the standard and silicone ear plug using funnel set-up. Although the acoustic noise of a silicone earplug results in 87dB at the ear drum which is 2dB above the recommended level [3], it is preferred over putty given their CE marking and does not require a specialist fitting training. The risk to the patient fitted with silicone plug is minimal given short scanning times [3] and can be further reduced by appropriate manipulation of sequence parameters.

Conclusion. The silicone ear plugs and are a viable alternative if a standard ear plug cannot be used. Although the 85dB(A) was not achieved, the occupational limits would have been exceeded after four hours of exposure at this level. Furthermore, sequence parameters could be adjusted to reduce acoustic noise generated by the scanner to achieve 85dB at the ear drum.

Key references.

[1] Hearing Calculator https://www.hse.gov.uk/noise/hearingcalc.xls
[2] Kurdila et al, Journal of Magnetic Resonance Imaging DOI: 10.1002/jmri.27656
[3] MHRA. Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use; 2021

General Implant Safety Polices (GISPs) for patients undergoing MRI in Scotland: how it started / how it's going

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Background. GISPs permit MR scanning to take place for a patient with a particular category of implant, without the need to explicitly determine the make and model of the implant. There are several benefits:

- Maintain patient safety to an acceptable level of risk
- Facilitate scanning when implant information is not readily available
- Avoids delay in scanning when implant information takes some time to obtain
- Avoids unnecessary cancellations
- Reduces resources required to obtain and evaluate specific implant information

We present how our governance process has evolved, and the learning gained in going from single health boards to being rolled out to almost all health boards with MRI in Scotland.

Methods. How it started. In GGC GISPs started out as locally derived policies which were the considered opinion of our MRI physics team, some literature was reviewed, but this was focused on where incidents had occurred or was based on empirical evidence and local experience. The policy was linked to a risk assessment and this was the basis for the policy statement. Other boards (Highland/Tayside/Lothian) had written more in-depth analysis of an implant category. While there was some variation in style across boards the content and approach were similar. The challenge was to create a consistent approach across all health boards which capitalised on the best bits of current practices. In order to operate at scale, it was essential a clear governance framework was established. We also sought to work with other professional groups to obtain their input and buy-in. Our initial and current governance frameworks are shown on the left and right hand side of figure 1 respectively. Key pieces of work include the detailed review, risk assessment and policy statement. Policy checking and who performs these functions is also detailed in the later governance framework.

Results. **How it's going?** We now have a more mature governance framework for developing GISPs. This has been used to adopt several GISP policies, see abstracts on cardiac occlusion devices (JMc), embolisation coils (BJ), scleral buckles (SAS) and shunts (RS). Others are in progress. The governance framework continues to evolve. In GGC we share our polices through our departmental website[1]. Not all of our local policies have been subject to the revised governance policy but that is our aim.

Discussion. What we learned? Not everyone's attitude toward risk is the same, not everyone will want to buy into the idea of using the GISPs. Having a governance framework will help when engaging with other groups, especially those who you are less familiar with, e.g., SLA partners. Radiologists and radiographers at SLA sites needed to know they personally were not accepting full responsibility for policy adoption i.e., formal adoption still had to be done at local board level by an appropriate governance committee. Engaging with radiographers and regional MR radiography groups was very helpful for input and buy-in and later for deployment and educational aspects too. Responding to new information quickly and having effective means to communicate policy changes quickly is a challenge but if done so well, will help build confidence in the process. Having clinical subject matter experts can be a big advantage for some GISPs – consider the limitations of your knowledge. We were lucky to have access to some GISP polices and procedure documents from elsewhere, this was helpful both to compare content and approaches. Further improvements may involve closer engagement with radiologists in the process and radiology groups more generally. Evolution of the MHRA guidance to acknowledge this practice would help some feel comfortable this is a valid approach.

Conclusion. We have a robust governance framework and several policies that have been subject to our full GISP process. These polices are shared on our departmental website. We welcome feedback (ggc.mrsafetyexpert@nhs.scot).

Key references. 1. NHS GG&C MR Physics website, https://www.mriphysics.scot.nhs.uk/implant-safety-policies/

