MR scanning of patients with temporary external pacemakers: Two case studies

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Key words: temporary pacemakers

Introduction

Temporary external pacemakers are often implanted in patients with life-threatening cardiac conditions as a bridge to, or for those who are unsuitable for, permanent devices. Historically these used floating passive pacing leads which have a high risk of displacement, leading to patients being restricted in mobility and would be classified as high risk for MR [1]. Furthermore, the pacing boxes for traditional temporary pacing systems are not designed to be MR conditional. An increasingly popular approach is to implant active fixation leads, with the generator left externally, referred to as temporary permanent pacemaker (TPPM) [2,3]. In this abstract we outline case studies of 2 patients with TPPMs scanned at our institution in 2022, outlining MR Safety and technical considerations and the impact on clinical care.

Methods

Two patients were referred for MRI (1 Brain & Spine under GA, 1 Cardiac MR awake) with otherwise MR Conditional TPPMs in-situ. Both were scanned approximately 9 days after implantation, with one patient undergoing a further MRI scan again 21 days later. A literature search conducted at the time found limited evidence for scanning externally implanted generators beyond a small number of case studies, only one of which provided technical MR Safety considerations and mitigations [4-6].

MR Safety Considerations

An individual risk assessment was conducted by an accredited Clinical Scientist and risk-benefit analysis and consent was performed by a consultant neuroradiologist or cardiologist, according to the clinical question. A decision was made to proceed with the MRI in all three cases. The highest risk score (6) was related to device or wire heating, this was mitigated using some of the suggestions below:

1. Scan at 1.5T in Normal Mode
2. Thick gauze between the generator/wires and patient skin
3. Tight fixation of the generator
4. No RF coils placed directly over the generator
5. Place device in MR Mode or sensing only mode and appropriate monitoring throughout
6. Low-SAR Brain & Spine protocol

Results

Both scans were completed without incident and the acquired images were able to answer the clinical query being posed. A previous case study including an example of brain MR used a Head/Transmit RF coil [6]. For our patient, due to the inclusion of spine imaging this was not a viable option, as a ventilated patient would have had to be transferred from the MR table in order to swap the coils. Therefore, a low-SAR head and spine protocol previously designed for spinal cord stimulator scanning was utilized, the average WB-SAR across the brain & spine study was 0.84 W/kg. The CMR protocol was run in Normal Mode (WB-SAR < 2 W/kg). This device was unable to be put in MR Mode due to issues with the lead, which resulted in a higher risk scoring in the risk assessment.

Discussion

These case studies contribute to the small but growing literature for scanning TPPMs. This is also further evidence to support the clinical benefits of using active fixated pacing leads, instead of floating pacing leads [1-3]. In 2022 Vuorinen et al. published a retrospective study of 17 patients who underwent CMR with TPPM between 2011-2019 and reported no adverse events [7]. Of these 17 patients, 1 had a Boston Scientific Essentio such as the one implanted in one of our patients described here. Only 1 of the 3 case studies found when preparing the risk assessment for these patients included extended technical information regarding risk mitigation related to MR, such as SAR considerations. The BMJ consensus published in 2022 stated only that this is a high-risk scenario (8). To our knowledge there are no comprehensive studies into the safety of scanning TPPMs and as such there is a need for further evidence and studies in this area.

References [1] Bhuva A et al. 2022 doi: 10.1136/heartjnl-2022-320810 [2] Rastan et al 2005, https://doi.org/10.1016/j.ejcts.2005.02.040 [3] Suarez K, et al 2019. doi: 10.19102/icrm.2019.100506 [4] Chaudhry et al. 2019 doi: 10.1093/ehjcr/ytz228 [5] McGuinn et al. 2016 doi: 10.1016/j.hrcr.2016.01.012 [6] Kovach et al. 2020 doi: 10.1016/j.hrcr.2020.06.012 [7] Vuorinen et al. 2022 https://doi.org/10.1161/JAHA.121.024257 (8) Bhuva A et al. 2022 doi: 10.1136/heartjnl-2022-320810

MOSAES – successes (and adverse events)

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Background. While there are mechanisms to record adverse events from MR scanning, no mechanism exists to capture scanning successes. This leaves us with a deficit in trying to advise patients as to risk of an adverse event in preparation for off-label scans, where scanning beyond or against the MR conditions may be desirable. To address this deficit the MOSAES (MR Off-label Scanning Adverse Events and Successes) platform was launched in December 2021 to provide a platform for recording the outcomes of off-label MRI scanning. Here we share the results of the events reported to MOSAES thus far and to raise awareness of this resource for future off-label risk assessments.

Methods. MOSAES uses MS Forms to record information on successes and adverse events from off-label MR scanning. No patient identifiable information is recorded, and this resource has been approved by the Information Governance team in NHS GGC. MOSAES is accessed via the NHS GGC MRI physics website (https://www.mriphysics.scot.nhs.uk/mosaes/). Two streams exist to submit data to MOSAES these are either individual patient cases or the option to submit legacy bulk data, 'off-label as a service' events.

Results. To date, 9 entries have been submitted to MOSAES. The majority of these have come from Scotland (7/9). Implants were predominantly active and individual patient events rather than a routine off-label service. The implants reported were CIEDs (2), VNS, SNS, depth electrodes, external fixation system, cochlear fixation system, an expandable orthopaedic implant and an aneurysm clip. To date, there have been no requests to access this information.

Discussion. The number of submissions has been low to date. It is unclear whether this is due to a lack of awareness of the platform, the additional burden of reporting benign events, the low number of off-label scans being performed, uncertainty around information governance or a general lack of interest in this service. The lack of requests for information may suggest either a lack of awareness or interest.

Conclusion. It will take time and greater engagement from the community for the MOSAES platform to build up enough cases to become a useful resource. This summary will hopefully raise awareness and we invite the community to get in touch to ask any questions or provide feedback or comments.

Case report:

Significant patient burn due to interaction of a complex sternal closure system and MRI

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Background

Burns are the most often reported MRI adverse incident [1]. There are a number of mechanisms that can give rise to burns in MRI, one of which is the interaction of the radiofrequency transmission field with metallic components on or in the patient [2]. MRI examination of patients with sternal wires is generally considered safe [3, 4].

Clinical details

A 2-year-old 14kg male patient underwent cardiac MRI under general anaesthetic on a Philips Ingenia 1.5T scanner in Normal Operating Mode [5] (38 sequences; cumulative scanning time = 20 minutes over a 70 minute period; total SED = 775 J/kg). Previously, the patient had a sternotomy with a Robicsek sternal closure system [6] being in situ at the time of MRI (fig. 1).

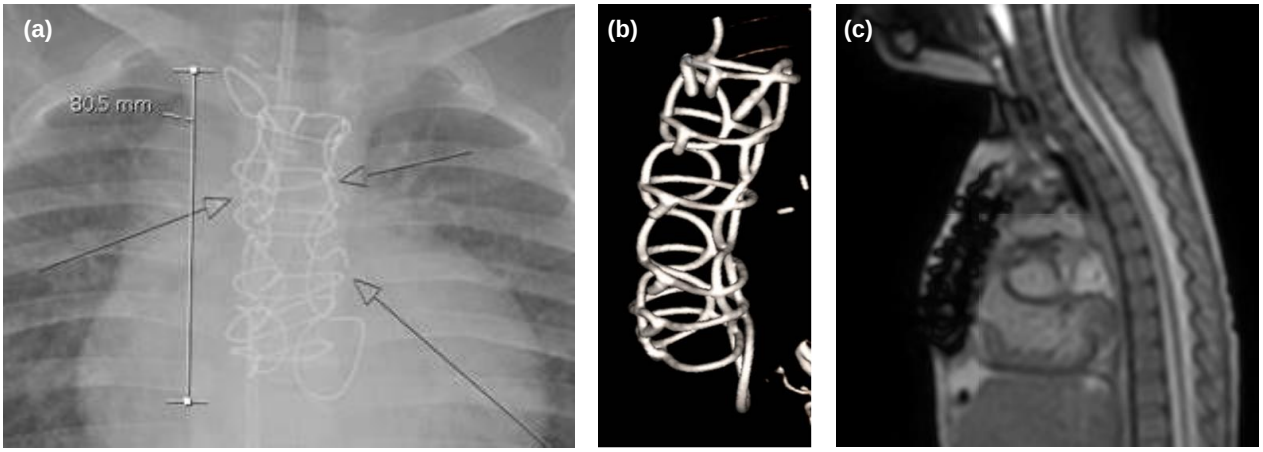

Figure 1*: (a) Chest x-ray showing sternotomy closure system, (b) thresholded, volume-rendered CT image of the sternal closure system and (c) sagittal localiser MRI scan showing susceptibility artefact of the closure system.
*Consent for use of patient data and images was obtained from the patient's parents.

The following day the patient's mother sent a photograph showing a large red mark in the centre of the patient's chest. This had not been visible at the end of the scan. It did not correspond with ECG pad or leads. This burn corresponded with the position of the patient's sternal closure system. The injury developed into a full thickness (3rd degree) burn [7]. Medical photography was taken and the Tissue Viability team assessed the injury. There were no long-term issues.

Discussion

To the best of the authors' knowledge, this is the first time such an incident has been reported. It is proposed that the radiofrequency field of the MRI scanner interacted with the complex, sternal closure system causing it to heat up, and a burn was evident involving the skin that was superficial to the patient's sternotomy site. MRI-related heating has been modelled in figure-of-8 and Robicsek interconnected sternal closures and significant temperature rises have been predicted [8]. We believe extra caution should be applied when MRI scanning patients with complex, sternal closures, where there is radiofrequency energy deposition over the region. We recommend that sternotomy patients that require MRI with direct RF irradiation over the chest are assessed prior to MRI. If the sternal closure system is simple (individual wire loops), then proceed as normal. If the sternal closure system is complex, then low SAR strategies should be considered. Additionally, if the sternal closure system is near to the skin surface, heat sink cooling mechanisms (e.g., ice pack / cold compress) should be considered.

Key references

[1] MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use v4.3 – Feb 2021
[2] McRobbie – Essentials of MRI Safety, First Edition, 2020, Wiley Blackwell
[3] Levine et al – American Heart Asso. Scientific Statement: Safety of MRI in Patients with Cardiovascular Devices - Circulation. 2007;116:2878-2891
[4] Leitgeb et al - MRI-induced tissue heating at metallic sutures – Jour. Electromagnetic Analysis and Applications, 2013; 5:354-358
[5] Robicsek et al – The prevention and treatment of sternum separation following open-heart surgery - J Thorac Cardiovasc Surg 1977 Feb;73(2):267-8
[6] IEC 60601-2-33:2022 - Medical electrical equipment - Part 2-33
[7] https://cks.nice.org.uk/topics/burns-scalds/diagnosis/assessment/#classification-of-burn-depth
[8] Zheng et al - Wire-based sternal closure - MRI-related heating at 1.5T and 3T - Magn Reson Med. 2020;83:1055–1065

Development of an MRI Generic Implant Safety Procedure (GISP) for sternal wires and fixation devices

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Background. The MRI subgroup of the Scottish Medical Physics and Clinical Engineering (MPCE) network have been working on shared MRI Generic Implant Safety Procedures (GISPs) - procedures which allow patients with implants of a particular category to be scanned without identifying the implant make and model. The process to create a GISP begins with a detailed review of the implant, followed by a risk assessment and, finally, 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 sternal wires and fixation devices.

Methods. The detailed review included examination of MRI implant safety databases, manufacturer's documentation and 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 found no reports of incidents relating to sternal wires or fixation devices in the literature. Zheng and colleagues (2020) estimated the worst case heating of a sternal wire would result in a temperature rise of 9.4°C but the experimental worst case temperature rise observed was 7.4°C[1]. The authors concluded that it would be safe to scan their patients in Normal Operating Mode. Anecdotal reports of potential hearing were identified but all reported that the potential heating sensation subsided when the MRI scan was stopped and no injuries were reported. There is a suggestion that this could be due to gradient induced vibrations that are perceived as heating.

No products in this category are labelled as MR Unsafe but many are MR Unlabelled and some manufacturers advise against MRI.

The MR Unlabelled KLS Martin Sternal Talon was highlighted as a potential higher risk implant in this category, due to the perceived increased risk of heating at the tips. If a patient has a sternal fixation device within the MRI field of view, the GISP recommends considering interleaving high and low SAR sequences but would consider this low risk.

Figure 1: KLS Martin Sternal Talon

Discussion. It is understood that, in reality, sternal wires and fixation devices have been scanned at many sites for a long time without any formal policy in place. This GISP aims to formalise this practice.

These implants could be argued to fall within the fixed, internal passive orthopaedic implant policy. However, given the frequency of sternal wire breaks and the fact that most of these devices aren't screwed into bone, it was felt they merited a separate detailed review and policy.

Conclusion. A sternal wires and fixation devices GISP was approved for use throughout NHS Scotland[2].

Key references.

1. Zheng, Jianfeng, et al. "Wire-based sternal closure: MRI-related heating at 1.5 T/64 MHz and 3 T/128 MHz based on simulation and experimental phantom study." Magnetic resonance in medicine 83.3 (2020): 1055-1065
2. NHS GG&C MR Physics website, https://www.mriphysics.scot.nhs.uk/implant-safety-policies/sternal-wires-and-fixation-devices/

MR safety update 2023 – **So, about your quench pipe.**

Aim and background

Having recently had several situations surrounding quench pipes (new installs, replacement installs, damage to insulation and repairs required underneath 2 quench pipe exits) as well as questions about what an annual check should involve and how best to achieve this, I thought it would be useful to cover some of these situations.

Methods

The presentation would cover the following situations:

- Design considerations of a new quench pipe within a lightwell and a new MR facility.
- Design considerations when replacing a 22-year-old quench pipe.
- How do you repair damage to a quench pipes insulation.
- How do you carry out repairs to a roof located underneath 2 quench pipes.
- How and what do you do for your annual quench pipes checks.

The presentations would cover each of the situations highlighting the design considerations for quench pipes and how this translates with real world examples.

It would cover issues that can occur during the process and how they were overcome.

There would be a section on how you can carry out repairs to a pipe or near to the quench pipe exit without shutting everything down based on real world examples with accompanying pictures. This would include the risk assessment process and conclusion, and again how this worked in actuality.

This ties in with what an annual quench pipe check should involve and suggestions on how to do this.

Results

The presentation would include pictures of completed projects and lessons learnt (who needs to be involved, what information do they need, and whether proposed solutions actually worked in practice).

Conclusion

The presentation would conclude with key advice learnt during all of the above situations and guidance on ensuring annual checks are completed satisfactorily.