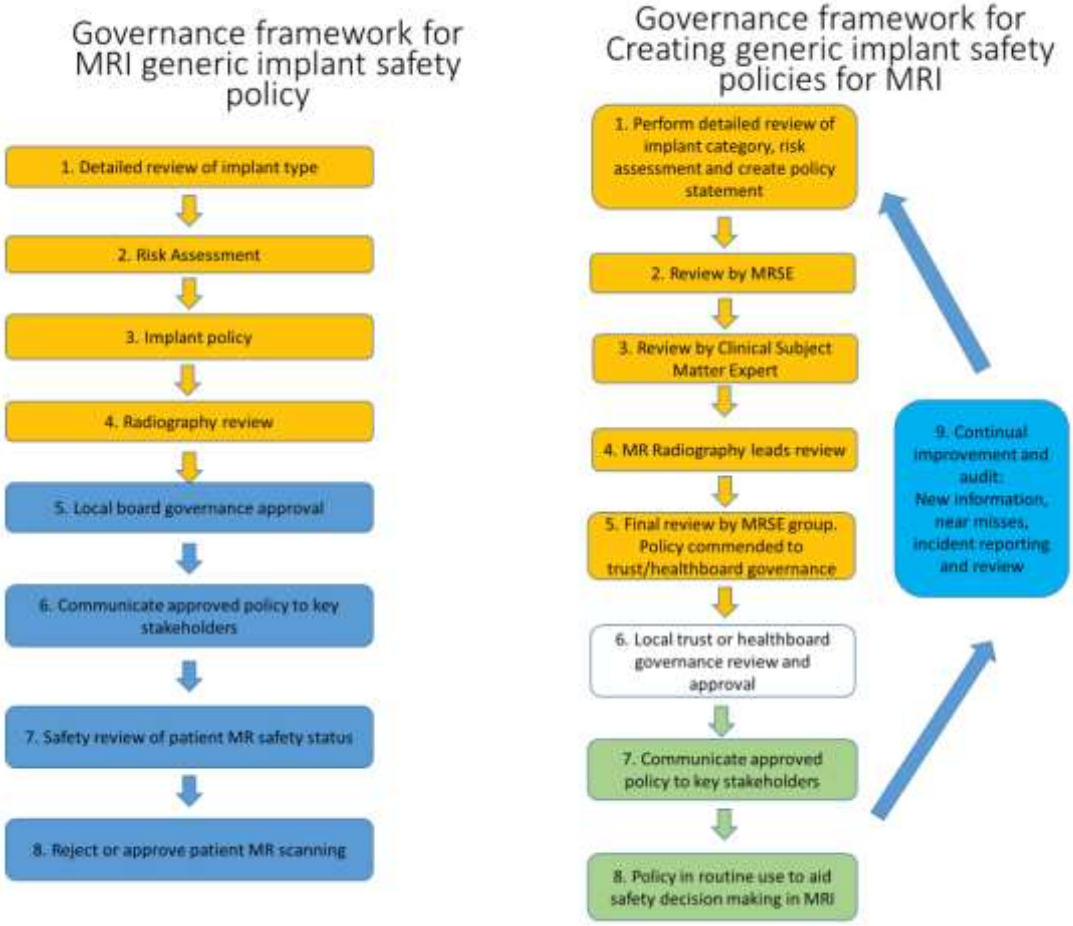

Figure 1: Early and later version of MPCE: MRI GISP governance framework

Sceral Buckling: Proposed Generic Implant Safety Policy for Scotland.

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Background:

In a Generic Implant Safety Policy (GISP), a general statement of MRI safety is made for a specific category of implants. We present a proposal for a GISP for scleral buckling based on a review of the evidence available in published literature, professional groups, mailbases and local knowledge.

Scleral buckling is a procedure used to repair retinal detachment, usually using a silicone band. Occasionally a metal clip or tack (usually tantalum, which is not ferromagnetic) might be used to secure the band. Reference [5] shows CT and MRI images of scleral buckles.

If a ferromagnetic component is used there is a risk it will deflect in the magnetic field and damage the eye. Any metallic components are very small and risks from RF heating are negligible at 3T and below. The hypothesis is that ferromagnetic components are not used and therefore scanning a patient who has had a scleral buckling procedure is low risk.

Methods:

An MRI physicist gathered evidence from MRI safety implant databases, a search of published literature on PubMed.gov, search of mailing list messages and online MRI safety groups, and contacted an ophthalmologist for further information.

A review and risk assessment were produced. These were reviewed and approved by an MRSE from a different health board. It will be circulated to all MRSEs in Scotland for final review and, if approved, will be commended to local board governance committees for formal adoption.

Results and Discussion.

Several publications state that scleral buckles are safe for MRI and a recent consensus paper states that screening for scleral buckles is not necessary [3]. All clinical examples of scleral buckling found in the literature use either tantalum clips or no metal.

There is one published example of an MR-unsafe stainless steel retinal tack [1]. We found no evidence that this tack was used as part of a scleral buckling procedure. Scleral buckling must not be confused with other types of retinal repair that may use retinal tacks. We recommend screening for retinal tacks and seeking information on make and model.

There is one proposed experimental device using magnets in scleral buckling (from 2017, experimental studies on cadavers, in Russia [4]), but this has not been trialled clinically. The risk assessment for scleral buckling should be reviewed yearly to assess whether MR unsafe devices are being developed.

Conclusion. We conclude that scanning a patient who has had a scleral buckle procedure is low risk. The risk assessment for scleral buckling should be reviewed yearly.

Key references.

1. Albert, D.W.et al (1990) ‘Magnetic Resonance Imaging and Retinal Tacks’, Archives of Ophthalmology, 108(3), pp. 320–1. doi: 10.1001/archopht.1990.01070050018007 VO 108.
2. Bakshandeh H, Shellock FG, Schatz CJ, Morisoli SM. (1993), ‘Metallic clips used for scleral buckling: ex vivo evaluation of ferromagnetism at 1.5 T’, J Magn Reson Imaging. 3(3):559.
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5. Reiter, M. J. et al. (2015) ‘Postoperative Imaging of the Orbital Contents’, RadioGraphics, 35(1), pp. 221–234. doi: 10.1148/rg.351140008.

General Implant Safety Policy (GISP) for patients with cardiac closure devices in Scotland

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Background. The MRI group of the Scottish Medical Physics and Clinical Engineering (MPCE: MRI) network have been working on shared MRI Generic Implant Safety Policies (GISPs). One such policy aimed to facilitate MR scanning of patients with a range of cardiac closure or occlusion devices used to treat Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Foramen Ovale (PFO). Commonly referred to as a hole in the heart.

Methods.

In keeping with the GISP governance framework, a detailed review, risk assessment and policy statement were produced. A range of sources were consulted to perform the detailed review. These included Dr Shellock's MRIsafety.com[1] website and SMRT google group, MRI safety facebook group and corporate websites and product IFU documents. The results of the review were then presented to a senior MR radiographer representative and to a radiologist for their view and then for a final time to a group of MRSEs before the policy documents were concluded before being adopted by local health boards and distributed.

Results.

There was no evidence to suggest any cardiac occlusion or closure device was MR Unsafe. Where these devices have been tested, they typically classed as MR Conditional. No reported adverse events or near issues could be found. Similarly, no adverse events as a result MR of a patient having had clips to perform a septal repair were noted.

On that basis it was concluded that implementing a generic policy for MR scanning at 1.5T and 3T of patients with these devices would be a low risk and as such this GISP should be enacted for use across our health boards

Discussion.

The MR safety status of a large range of cardiac closure devices has been reviewed. Where it was possible to obtain them, the MR Conditions were reviewed. Beyond that, opinion in the MR community as to the safety of this class of devices was reviewed. Perhaps the trickiest part of this GISP to quantify was the MR safety status of the clips used for septal repair. However, on the basis of how such clips are treated more generally for patients undergoing MRI and the lack of any empirical evidence to the contrary, it seems exceptional unlikely these would be anything other than a very low risk as a result of MRI.

Conclusion.

A GISP for cardiac closure devices was performed and brought into use across almost all health boards across NHS Scotland by the MPCE:MRI group. The policy is available on the NHS GGC website https://www.mriphysics.scot.nhs.uk/implant-safety-policies/ [2] for wider consideration. This policy will be reviewed annually. Our group also monitors forums on MR safety so any new events or information to contradict this policy are likely to be picked up more quickly than the annual review. We welcome any feedback (ggc.mrsafetyexpert@nhs.scot).

Key references.