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Lessons learned from a 3-year running safety ticketing system (CIED focus)

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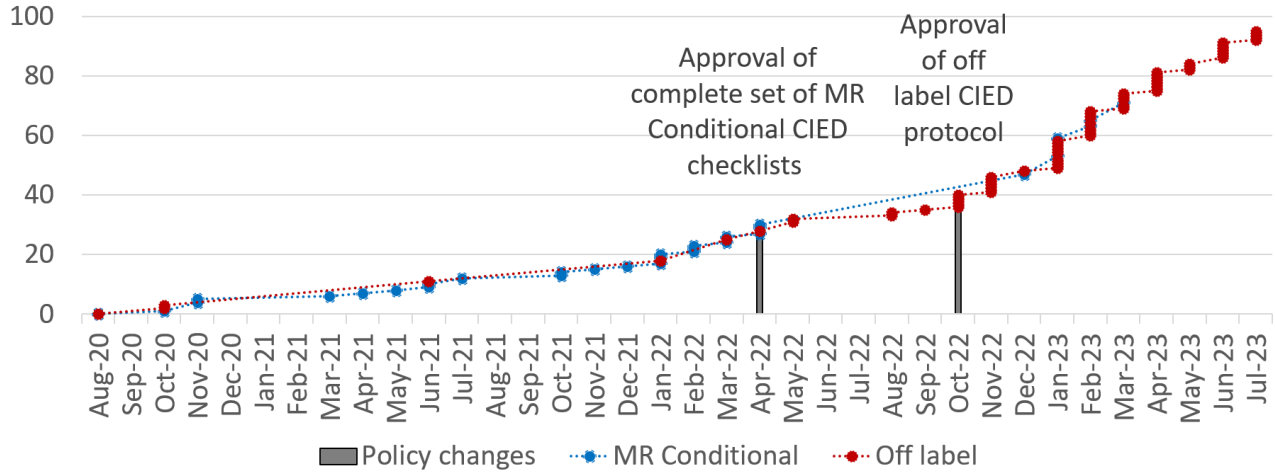
Background: The Swansea Bay MRI Physics Group was formed in April 2020, and a safety ticketing system (using ActionPoint [1]) was implemented soon after. The aim of this work is to audit the information stored in the ticketing system and its clinical utility.

Methods. All safety queries submitted to the ticketing system were queried and classified according to the predefined logging categories (Fig 1). The cardiac implantable electronic devices (CIED) queries were then further divided according to the MRI status of the device (MR Conditional vs not MR Conditional, so off label required for scanning) and plotted over time. Two key local events in the timeline (the approval of a set of MR Conditional CIED checklists, and the approval of an off label CIED MR Protocol) were also marked in the timeline graph (Fig 2).

Fig 1: Safety queries (Aug 2020-Jul 2023)

Fig 2: CIED Safety queries (Aug 2020 - Jul 2023)



Results. CIEDs are the main source of logged safety queries (26%) in the last 3 years. MR Conditional CIED queries dominated during the first two years, whilst off label requests have grown rapidly following approval of a local off label CIED MR protocol (based on recently published guidelines [2]) and now represent the vast majority of CIED tickets.

Discussion/conclusion. The safety ticketing system has allowed us to prioritise resources and focus our efforts (checklists/protocols/generic implant policies, etc.) according to demand, and also to evidence the clinical impact of the MRI Physics service since its creation for CIED patients.

[1] https://actionpoint.cymru.nhs.uk/ [2] Bhuva A, Charles-Edwards G, Ashmore J, et al Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices; BMJ Heart; September 2022

Adverse incident recommendations – projectile and screening incidents.

Daniel Wilson. Department of Medical Physics, Leeds Teaching Hospitals NHS Trust

Background

Despite numerous safety guidelines (1,2) adverse incidents occur within MRI units. It is important that lessons are learnt from all of these and that this learning is shared. This abstract presents lessons learnt from projectile and screening failure incidents from multiple separate organisations.

Methods

Projectile incidents and screening failures when attending scans were included. Screening failures which were only at the referrer stage were excluded. Lessons learnt were extracted from adverse incident investigation reports.

Results

None of the reviewed incidents caused any physical harm.

i) Projectile incidents - All projectile incidents involved items which were not labelled being taken into the magnet room.

Recommendations:

1. Frequent staff training revisions – daily safety huddles or brief focussed learning bursts.
2. Establish quarantine areas / keep MR UNSAFE equipment out of MR Controlled Access Area.
3. Ensure MR SAFE / MR CONDITIONAL labelling is clearly visible. It can be difficult to do this on wheelchairs / trollies. Consider imaginative solutions (e.g. MR SAFE flags).
4. Consistent signage which is incorporated and restated within training (e.g. floor signs).
5. Establish a formal pause procedure for all patients before entering the magnet room.
6. Establish a buddy system where appropriate (e.g. academic units with multiple researchers).

ii) Screening failures - All screening failures involved items declared on the patient screening form which had not been appropriately safety cleared before the patient was taken into the magnet room. No patients were harmed by the screening failures.

Recommendations:

1. Ensure referrers are aware of their responsibility for declaring implants.
2. Record step by step screening process in an SOP.
3. Screening form location should be specified within pathway through department.
4. Simple safety form sign off to say safety checks have been completed.
5. Formal stop and check for screening requiring a visual check of the signed screening form. Do not rely on verbal confirmation.
6. Audit screening forms regularly.
7. Minimise distractions / pressure when going through screening form (e.g., when training).
8. Training recommendations:
    a. Ensure it reflects the screening process details and is appropriate and regularly updated.
    b. Ensure all staff are aware of current authorisation level of new staff.
9. Ensure that all unconscious patient checks are reviewed for each attendance in case cleared for safety, but person has an MR conditional device.

Conclusion

Improvements in safety within MRI units involves learning from any adverse incidents that occur. The lessons from these incidents should be widely disseminated. A nationally available repository containing the brief descriptions of incidents and lessons learnt would be a very useful resource. All incidents involve an element of human error and processes should be designed to minimise this from happening.

References

(1) Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. MHRA February 2021.
(2) ACR Manual on MRI Safety (2020).

Keywords: MR Safety, Adverse Incidents

Audit of MR Unlabelled & Off-Label Risk Assessments

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Background. CMPE, as a regional MR physics service, has received a steady increase in MR safety queries since 2020 for MR scans required for a patient with an implanted device that is MR Conditional but where the manufacturer's guidance cannot be met, or the patient has an MR Unlabelled device or foreign body, where the MR safety status is not known. Whilst referrals for patients with such devices *in situ* would previously have been automatically rejected, there is growing evidence that such scans can often be performed successfully; for example, the joint British society consensus recommendations for MR imaging for patients with non-MR Conditional CIEDs [1].
The MHRA guidelines [2] recommend that prior to scanning such off-label or MR Unlabelled implants a patient specific risk assessment is performed by a multidisciplinary team, including the MR Responsible Person, MR Safety Expert, a radiologist and referring clinician. We reviewed risk assessments performed since January 2020 to identify key trends.

Methods. Risk assessments performed since January 2020 were reviewed to assess the foremost requirements for the risk assessment (e.g. type of implant), clinical indications for the scan, and the outcome for the patient.

Results. The highest number of risk assessments (39%) were performed for non-MR Conditional CIEDs, predominantly those with components from multiple manufacturers, followed by metallic fragments *in situ* (35%) and neurostimulators (16%), often in untested configurations. Clinical indications were predominantly for brain (25%) and spine (42%) scans. The risk assessments resulted in a successful MR scan in 45% of cases, with the remainder either not undergoing MR (37%) or the outcome being unknown (Figure 1). The main reasons for patients not going on for MR was down to the patient being referred for alternative imaging or the radiologist or referring clinician not signing off the risk assessment due to an unfavourable risk-benefit analysis or the perception that off-label scanning is always a high risk option (Figure 2).

Figure 1: Outcome of risk assessment

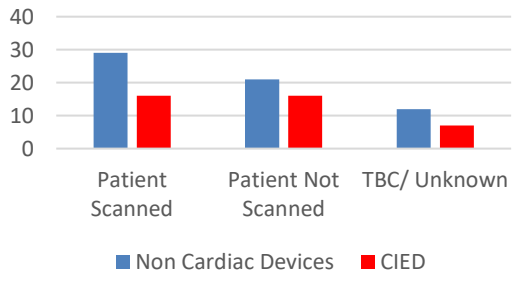
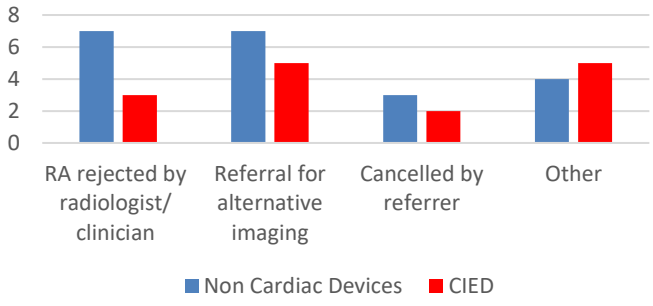


Figure 2: Reason for lack of scan



Discussion. A risk assessment produced a positive outcome for most of the known cases which is encouraging, as access to MR should be available for patients as long as MR safety can be maintained. A positive outcome was more likely for patients with non-CIED implants, however increasing experience in scanning patients with non-MR Conditional CIEDs should rectify this situation. The final decision as to whether to proceed to MR is down to the radiologist and referring clinician; whilst many have a realistic appreciation of the risks involved, further education could reduce the number of risk assessments unnecessarily rejected.

Conclusion. A review of risk assessments since January 2020 for patients with MR Unlabelled or off-label implants revealed a positive outcome in the majority of cases.

Key references.

[1] Bhuva A, Charles-Edwards G, Ashmore J, et al Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices Heart Published Online First: 14 September 2022.

[2] Medicines and Healthcare products Regulatory Agency. Safety guidelines for magnetic resonance imaging equipment in clinical use, 2021. Available: https://www.gov. uk/government/publications/safety-guidelines-for-magnetic-resonance-imagingequipment-in-clinical-use

Can 3T MRI with a Leksell G-Frame be used for planning stereotactic neurosurgery without introducing significant distortions?

Kiran Seunarine, Martin M Tisdall, Enrico De Vita.

Background. Stereotactic neurosurgery can be used for biopsy or implantation of stereo electroencephalography (sEEG) electrodes(1), valuable for localising seizure-onset zones in focal epilepsy. Pre-surgical planning typically combines geometrically accurate CT, with MRI images, providing fine cerebral tissue contrast. An MR-only approach would be valuable to avoid CT-related radiation, especially in children. There is no consensus on whether the distortion induced by the metallic stereotactic frame pinned to the patient head is acceptable at 3T(2,3,4); however some of these studies only used phantom experiments. We evaluated distortion in presence of the Leksell G-frame (Elekta) at 1.5T and 3T on in-vivo adult brain MRI.

Methods. Two adult volunteers were scanned with and without G-frame holder plus G-frame with titanium pins plus MR-indicator box (**Figure**). The G-frame rested on the head, with the flat back of the pins touching the back of the skull, separated by laminated card. The front pins were positioned with pointed tips resting just above paper tape placed on the participant's forehead. Scans without G-frame were repeated in a different session to assess the geometric accuracy of scan-rescan registration for comparison. Data was acquired on Siemens 3T Vida and 1.5T Avanto MR scanners using Tx/Rx head coil or 2x 18-element flex coils. 3D-T1-weighted MPRAGE acquisitions were performed (1.5T: TR/TI/TE=2400/1000/3.71ms, 1mm^3 voxels, 8° flip-angle, 8'06" acquisition; 3T: TR/TI/TE=2000/909/3.41ms, 1mm^3 voxels, 8° flip-angle, 5'31" acquisition. For each pair of images (i.e. scan/rescan or frame/no-frame) the following steps were performed: (i) bias correction using SPM12 (5); (2) rigid registration using nifty-reg (6); (iii) non-linear registration using CAT12 (7). Displacement maps and magnitude were computed from step (iii) and histograms calculated within the brain (FSL BET (8)).

Results. The greatest displacements were observed next to the frame and pins. However within the brain the distortion observed in the frame vs no-frame case was only marginally greater than for the scan-rescan cases, at both 1.5T and 3T, see Figure and Table. The median distortion was less than .24mm in all cases and the 95th percentile of the distortion magnitude histogram was <.29mm for scan-rescan and <.54mm for frame vs no-frame.

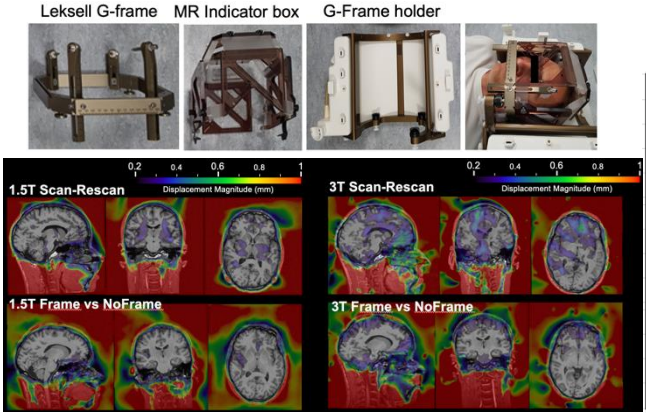


Table: Distortion magnitude (mm)

Pair	B0	Coil	vol	Peak	Median	95th %	Mean±SD
Scan/Rescan	1.5T	TxRx	A	0.12	0.14	0.29	0.15±0.07
Frame/NoFrame	1.5T	TxRx	A	0.21	0.24	0.54	0.26±0.14
Scan/Rescan	1.5T	TxRx	B	0.13	0.14	0.28	0.15±0.07
Frame/NoFrame	1.5T	TxRx	B	0.21	0.22	0.43	0.24±0.11
Scan/Rescan	3T	TxRx	B	0.10	0.12	0.24	0.13±0.06
Frame/NoFrame	3T	TxRx	B	0.12	0.16	0.40	0.19±0.11
Frame/NoFrame	3T	TxRx	A	0.15	0.19	0.48	0.22±0.12
Frame/NoFrame	3T	2x flex18	A	0.14	0.22	0.51	0.24±0.14
NoFrame	1.5T vs 3T	TxRx	A	0.56	0.58	1.04	0.60±0.25
1.5T NoFrame vs 3T with Frame		TxRx	A	0.64	0.63	1.17	0.65±0.28
NoFrame	1.5T vs 3T	TxRx	B	0.41	0.50	0.96	0.53±0.24
1.5T NoFrame vs 3T with Frame		TxRx	B	0.53	0.52	0.98	0.54±0.23

Discussion and Conclusions. We have shown that the additional distortion attributed to the stereotactic frame is <1mm in most voxels within the brain in adult volunteers with conventional 3D T1-weighted sequences and is comparable at 3T and 1.5T. This level of geometric accuracy is generally considered acceptable as the surgeons already allow for a margin of few mm around blood vessels (9). Further work will evaluate the effect of distortion on the appearance of the MR indicator box, which is used for registration during surgery, before considering piloting the direct comparison of presurgical MRI and CT with stereotactic frame in patients.