1. www.mrisafety.com, Dr F Shellock

2. NHS GG&C MR Physics website, https://www.mriphysics.scot.nhs.uk/implant-safety-policies/

Findings from an embolisation coil detailed review

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Background. The MRI branch of the Scottish Medical Physics and Clinical Engineering (MPCE) network have been working on shared MRI Generic Implant Safety Policies (GISPs). The process to create a GISP begins with a detailed review of the implant, followed by a risk assessment and, where possible, a policy statement. These documents are reviewed by a nominated MRSE and MR Lead Radiographer and then by all the Lead MRSEs from each major health board in Scotland before they can be approved. The aim of this study was to create a GISP for embolisation coils and other embolic devices used in aneurysms or vessels to reduce blood flow and promote clotting. A range of metals have been used in embolisation coils including nitinol, platinum, stainless steel, inconel, tungsten and iridium. Liquid embolic agents typically contain a metallic powder such as gold or tantalum. Woven EndoBridge (WEB) devices are made from nitinol and platinum.

Methods. The detailed review included examination of MRI implant safety databases, 116 different models of embolisation coils, WEB aneurysm embolisation devices, liquid embolic devices and radioembolisation microspheres and 83 articles in peer-reviewed literature. Other sources of evidence were reviewed such as the SMRT MR Technologist mailbase, UK MRI Physics mailbase, a general internet search and MRI safety Facebook groups. GISPs shared from other centres and local information and anecdotal data were also included. Further discussion with manufacturers and prominent figures in MRI safety were included in the review process.

Results. Our review established that most embolisation coils are MR Conditional for 3T or less. The main risk identified for cerebral aneurysm coils was the potential for confusion with aneurysm clips.

However, a significant gap in the MRI safety testing of non-cerebral embolisation coils was identified as they have only been tested in individual or bundles of spherically shaped coils. If a large length of coil (greater than 10 cm) were to be left uncoiled within the vasculature, then there is a potential for heating. This is not uncommon for varicocele or ovarian coiling (Figure 1). All embolisation coils where the manufacturer's MR Conditions could be identified stated no conditions relating to the placement or application of the coil.

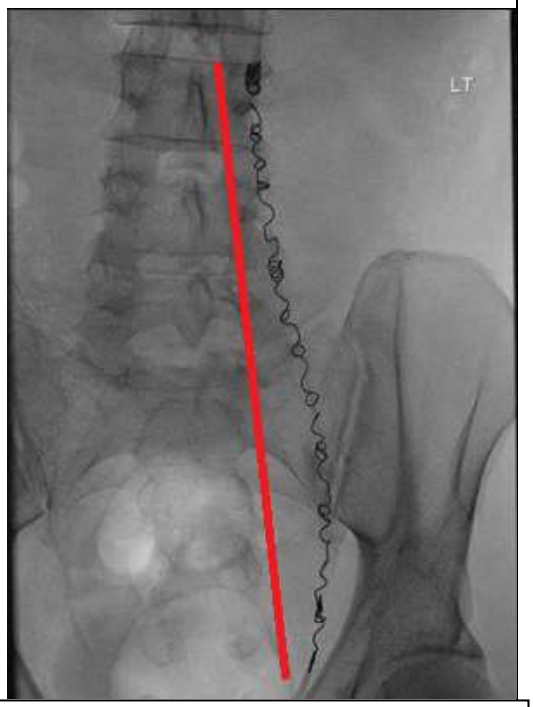

Figure 1: Illustration of the end-to-end (red line) length of an embolisation coil.

Discussion. Whilst a significant gap in the MRI safety testing of elongated embolisation coils was identified, a GISP was approved for use throughout NHS Scotland[1]. Further studies are underway to determine whether this theoretical risk results in a significant heating risk in practice.

Conclusion. The detailed review process for GISPs in NHS Scotland has identified in a gap in the literature, improving our understanding of MR safety. Whether this theoretical risk results in demonstrated heating will be tested as a result of this detailed review.

Key references.

1. NHS GG&C MR Physics website, https://www.mriphysics.scot.nhs.uk/implant-safety-policies/embolisation-coils-and-other-embolic-devices/

Outcomes of an in-depth review of non-programmable CSF shunt valves

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Background. There has been an NHS Scotland wide effort within the MRI Physics community to develop generic implant safety policies (GISPs). This process involves an in-depth review of specific implant categories, followed by the completion of a risk assessment which may be used to inform an MRI safety policy statement. This work aimed to develop a GISP for non-programmable cerebrospinal fluid (CSF) shunt valves used to treat patients with hydrocephalus. A CSF shunt system comprises of a proximal and distal catheter connected by a valve (non-programmable or programmable) which diverts excess CSF in the brain to some absorption site [1]. It may also include internal accessories. Whilst most non-programmable valves are devoid of metal, older designs have caused uncertainty regarding their MRI safety status.

Methods. MRI safety resources reviewed include mrisafety.com, MRI safety statements from shunt manufacturers, and peer reviewed literature. Anecdotal and empirical data was collated from further resources such as the SMRT Technologist mailbase, UK MRI physics mailbase, the MRI safety Facebook page and a general internet search. Discussions with manufacturers and leading MRI safety authors have been considered in the process as well as work shared by other UK centres.

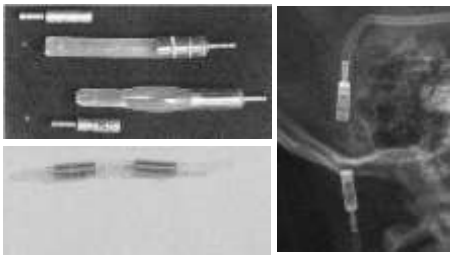

Figure 1. Top Left: (a) Old and (b) new Holter valves [4]. Bottom Left: Hakim valve [2]. Right: X-ray of a Holter type valve [5].

Results. Our review has established that the majority of known non-programmable CSF shunt valves are MRI Safe or MRI Conditional up to 3T. MRISAFETY.com highlighted two shunt valves (see Fig.1) and an internal accessory (see Fig. 2) with MR Unsafe labelling: a Holter type valve (type unknown), Hakim valve, and an unnamed right angle stainless steel ventricular shunt tube connector. Limited evidence in the literature accounts for this MRI Unsafe labelling with "slight ferromagnetism" seen at 1.5T for the shunt valves [2], and "measurable ferromagnetism" seen at 1.44T for the connector [3]. The literature has further highlighted a potentially unsafe ventricular shunt catheter with metal connector (see Fig. 2) which exhibited "evident ferromagnetism" at 1.5T [2]. Empirical evidence highlights variations of the Holter valve have been scanned safely both locally (NHS GG&C) and internationally (University of Leipzig, Germany) at 1.5T [5]. No patient incident/injury related to the MRI scanning of a non-programmable CSF shunt system has been reported.

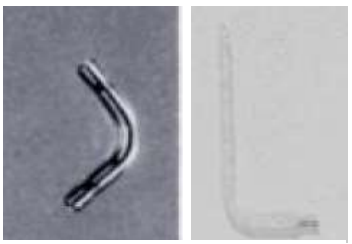

Figure 2. Left: Unnamed right angle stainless steel ventricular shunt tube connector [3]. Right: Ventricular shunt catheter with metal connector [4].

Discussion. The most restrictive MRI Conditional labelling limits the magnetic field strength to ≤3T, the spatial gradient to ≤720G/cm, and the SAR to ≤3W/kg. The GISP contains the same conditions but without the spatial gradient limit which is typically a limit of the testing equipment. A risk assessment was undertaken on the older MR Unsafe shunt valves and accessories. It was decided to include these in the GISP given the poor evidence of the hazard level and the lack of reported incidents.

Conclusion. The detailed review process highlighted a low risk for scanning non-programmable CSF shunt valves allowing them to be scanned under a generic policy. Care must be taken, however, to confirm a patient's shunt valve is indeed non-programmable and not programmable. We will present a decision tree which has been developed for this purpose.

Key references. [1]. Garrett J Soler et al. YJBM. 91:313-321, 2018. [2]. Go et al. Clin Neurol Neurosurg 91(2):109-115, 1989. [3]. New et al. Radiology 147:139-148, 1983. [4]. Hassler et al. J Neurosurg 57:633-636, 1982. [5]. University of Leipzig, http://www.kinderneurochirurgie-leipzig.de/.

Development of a MRI Generic Implant Safety Policy (GISP) for Patient Implants - Heart Valves and Annuloplasty Rings

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Background.

Ensuring the safety of patients undergoing MRI is of paramount importance. An appreciable portion of the population has medical implants or devices. Identifying every patient implant can be difficult for a number of reasons and the purpose of a Generic Implant Safety Policy (GISP) is to review specific categories of implants such that general statements of safety can be made. This will have the benefits such as facilitating scanning when precise implant information is not readily available, avoiding unnecessary cancellations, and reducing the resources required to obtain and evaluate specific implant information. A GISP was developed for heart valve and annuloplasty rings.

Methods.

A detailed MR safety review of heart valves and annuloplasty rings was performed. This involved the following four key steps, in the following order: (i) thorough review of available MR safety databases and manufacturer information for n=231 heart valves and annuloplasty rings to compare their MRI safety status; (ii) an in-depth look at the MR safety restrictions (field strength, spatial gradient and SAR limits) for all implants within this category; (iii) literature review of key publications related to the MR safety status of any identified implants of concern, as well as publications discussing incidents or injuries as a result of these implants; and, (iv) a review of MRI safety discussion mail bases and existing local NHS Scotland policies already implemented for these implants. This information was collated with the objective of deriving a generic recommendation for MR scanning conditions that all patients with implants in this category could be safely scanned under. In addition to the detailed review, a risk assessment and implant policy was produced. These documents were reviewed by the Scottish MRI physics leads and the MRI Radiography Leads for comment before being signed off as ready to be implemented at all Scottish centres.

Results.

The evidence collected within the above review concluded that patients with heart valves or annuloplasty rings can safely be scanned immediately after implantation, provided the following conditions are adhered to:

- Field strength of 1.5 or 3 Tesla.
- Whole body averaged specific absorption rate (SAR) of 2 W/kg (operating in the Normal Operating Mode for the MR System).
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient allowed).

Discussion.

The adoption of this policy will significantly reduce the work load of those who are requested to assess medical implants prior to an MRI scan. At NHS Tayside in 2016, a total of 136 heart valves and annuloplasty rings were earmarked for MR safety assessment prior to the patient being scanned. Therefore, the adoption of this GISP will allow a significant number of patients to be booked faster as they won't have to wait for a full safety assessment and it will also avoid patients being sent home and re-booked if they have an undeclared implant.

Conclusion.

The process of developing this GISP has demonstrated that heart valves and annuloplasty rings are low safety risk with regards to MRI scanning. The adoption of this GISP will decrease the MR safety assessment workload as well as improving patient throughput and reducing waiting times for patients with these implants.

Key references. Annuloplasty Ring, Heart Valves, MRI Safety

RF simulations of cranial fixation plates in 7 tesla MRI.

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Background.

MRI safety information is under-represented at ultra high field strength, for example, testing of passive medical implants. Kraff et al [1] assessed heating of cranial fixation plates at 7T; they noted that using (12.5x12.5) cranial fixation plates yielded no significant heating post craniotomy using their coil model. However, for other coils, a 10% reduction in power was recommended to account for variation in Specific Absorption Rate (SAR) until the simulations specify otherwise.

In this project, simulations were used to establish how the presence of cranial fixation plates affects SAR distribution in the head for 7T scanning using a computer model of an 8-channel transmit head coil which was designed and built at the University of Glasgow [2].

Methods.

The software CST Studio Suite [Dassault Systems, France] was used to estimate the SAR in the Duke voxel model. Figure 1 shows cranial fixation plates placed into the skull of Duke. We investigated how E-field and SAR vary dependent on location of these plates including spacing of the plates from one another.

Results and Discussion.

In CP mode using an input power of 8W, the local SAR around the cranial fixation plates shown in figure 1 was 0.7W/kg, approximating to a temperature rise of 0.25 degC over 15 minutes. The maximum local SAR of 2.3W/kg was in the parietal lobe and was not caused by the cranial fixation plates.