Key references. (**1**) De Benedictis A (2017), Neurosurgical Focus, 42(5):E7; (**2**)Theocharis (2022), PLos ONE, 17(5): e0268925; (**3**) Nakazawa, H (2014) Journal of Radiation Research, 55: 1184-1191; (**4**) Poulen, G, (2020), Stereotactic and Functional Neurosurgery, 98:337-344; (**5**) https://www.fil.ion.ucl.ac.uk/spm/software/spm12/; (**6**) http://cmictig.cs.ucl.ac.uk/wiki/index.php/NiftyReg; (**7**) https://neuro-jena.github.io/cat/; (**8**) https://fsl.fmrib.ox.ac.uk/fsl ; (**9**) Sharma, J.D. (2019), Journal of Neurosurgery, 23(3):297-302

An unusual presentation of an RF burn associated with invasive blood pressure monitoring

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Abstract no more than 1 page in Arial 11 point, presenting speaker underlined

Proffered papers - please follow the style below:

Background:
This work describes the initial presentation, follow-up and learnings from an unusual RF burn noted at one of our sites on a 1.5T scanner. The particular burn was associated with invasive blood pressure monitoring.

Methods:
An ICU patient had a transducer fitted in ICU prior to their scan and, when brought to MR, the transducer was connected to an MR Conditional monitor and associated cable. The mechanically ventilated patient had been positioned in the routine manner using the standard departmental setup for invasive blood pressure monitoring. There were no loops in the cabling, however, the cable was within the bore of the magnet while scanning and it was in contact with the patient's shoulder. Upon completion of the exam, a 2cm linear wound indicating a potential burn was visible on the patient's shoulder.

Results:
The multidisciplinary response to the RF burn raised issues in terms of in-house procedures for invasive monitoring of critically ill patients in MR. Issues were raised regarding the education and training associated with each piece of equipment brought into the MR scan room. In some cases the information on conditions was not readily available. Further issues came to light around CE marking of combined products and the MR conditions of such devices.

Conclusions:
This was the first report of a burn at any of our sites. The follow-up from the burn enabled us opportunity to review safety protocols and governance for invasive monitoring of critically ill patients in MR while being cognisant of balancing the MR risks with clinical risks.

Key Words:
MRI safety; Invasive blood pressure monitoring; RF burn

A Case Study on the MRI Safety of Fire Extinguishers

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Background. The Medicines and Healthcare products Regulatory Agency (MHRA) recommends that MR Conditional fire extinguishers are provided within the MR Controlled Access Area (MRCAA) [1]. MR Conditional status is required to ensure these do not pose a projectile risk. They are also required to have been tested to be functional in the presence of a strong magnetic field.

Methods. The presence and MR safety status of fire extinguishers were investigated across the trust's 6 MRI units as part of routine MR safety audits and scanner acceptance testing. The MR safety labelling was assessed, and the extinguishers were tested for ferromagnetic content using handheld test magnets. Further clarification of MR safety status was sought from manufacturers/suppliers via colleagues in estates and fire safety teams.

Results. Handheld magnet testing identified ferromagnetic components in several extinguishers from 2 manufacturers across 5 out of 6 MRI units. Parts identified as ferromagnetic included the handle, the hinge of the handle, the pin, and the nut. These parts were found both on new extinguishers and on extinguishers tested after servicing despite previously no ferromagnetic parts having been found, and despite the manufacturer's labelling of "Non-Magnetic" and "MRI Safe". The manufacturer/supplier statements on the MR safety status of one of these extinguisher models obtained via the supplier read *"(extinguisher model) has been tested in an MR System. The evaluation demonstrated that each product is MR conditional of 7-Tesla or less"* and *"This Extinguisher is Manufactured from Non Magnetic Components and is specifically assembled for use in the MRI Environment, Do not replace components without reference to the Manufacturer"*. No reference was made to ASTM testing and labelling standards for MRI [2] or the MRI scanner used for testing. Our investigations revealed that some sites were carrying out part of the fire extinguishers services in-house, and using parts that were ferromagnetic. Furthermore, standard fire extinguishers (i.e. where manufacturers/suppliers offer no suggestion of use in the MR Environment) were located in multiple MRCAAs. These had multiple strongly ferromagnetic parts including the cylinder, and contained extinguishing substances that may be inappropriate for use on electrical fires. All fire extinguishers were subsequently labelled with MR Unsafe stickers, removed from the MRCAA as appropriate, and a suitable supplier of MR Conditional extinguishers was sought.

Discussion: The issues identified highlight the importance of correct equipment labelling, testing, and maintenance in ensuring equipment is and stays fit for purpose, but also the importance of audit, communication, and safety training in ensuring that such issues are identified and incidents are avoided. Our trust is federal in nature, with each site operating semi-independently and with different management and reporting lines for each Radiology department. Each site also has different fire safety and estates staff. To complicate the situation some sites are Private Finance Initiatives (PFIs) whilst others are not, increasing the numbers of stakeholders, with Imaging and Estates departments also playing a role in the procurement and delivery of fire extinguishers.

Conclusion. It is important to communicate with all stakeholder staff to share MR safety knowledge, particularly when MR safety labeling is non-standard or misused by fire extinguisher manufacturers/suppliers. Fire extinguishers should be tested for ferromagnetic components at acceptance and regularly at the time of servicing to establish and maintain MR Conditional status.

Key Words: Fire extinguisher, equipment, audit, MR Conditional, projectile, MRI Safety

References: [1] MHRA, "Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use", 2021

[2] ASTM, "ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment", 2023

Safety audit of MRI procedures involving the provision of anaesthesia

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2) St George's University Hospitals NHS Foundation Trust, London, UK
3) Division of Radiotherapy and Imaging, The Institute of Cancer Research, London, UK

Aims & Background. UK guidelines recommend auditing procedures to ensure that MRI exams involving anaesthesia are carried out safely[1]. We audited the MRI safety of these procedures at our institution, which carries out ~200 such exams per year, against published guidelines[1,2].

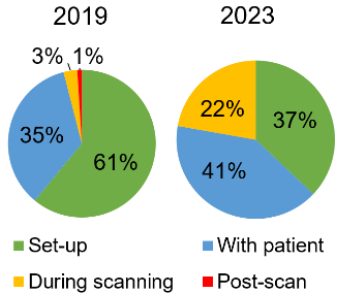
Methods. Five procedures over three months at one NHS trust were audited by the same observer. Each procedure was assessed using seven criteria derived from published guidelines[1,2], as shown in Table 1. An equipment inventory was recorded, including a log of when the equipment entered the MR Environment (MR-E). The audit was approved by the Trust's Clinical Audit Committee. We also compare the results of this audit to another carried out in 2019[3]. Since then, there have been significant changes to the MRI unit layout and the workforce involved.