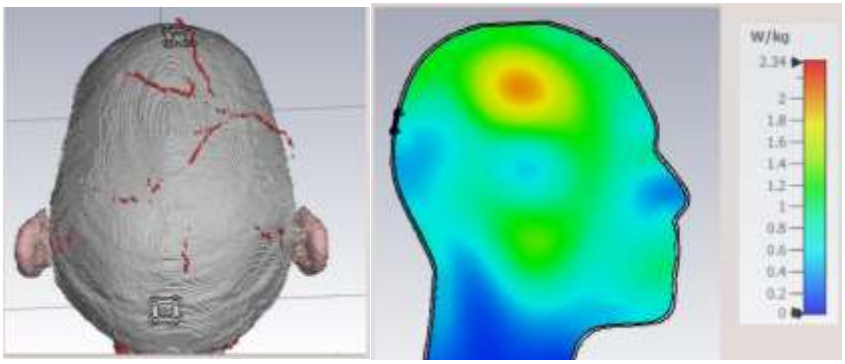

Figure 1 (a) Cranial plates placed on skull of Duke model, (b) SAR distribution for 8W input power.

Conclusion.

In simulations of the 8-channel transmit head coil in CP mode, cranial fixation plates did not cause a significant temperature increase, indicating that it may not be necessary to impose additional SAR restrictions for CP mode scanning of cranial fixation plates in this head coil.

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2. Williams SN, Allwood-Spiers S, McElhinney P, Paterson G, Herrler J, Liebig P, et al. A Nested Eight-Channel Transmit Array With Open-Face Concept for Human Brain Imaging at 7 Tesla. Frontiers in physics. 2021;9. doi: 10.3389/fphy.2021.701330

Assessment of a Ferromagnetic Detection System (FMDS) for Identifying Patient Implants and Implementation into a Clinical MRI Setting

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Background. Ferromagnetic objects carried on or in patients into the MRI Environment account for many adverse events reported [1]. Comprehensive pre-screening procedures, integral to patient safety, can fail when honest, accurate, and complete information is not given. This has been acknowledged by regulatory and professional bodies who recommend ferromagnetic detection systems (FMDSs) as a useful adjunct for identifying removable ferromagnetic objects [2]. Furthermore, studies suggest a FMDS has the capability to detect ferromagnetic objects in-vivo given human tissue is a transparent carrier [3]. This project aims to assess a specific FMDS (*FerrAlert Essence*, Kopp Development) in the NHS Highland MRI department with regards to its detection efficiency for a range of patient implants. Of interest locally was the detectability of cardiac implantable electronic devices (CIEDs) and programmable cerebrospinal fluid (CSF) shunt valves.

Methods. Investigated in this work is a pillar-type FMDS comprising of anisotropic magnetoresisitive (AMR) sensors, a range of sensitivity settings and 5 detection zones allowing for the presence and location of a moving ferromagnetic object to be identified. 13 volunteers were recruited and patient implants (CIEDs [n=4], magnetically active orthopaedic implants [n=3], programmable CSF shunt valves [n=4], endoscopic clip [n=1], endovascular stent graft [n=1]) attached in clinically feasible locations. 20 male Cardiac Physiology outpatients were recruited to determine whether the FMDS could reliably identify CIEDs in-vivo. Both volunteer and patient subjects were asked to perform and repeat 2 motions in front of the FMDS:

A. 360 rotation
B. Hip twist.

For volunteers only: motion (a) and (b) were performed at a slow and fast speed to simulate patients with limited and increased mobility respectively, and a third motion using a non-ferrous wheelchair (WC) performed to account for non-ambulatory patients. The probability of detection for each motion was determined. The FMDS was set to its default sensitivity for testing on both subject groups. The maximum sensitivity setting was tested on volunteers only.

Results.

Volunteer Subjects: On average, the highest probability of detection across all ferromagnetic implants was 77% for motion B (fast) at the maximum sensitivity setting. For CIEDs specifically, this detectability was 59% for volunteers. For motions A and B, the maximum sensitivity setting resulted in 100% detection of 3 CSF shunt valves. The fourth shunt was not detectable. In all three cases (all implants, CIEDs only, CSF shunts only), the maximum sensitivity setting significantly ($p<0.005$) increased the detection rate for the WC motion.

Patient Subjects: A fast twist motion improved detectability of CIEDs (87%) compared to that for volunteer subjects.

Conclusion. The maximum sensitivity setting should be used to enhance the detectability of ferromagnetic implants in-vivo. This is particularly important for patients in a wheelchair where the distance between the sensors and the implant is increased. Whilst a 360 rotation is recommended by the manufacturer, a hip twist motion may facilitate increased detectability of ferromagnetic implants located in the trunk and head of the body. The results suggest a high probability in detecting patients with CIEDs and shunts. However, the FMDS should supplement existing screening methods given a 100% detectability was not obtained for all CIED and shunt devices.

Key references. [1] Landrigan et.al. The New England Journal of Medicine, 345(13):1000-1001, 2001. [2] Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, Medicines and Healthcare Products Regulatory Agency. 2021. [3] Shellock, et.al. American Journal of Radiology, 201:720-725, 2013.

Standardised approach to MR Controlled Access Area maps

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Background

The MHRA Safety Guidelines for MRI Equipment in Clinical Use [1] defines a number of regions around an MRI scanner:

- MR Environment - the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.5 mT field contour.
- MR Controlled Access Area – a locally defined area of such a size to contain the MR Environment.

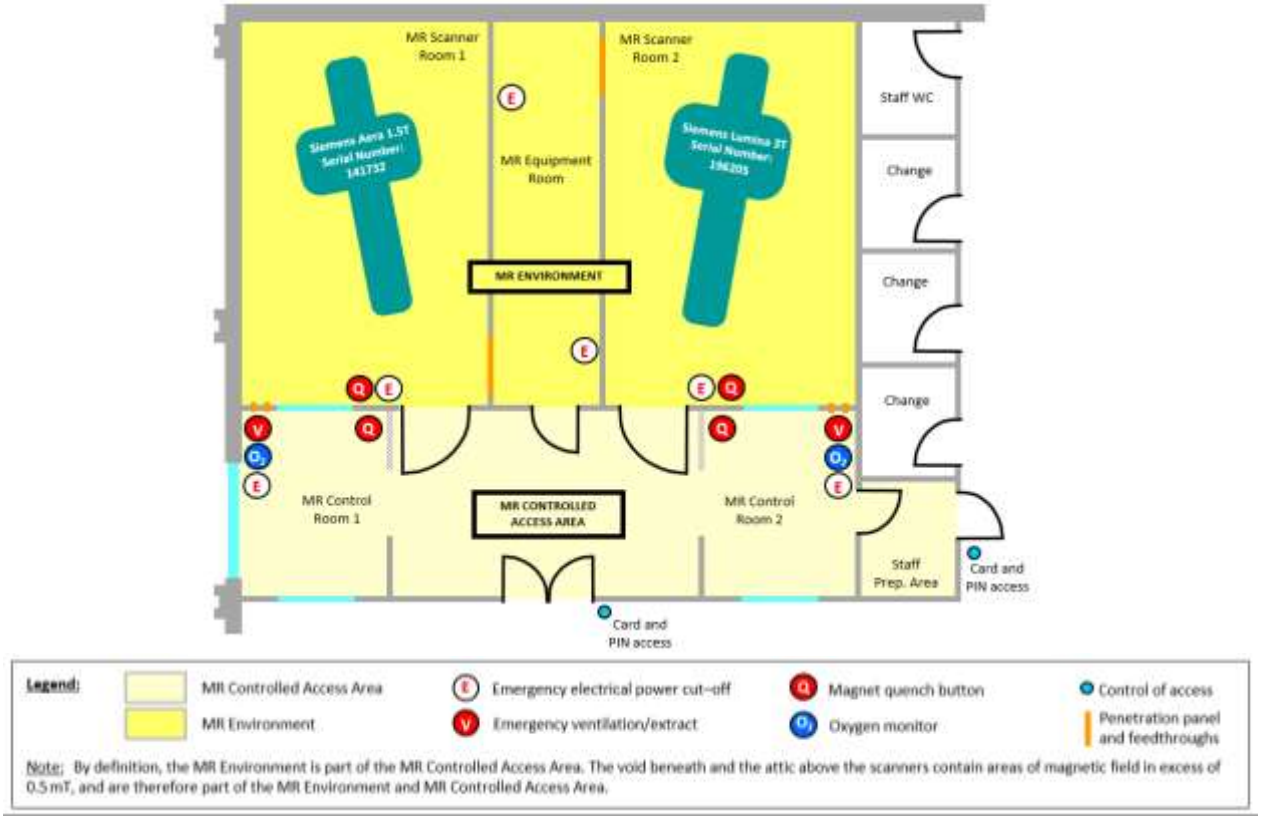
The MHRA guidelines also state that "*it is absolutely vital to control access of personnel and equipment to the MR Controlled Access Area*".

Methods

In the last 15 years, the Northern Ireland Regional Medical Physics Service has assisted with MR safety and suite design of more than 60 MRI scanners. To aid MRI safety management, during commissioning maps of the above key areas are created for display and are a key component of the Local Rules. A standardised approach and colour coding has been developed.

Results.

An example of a standardised MR Controlled Access Area map is shown below.



Discussion/Conclusion

A clear, standardised approach to maps of the key regions around an MRI scanner has been developed. Key emergency features are represented, as well as access control points. It has the added advantage that staff working across different sites are familiar with the style of the maps. It would be beneficial if national guidance existed to guide MRI staff on the production of these maps.

Key references

[1] MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use v4.3 – Feb 2021
https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use

Radiofrequency-Induced Heating of MR Compatible Intraoperative Monitoring Electrodes

Background Intraoperative monitoring (IOM) is a valuable tool for assessing the integrity of neurological pathways of a patient during surgery. Nerve pathways can be monitored with subdermal needles attached to long twisted pairs of copper cables. For patients undergoing intraoperative MRI, it would be advantageous to leave IOM electrodes *in situ* during imaging. However, electrodes are prone to RF-induced heating during MRI [1], [2]. To date, only a small number of studies have investigated the MR safety of IOM electrodes [3], [4], and despite these suggesting an overall low risk, occasional incidences of skin burns were reported in both studies. Furthermore, only one manufacturer currently supplies 'MRI Compatible' IOM electrodes (*SpesMedica*, Italy), and the RF heating of these in the MR environment has not yet been reported. The aim of this study was to characterize the potential for RF heating of these IOM electrodes, to help determine if they can safely remain *in situ* during intraoperative MRI.

Methods A gel phantom was prepared according to the specifications set out in ASTM F2182-11a [5]. This compromised a plastic container filled with gelled saline solution. A pair of *SpesMedica* MRI Compatible IOM electrodes (Model MN4013D15A/SMRI) were embedded approx. 1cm below the gel surface, with a a fibre optic temperature sensor at the tip of the electrodes. An additional temperature sensor was placed in the gel, remote from the electrodes. The electrode cables (1.5 m twisted pair of copper wires) were placed outside of the phantom, and arranged in multiple configurations (Fig 1). Testing was performed over three sessions, using two 3T MRI scanners (Siemens Vida and Prisma). A TSE sequence with a scanner-reported head SAR of 2 W/kg was applied for an average period of 12.1 minutes per test.

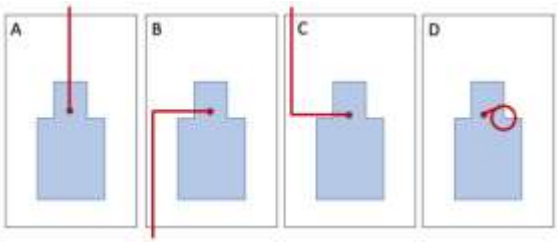


Figure 1 *Different configurations of electrode cables (red lines), relative to the gel phantom (blue) and magnet bore (black rectangle). A: cables existing along isocentre, head end; B: cables exiting along bore, foot end; C: cables exiting along bore, head end; D: cables coiled close to isocentre (diameter=7cm, 4 turns)*

Results The maximum recorded temperature rise measured at the electrode needles was 3.2°C after 15 mins (Fig 2A); this was with the electrode cables running along the isocentre (Fig 1A). On average, the temperature rise was slightly higher when the cables exited the scanner along the isocentre (mean dT = 2.5 °C), compared to when the cables were adjacent to the scanner bore (mean dT = 2.0 °C; Fig 2B).