Table 1: Audit assessment criteria

Criteria	Target	Result
Anaesthetists in the control room have an unobstructed view of the remote monitor, anaesthetic machine, and patient.	100%	100%
An appropriately trained and experienced anaesthetist must always attend the patient when anaesthetics are being administered.	100%	100%
An MRI GA safety checklist is completed and signed for every patient and kept in their record.	100%	20%
All equipment used in the MR Environment is MR Conditional or MR Safe and appropriately labelled.	100%	27%
The MR Unit layout and is suitable for MRI procedures involving provision of anaesthesia.	100%	100%
Anaesthetic staff designated as MR authorised persons after suitable training work in the MR-E under the supervision of a radiographer.	100%	100%
Records of staff screening and training are complete.	100%	50%

Results. The procedures met the target threshold in 4/7 assessment criteria. The MRI unit has a designated Controlled Access Area (CAA) and MR-E, clear visibility of the patient from the MRI Control Room, space and access to anaesthesia supplies in the MR-E and the anaesthetic prep room which had clear and close access to the MR-E. 58% (n=7) of the equipment items brought into the CAA by the anaesthetics team were MR Unsafe. No MR Unsafe devices were brought into the MR-E. Figure 1 shows that 78% (n=21) of equipment brought into the MR-E was during the set-up phase or with the patient, of which n=20 were brought in by a member of non-MR staff. 27% (n=3) of items stored in the CAA had labelling conforming to ASTM F2503 standards. 22 different members of staff attended the procedures, with various levels of MHRA-defined authorisation[2]. Correct documentation of staff authorisation and screening as required by the local rules was found for 100% (n=8) of Authorised Persons (Supervisor), 20% (n=2) of non-MR environment staff and 25% (n=1) of unauthorised staff. For 5/5 exams observed, the checklists covering the MR safety of the patient and staff were followed and completed, but only correctly recorded in the electronic patient record (EPR) for 1/5. It is important to note that a new EPR system was introduced at the hospital during the audit period.

Figure 1: Phase of exam in which equipment was brought into the MR-E



Discussion & Conclusion. We have evaluated the MRI safety of the procedures against published guidelines. The layout of the unit allows the procedures to be carried out safely. We show that the risk of projectile incidents is highest during the set-up phase and when the patient enters the MR-E, which is consistent with the previous audit[3]. Staff should be most vigilant during these phases of the examination. Although no safety incidents were observed during the audit, compared to three observed in the 2019 audit[3,4], two metallic clothing items were reported on anaesthetised patients during subsequent examinations outside the audit period. This work reinforces the importance of training for non-specialist staff, and following procedural checklists, to reduce the risk of MR safety incidents. Overall, these results highlight the importance of developing and following a framework of safe working practises in MR units that provide anaesthetic services.

Key Words: MRI safety, audit, anaesthesia.

Key references. ***1.*** *Guidelines for the safe provision of anaesthesia in magnetic resonance units 2019*. **2.** *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use* (2021). **3.** *Safety Audit of MRI Procedures Involving the Provision of Anaesthesia,* tinyurl.com/yzxn2npw. **4.** *MR Safety case study*. The British Institute of Radiology tinyurl.com/4yahbdjv

Acknowledgements: Julie Hughes and Erica Scurr (MRI Superintendent Radiographers).

Title of Study: Retrospective Assessment of the Time-Efficiency of GISPs

Submitters details: Adlard, W.[1] Wilson D.[1]
1. Department of Medical Physics, Leeds Teaching Hospitals NHS Trust

Background.

At Leeds Teaching Hospitals NHS Trust, various Generic Implant Safety Policies (GISPs) providing advice on lower-risk implants have been implemented. GISPs provide a straightforward way for radiographers to scan common implants, particularly where manufacturer information is difficult to obtain or unavailable. The process of implementing a GISP involves an exhaustive literature search of the implant type, followed by routine reviews to confirm there are no devices available which fall outside the policy.

GISPs are thought to be a time-efficient way of providing safety advice for scanning implants; however, this has not been verified. The aim of this work was to verify the effectiveness of GISPs.

Any safety advice provided by Leeds MR physics is recorded in a database, including the implant type, advice given, and time spent on the query. Since 2015, over 3000 safety advice entries have been recorded. This work reviewed the safety database to assess the effectiveness of GISPs.

Methods.

Six of the most recent GISPs were selected: vascular access ports, biliary metal stents, breast clips, surgical clips, gastric bands, and cardiac closure devices. For each GISP, the safety database was searched to identify relevant safety queries before and after GISP implementation. For each query metrics were recorded and analysed, including the number of queries, time per query, and number of scans per query.

Results.

Following GISP introduction, the mean time for MR physics staff to resolve implant queries was reduced for all implants (figure 1).

The number of scans per query increased for 3/6 implants (table 1). Surgical clips were the most common implant query, with one query received every 10,000 scans (pre-GISP) and 5000 scans (post-GISP).

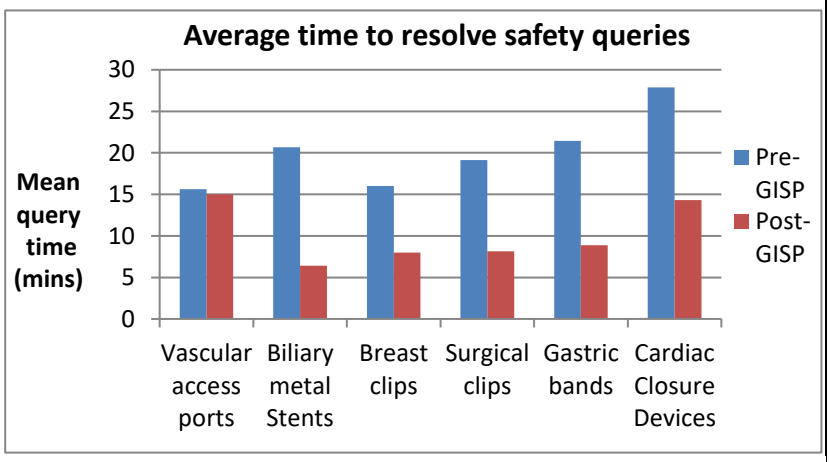


Figure 1: Mean time required for MR physics staff to resolve safety queries before and after GISP implementation.

Surgical clips provided the greatest time saving (363 mins). In total, over 13 hours of MR physics time has been saved to date from the 6 GISPs.

Implant	No. of scans (1000s) per query (queries) pre	post	Medphys time saved (mins)
Vascular access ports	63 (8)	67 (1)	1
Biliary metal stents	42 (11)	22 (5)	71
Breast clips	56 (7)	60 (3)	24
Surgical clips	10 (38)	5 (33)	363
Gastric bands	16 (23)	33 (6)	105
Cardiac closure devices	14 (23)	13 (20)	120

Table 1: Summary of the number of scans per query before and after GISP implementation, and resulting time saved by medical physics.

Discussion.

This work demonstrates time savings achieved by GISP implementation in a large NHS Trust. However, this work did not account for the time required for initial and on-going implant reviews.

Unexpectedly, the incidence of safety queries increased for 3/6 implants. This may be due to GISPs drawing attention to these implants. GISPs also provide benefits not covered by this work, such as timely scanning of implants, and avoiding unnecessary cancellations.

Conclusion.

This work validates the GISP paradigm as a time-efficient method for safety query resolution.