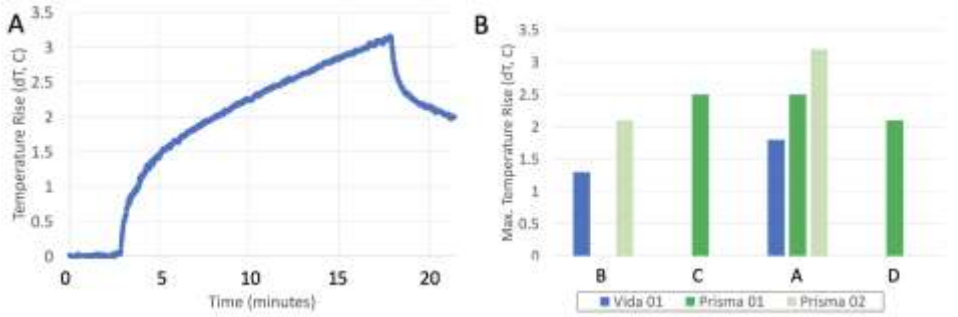


Figure 2 *(A) Worst-case temperature rise timeseries, recorded using configuration A in Figure 1. (B) Maximum recorded temperature rise for different electrode cable configurations (see Fig 1), and MRI scanners. The tests were run once on a Siemens 3T Vida, and twice on a Siemens 3T Prisma*

Discussion/Conclusion The relatively small maximum temperature rise suggests that, under the conditions tested, the risk from thermal injury from these IOM electrodes is low. However, a steady state had not been reached after 15 minutes, and further temperature rises would be expected for a longer active scanning period. The slightly reduced heating when the cables were adjacent to the scanner bore was an unexpected result which warrants further investigation.

Key references. [1] S.-M. Park et al. *JMRI*, 26 (5) 1278–1285, 2007; [2] J.B. Erhardt *et al.*, *NeuroImage*, 195 272–284, 2019, [3] J. Sarnthein et al. *World Neurosurgery*, 93, 168–174, 2016, [4] T. M. Darcey *et al.*, *Neurosurgical Focus*, 40 (3), p. E19, 2016, [5] ASTM *Designation F2182-011.* ASTM, West Conshohocken, PA, 2011.

MRI Safety pathway at Institute for Neurological Sciences.

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Background

Magnetic Resonance Imaging (MRI) is a vital imaging technique but presents several hazards that could result in serious injury or death, due to its use of magnetic fields and radio waves. It is important to get a history of surgeries or interventions that a patient has had, to determine whether they have any metallic or conductive implants that may pose an additional risk. Implants may be MRI safe, MRI conditional, MRI unsafe, or MRI unlabelled.

The referrer is required to declare the make and model of implants that the patient has allowing the radiographer to check the appropriate MRI safety information for the implants. Scanning can then proceed in accordance with the MRI conditions for the implant, ensuring clinically diagnostic images can be collected safely.

In reality referrers do not always have access to the make and model of every implant, manufacturers do not always provide MRI safety information, and MRI conditions from the manufacturers can sometimes be too limiting to answer the clinical question. Uncertainty on the responsibilities for providing information and making decisions could cause delays for the patient and additional time for referrers, radiologists, radiographers and MR safety experts in seeking missing information.

Methods

A clear pathway providing details of the information and decisions required from each person involved in the referral and scanning was created to provide clarity and ensure that a timely decision could be made on whether the patient can be safely scanned with MRI.

Results

Taking a collaborative approach neuroradiologists, MRI physicists, and radiographers devised a new implant safety pathway which was presented to and implemented by the MRI safety committee, at one site initially.

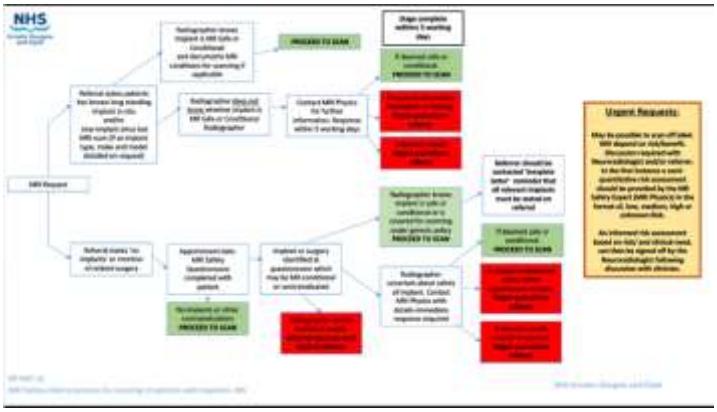

Figure 1: MRI safety referral process for scanning of patients with implants.

Discussion and Conclusion

This pathway provides clear information on responsibilities and ensures the correct personnel are involved at the correct stages of the safety process. There are plans to roll this or locally modified pathways to all other sites within GG&C.

Key references

Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. February 2021

MRI Physics Group Website: https://www.mriphysics.scot.nhs.uk/mri-safety/

An Audit of MRI Off-Label Spinal Scans of Patients with Medtronic Interstim II Sacral Nerve Stimulators (SNS)

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Background

Sacral Nerve Stimulators (SNS) are implanted to help patients suffering with incontinence or issues with bladder control. Spinal scans of Medtronic Interstim II devices are not manufacturer recommended, however, as per MHRA guidelines off-label scanning may be performed where the clinical benefits outweigh the risk to the patient. There are several studies where patients have safely undergone 'off-label' spinal scans with these devices [1-6]. The aim of this work is to review SNS spinal MRI scans at STH over a 4 year period, to re-evaluate the associated risks and audit complication rates.

Methods

MRI records were queried for patients with SNS stimulators who had undergone off-label spinal MRI scans. The event records from each scan and DATIX reports were checked to determine if any issues had occurred. The scans were exported from PACS and the SAR values for each scan extracted from the DICOM header.

Results

A total of 7 scans from 6 patients were assessed. Table 1 summarises the scans and corresponding average whole-body SAR values. 6 scans were successfully completed without any issues. Following the sag T2 TSE sequence patient A reported that the SNS implant was heating up. Post-MRI, Patient D reported increased pain around the implant site at a follow-up clinic.

Patient	A	B	C	D	E	C	F
Acquisition Date	**08/17**	**01/18**	**04/18**	**04/19**	**08/19**	**09/19**	**05/20**
Localiser	0.03	<0.01	0.02	0.04	0.02	0.04	0.05
T2 TSE Sagittal	0.27	0.14	0.46	0.37	0.20	0.41	0.44
Weight (kg)	71	92	60	57	71	60	95

Table 1: Average SAR values (W/kg) each patient received from each scan.

Discussion

Generally, all whole-body SAR values are low; however, this may not tell the full story in terms of heating. Due to the variations of conductivity and permittivity between tissues, imperfect B1 uniformity and variations in patient size, not to mention the presence of a conducting implant, local SAR hotspots can occur. Clearly the conductivity of a metallic implant such as the Interstim II increases the risk of localised heating around the device and this risk was considered and communicated to the patient before commencing these scans. Localised warming was felt by 1 patient (A) during the MRI scan with no long term affects.

At a clinic visit subsequent to the MRI scan patient D reported increased pain around the implant site. Following investigation, it was determined to be likely related to the long-term pain felt in this region and unlikely to be related to the MRI. Guzman-Negron [5] reported a similar heating event with no long-term effects, from a cohort of 11 patients. From the literature [1-6] there have been 44 successful MRI scans of SNS patients, suggesting that the risk of complications is low.

Conclusion

A series of patients with SNS stimulators have been scanned safely off-label using a low SAR protocol. One incident of localised warming during a scan with no after-effects was reported. This contributes to the existing published data indicating that complication rates are low and that MRI scanning of this patient cohort may be considered where the clinical benefits outweigh the potential risks.

Key references

[1] Alsyouf M, et al. Can J Urol. 2016 Feb 1;23(1):8168-70. **[2]** Fry A, et al. BJR Case Rep. 2017 Oct 13:20170064. **[3]** Chermansky CJ, et al. Neurourol Urodyn. 2011 Nov;30(8):1486-8. **[4]** Elkelini MS, Hassouna MM. Eur Urol. 2006 Aug 1;50(2):311-6. **[5]** Guzman-Negron JM, et al. J Urol. 2018 Nov;200(5):1088-92. **[6]** Heidler S, et al. Neurourol Urodyn. 2020 Nov;39(8):2368-72.

Are low dose CT head/neck scouts suitable for MR safety screening of subjects with unknown medical history?

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Background: The use of MRI in acute care is increasing [3,4]. Working in a tertiary referral centre, we are seeing larger numbers of patients for whom complete and accurate medical histories are not available to the MRI team, particularly for urgent scans. When screening patients who are unconscious, unresponsive and cannot provide their own reliable histories, or for whom such histories cannot be reliably obtained from others, plain film x-rays are recommended to identify implants [2]. These should include the head/neck, chest, abdomen/pelvis, and the extremities if there are obvious post-traumatic changes. CT scout images are faster and easier to acquire than plain film x-rays, with a comparable radiation dose [1]. The aim of this study is to evaluate the performance of CT scouts in MR safety screening of head/neck implants.

Methods: 40 head/neck CT scouts were retrospectively selected, with 24 of these including one or multiple internal implants (medical and non-medical, Table 1), whose presence is not detectable by externally inspecting the patient. Two readers were presented the images in a random order and asked to review them for possible implants. The readers, one medical physicist (MR Safety Expert) and one senior MRI radiographer, inspected the CT scouts on the PACS system, and were blind to any other patient details or image sets.

Results: Readings were categorised as per Table 1.

Implants: *aneurysm clips, embolisation coils, surgical staples, neurovascular stents, Intercranial Pressure (ICP) bolt, orthopaedic metalwork, Onyx glue, piercings, Deep Brain Stimulator (DBS) electrodes, Vagal Nerve Stimulator (VNS), pacemaker, programmable and non-programmable shunts, metallic fragment (foreign body), dental work/implants.*

Reader	Identified all implants (or their absence)	Found all implants but failed to identify some	Found/ identified some implants	Found implants where not present	Did not find implants where present
1	26	8	3	1	2
2	29	7	1	0	3

Table 1: Scoring of CT scout images and implant list.

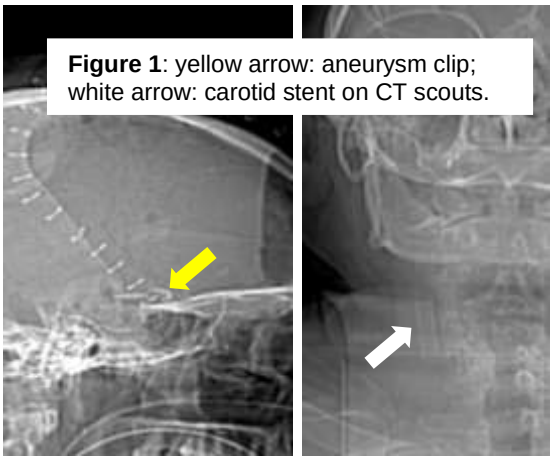

Figure 1: yellow arrow: aneurysm clip; white arrow: carotid stent on CT scouts.

In 88% of cases all implants (or their absence) were found, and in 69% they were all correctly identified. The two readers scored similarly, with a slightly better performance from reader 2 who has more experience of reviewing CT images. Both readers failed to identify two neurovascular stents and one of the two carotid stents. Both readers also missed a hidden frenum piercing. All implants that have led to documented injuries or death following MRI, such as aneurysm clips and DBS electrodes, were identified. All active implants were found, but in some cases were incorrectly identified (e.g., pacemaker instead of VNS).

Discussion: Although CT scouts have lower resolution and quality than plain film x-rays, they revealed most of the implants listed in Table 1. However, some of them were missed by both readers. Most notable were the neurovascular stents which, despite being radiopaque, had too fine a mesh to be reliably detected on this type of image. Similarly, carotid stents can be difficult to identify in some cases (e.g., in a crowded projection, or as in this case, because of their placement at the edge of the field of view). Some implants, like the frenum piercing, might be rare or unexpected, making them hard to recognise regardless of the imaging modality.

Conclusion: All implants with life-threatening consequences when exposed to MRI were found on CT scouts. We believe that with sufficient training and dedicated experience, at least some of the above missed implants could be detected. CT scouts are already being used as a screening tool for other purposes [1], and our work explores their potential use in MRI screening. In future work we plan to compare their performance to that of the recommended imaging modality, plain film x-rays, and to extend this evaluation to body implants and readers with different experience. Ultimately, we aim to turn this work into an educational tool, as dedicated training on this very relevant aspect of MR safety is currently missing in clinical practice.

Key references:

1. Gohmann, R.F., Hecker, F., Uschner, D., et al. Open Journal of Radiology. 2017; 7: 112-120
2. Medicines and Healthcare products Regulatory Agency. Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. 2021.
3. Seif, M., Curt, A., Thompson, A.J., et al. NeuroImage: Clinical. 2018; 20: 556–563.
4. Yue, J.K., Upadhyayula, P.S., Avalos, N.L., et al. Medicina. 2020; 56(2);8