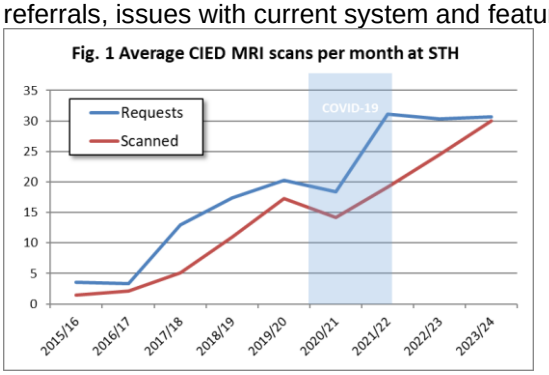
Key references. In alphabetical order, numbered.

Establishing and growing a service for MRI scanning of Cardiac Implantable Electronic Devices (CIEDs).

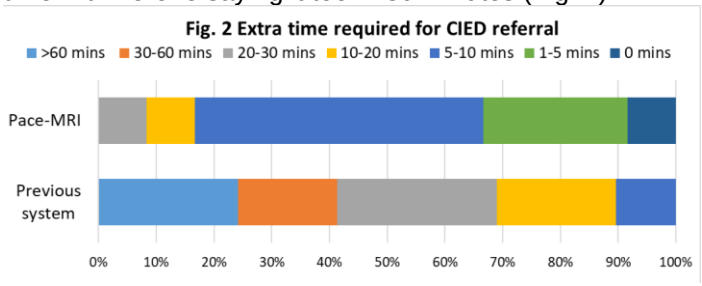
A Fry[1], S Powell[1], A Goodall[1], A Bhuva[2]. [1]Sheffield Teaching Hospitals. [2] Barts Health Trust

Background MRI scanning of CIEDs has been taking place at Sheffield Teaching Hospitals since 2015. From the nervous first scan to routine practice of 30+ patients per month, much has changed, and many challenges have been overcome. In 2017 and 2018 professional societies championed the cause of CIED patients accessing MRI while recognising the operational barriers to making this reality[1,2,3]. This presentation will describe the current state of play for device scanning, the challenges for sites establishing or growing a service and the additional complications around MR Unlabelled devices. We also introduce the pioneering Pace-MRI[4] system, created by Barts Health Trust, that has revolutionised our management of CIED scans and catalysed our ability to scan off-label.

Methods We describe from personal experience the early years of setting up a pacemaker MRI service, the changes in devices, demand, and practice, and, more recently, introduction of Pace-MRI and MR Unlabelled device scanning. KPI data shows the objective side of demand, throughput, and staff time required for such a service. Questionnaires pre-/post-introduction of Pace-MRI captured user satisfaction, time spent on referrals, issues with current system and features required in a referral system.



Results The number of pacemakers scanned at STH has risen from 1-2 to >30 per month (left). Requests have been significantly higher than scans performed, but the gap is reducing as the number of available slots increases, and off-label scanning grows. Pre-implementation questionnaire showed user satisfaction at 2.4/5 ("poor") (n = 29). Significant problems included obtaining pacemaker details, extra time required, and understanding device naming to fill out form correctly. Key features requested were online, self-contained process, ability to see if MR Conditional, remove requirement to supply device details, and to see progress of referral (strongly agree - 76%, 72%, 72%, 66%, 52% respectively). 83% of responders strongly agreed the process should be integrated into the requesting system (ICE). 69% of responders said it took over 20 minutes extra to make a pacemaker referral, with 24% saying it took >60 minutes (Fig. 2). With Pace-MRI, referrers rated the system as 3.8/5 ("good"). The following issues previously identified were rated better or much better: obtaining device details 33%, accessing referral form 83%; entering device details 67%. 83% of responders said it took <10 minutes extra time with no-one saying it took >30 minutes (Fig. 2).



Discussion The original referral system for pacemakers required the clinician to provide device details and answer various technical questions. Information was provided on a PDF form and emailed. CIED referrals are complex and can require input from >7 different teams. This was complex, inefficient, and hard to manage, potentially leading to delays or compromising patient safety. Pace-MRI has proven to be more streamlined, self-contained, and accessible. It has also integrated the governance features required for off-label scans, improving the efficiency of the complex process of communicating risk, vetting, justifying and consenting these scans. The automated risk statements based on the selected device/patient features enable clinicians to accurately understand the risks and counsel patients. While Pace-MRI is no panacea, it has been an invaluable tool in enabling higher patient throughput, and crucially, to establish MR Unlabelled scanning in an efficient, safe, and governance-assured manner. The ongoing development and roll-out of features has fine-tuned the experience further.

Conclusion The development and challenges of establishing and growing a CIED MRI service are described, with a focus on enabling others to navigate this well. We describe the recent service developments in establishing routine off-label scanning and implementing Pace-MRI. This enabled increased patient throughput, reduced referral time, improved safety and reduced administration, resulting in improved equity of access for a disadvantaged patient group.

Key references 1. Strickland & Ray, Letter, BCS and RCR, 2018; **2.** Indik et al. Heart Rhythm, 2017;14(7):e97-e153; **3.** Sabzevari et al. Europace, 2017;19(3):425-431 **4.** Dowsing et al. Heart, 2021; 107 (Suppl 1):A129.

Key words MRI, Pacemaker, Cardiac implantable electronic device, CIED, ICD, Pace-MRI, MR Unlabelled, off-label

A review of off-label MR CIED systems and impact on CIED MRI pathways.

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Background. Since release of the first MR Conditional pacemaker in 2008[1] on-label scanning of patients with cardiac implantable electronic devices (CIEDs) has become well established. Recently there has been interest in widening access to patients with CIEDs where MR is off-label [2,3], both of which cite the growing body of evidence supporting the low risk profile of such scans where appropriate precautions are followed. In light of these, established protocols for scanning patients with CIEDs at Leeds Teaching Hospitals NHS Trust (LTHT) have been reviewed with an aim to reduce blocks or inefficiencies in the process.

LTHT operates an MR Conditional CIED pathway (with patient risk assessment if conditions are breached but MRI mode remains available) and a Non-MR Conditional CIED pathway where MRI mode is unavailable (where the implanted pulse generator (IPG) is not MR Conditional, or where a breached condition prevents MRI mode being used on an MR Conditional IPG). Key differences of the Non-MR Conditional pathway include consultant level referral, risk/benefit analysis and informed patient written consent, MR physics to attend and cardiac physiology to remain throughout the scan and a 1 month post MRI cardiac physiology follow-up.

Consideration is being made to separate the MR Conditional CIED pathway into fully on-label and risk assessed cases. Generic risk assessments have been produced for commonly encountered breaches of manufacturer's conditions (to improve consistency and to reduce replication of work) while patient specific risk assessments will still be produced where required. To ensure patients remain fully informed a patient information sheet outlining why a system containing an MR conditional generator is off-label has been produced which will be given to all appropriate patients. The extra requirements of the Non-MR Conditional pathway are also being reviewed for appropriateness.

Methods. Scans of patients with CIEDs within Leeds Teaching Hospitals NHS Trust radiology service were reviewed from the period 1st June 2022 to 31st May 2023. Scans were categorised as on-label and off-label, with the latter sub-categorised based on the reason(s) for non-compliance with manufacturer's guidance. N.B. cardiac monitors (loop recorders) were not included in the scope of this work.

Results. Of 197 scans, 3 (1.5%) were on the Non-MR Conditional pathway and 12 (6.1%) on the MR Conditional pathway were risk assessed. No adverse consequences were observed.

Table 1 - reasons for MR risk assessments

Conditional pathway		Non-conditional pathway	
Non-conditional/mismatched leads	6	Unlabelled IPG	1
Retained leads/fragments	2	Unlabelled IPG + mis-matched leads	1
Metal near leads	2	Unlabelled IPG + abdominal IPG/ epicardial leads	1
Capture threshold out of range	2		

Discussion. A significant minority (7.6%) CIED scans in LTHT radiology were risk assessed for various reasons, most commonly for mis-matched/non-conditional leads, followed by retained leads/fragments and unlabelled IPGs. A majority of the unlabelled IPGs had at least one further risk factor, highlighting that these may be more complex cases for risk assessment. The issues encountered spanned most of the range of risk categorisation in the Joint Society guidelines, from "Lowest" to "Higher", although no "Avoid" category scenarios were encountered.

Conclusion. The above findings can be used to inform the updating of processes for scanning patients with CIEDs, including identifying priority areas for development of generic risk assessments for commonly encountered breaches of MR conditions.

Key references. 1: Ferreira A et al, 2014, Med Devices (DOI: 10.2147/MDER.S44063), 2: Clinical Imaging Board and British Cardiovascular Society, 2018, Joint statement: MRI for pacemakers and implantable cardioverter-defibrillators 3: Bhuva A et al, 2022, Heart (DOI:10.1136/heartjnl-2022-320810)

Key words: MR Safety, CIED, off-label

A review of off-label risk assessments and mitigations from 2020 – 2023.

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Background. LTHT scans devices where there are no MR conditions or where it would be necessary to scan outside the implant manufacturer's MR conditions, provided a suitable risk assessment and risk-benefit analysis is documented.

Methods. All risk assessments performed from Dec 2020 to June 2023 were reviewed and the following information collected: risk assessment reason, favourable risk-benefit, risk scores for different hazards, risk mitigations and any adverse events.

Risk assessments were performed by a multidisciplinary team which included an MR Safety Expert and a radiographer with competencies to perform the risk assessment. In most cases this also included a consultant radiologist or clinician / health care professional with specialist knowledge of the particular device. Risk scores for likelihood (1-5) and severity (1-5) and overall residual risk were recorded. A residual risk score of 4 or above required a risk benefit to be completed by a clinician and written patient consent to be obtained.

Results. The table below summarises the 66 risk assessments that were reviewed:

Categories	No.	Details	Heating score		Movement score		Stimulation score		Did not proceed	
			Modal	Max	Modal	Max	Modal	Max	No.	%
Abandoned lead - CIED	5	17mm - 58cm	1x3	2x3	-	-	1x3	**3x3**	1	10
Abandoned lead - NS	5		-	-	-	-				
CIED	15	Mismatched leads; Non-conditional leads; Unknown leads; Epicardial leads; High RV capture threshold; Implant <5cm from leads; Raised arms	1x3	2x3	-	-	-	-	5	33
Foreign Body	10	Shrapnel; metal / needle fragments; bullets; all <15mm	-	3x3*	2x3; 2x4	**3x3**	-		5	50
NS - Abandoned system	8	Device status unknown	1x3	2x3	-	-	1x2	2x2	0	14
NS - Leads outside allowed location	6		1x4	**2x4**	-	-	2x2	-	2	
NS - Isocentre/coil not allowed	2		1x3	2x3	-	-	-	-	0	
NS - Lead impedance out of range	3		1x4	1x4	-	-	-	-	0	
NS - Miscellaneous	2	Under GA; metal <15cm	1x3	1x4	-	-	1x3	1x3	0	
NS - Unlabelled	1	Unknown make and model	-	-	-	-	-	-	1	
Other - Miscellaneous	2	Under GA (Synchromed II); Hair extensions	1x2	1x3	2x1	-	2x1	-	0	0
Other - Unknown make and model	7	3 aneurysm clips; 1 atrial closure device; 1 duodenal stent; 1 coronary artery graft; 1 cardiac loop recorder	1x2	1x3	1x4	2x4	-	-	2	29

Risk scores for heating, movement and stimulation (see table) were kept low with mitigations. Typical mitigations for heating included one or more of: maximised distance between isocentre and implant, reduced SAR scan (0.4-2 W/kg whole body), gaps between scans, minimised number of sequences, and use of local T/R coils. Movement mitigations usually involved restricting to a 1.5T field strength and positioning to avoid the highest spatial field gradients. Mitigations for gradient induced stimulation were reduced gradient slew rates.

There was one reported adverse incident where heating was reported for a 1.3 cm needle fragment. This lead to a higher risk score (3x3*) for a subsequent risk assessment for this patient. A causal relationship between the reported sensation and the MRI scan was not established.

Discussion. These scan types can be managed effectively for many patients. All scans that proceeded produced satisfactory quality scans. The largest proportion of scans that did not proceed were associated with foreign bodies due to concerns about movement near to critical structures.

Conclusion. Patients benefit from having individual assessment of risks and benefits associated with an MRI scan.

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

Keywords: MR Safety, Off-label

Comparison of B1+rms and whole-body SAR between 1.5 T MRI systems made by the same manufacturer in phantoms and volunteers

Elisabeth Pickles[1], Caitlin O'Brien[1], Anthony Price[1], Ariona Kruezi[1], Elizabeth Stamou[1], Elizabeth Gabriel[1], Rachael Franklin[1], Rebecca Thornley[1], Geoff Charles-Edwards[1], Simon Shah[1]
[1]Medical Physics, Guy's & St Thomas NHS Foundation Trust, London, UK

Background. MR Conditional medical devices typically specify an MR Condition for SAR and/or B1+rms [1,2,3], with an increasing move towards B1+rms limits. To satisfy these conditions clinical sequences may need to be modified and tested. Ideally, these protocols would be tested on a phantom (rather than a volunteer) and would be transferable between 1.5 T scanners without the need for re-testing. However, given that SAR includes a human model, testing using a phantom has limited utility for SAR limits. Additionally, SAR can be different between different scanners [4,5], even between two 1.5 T scanners of the same manufacturer [4]. The aim of this work was to investigate how B1+rms varied between phantoms and volunteers on different 1.5 T systems from the same manufacturer, and how these compared with variations in whole body SAR.

Methods. A phantom was scanned across four Siemens 1.5 T scanners and a volunteer across two of the four scanners. Scanner details are given in Table 1. The positioning was kept as consistent as possible between scanners. Lumbar spine sequences were set up on the Avanto Fit scanner to have B1+rms ≤ 2 µT. The protocol was transferred to the other scanners which resulted in some small changes to echo spacing (maximum difference from initial scanner was 0.8 ms) and TE (maximum difference from initial scanner was 6 ms). The whole-body RF transmit coil was used on all scanners. Predicted whole body SAR and B1+rms were recorded.

Model	Software version	Max gradient amplitude (mT/m)	Max slew rate (T/m/s)	Max dB/dT (T/s)	Bore Diameter (cm)	Magnet Length (cm)
Avanto Fit	VE11C	45	200	260	60	150
Aera RT Pro	VE11C	45	200	311	70	137
Aera 1	VE11C	33	125	216	70	137
Aera 2	VE11E	45	200	311	70	137

Table 1 Scanner details

Results. Figure 1 shows the results for SAR and B1+rms.

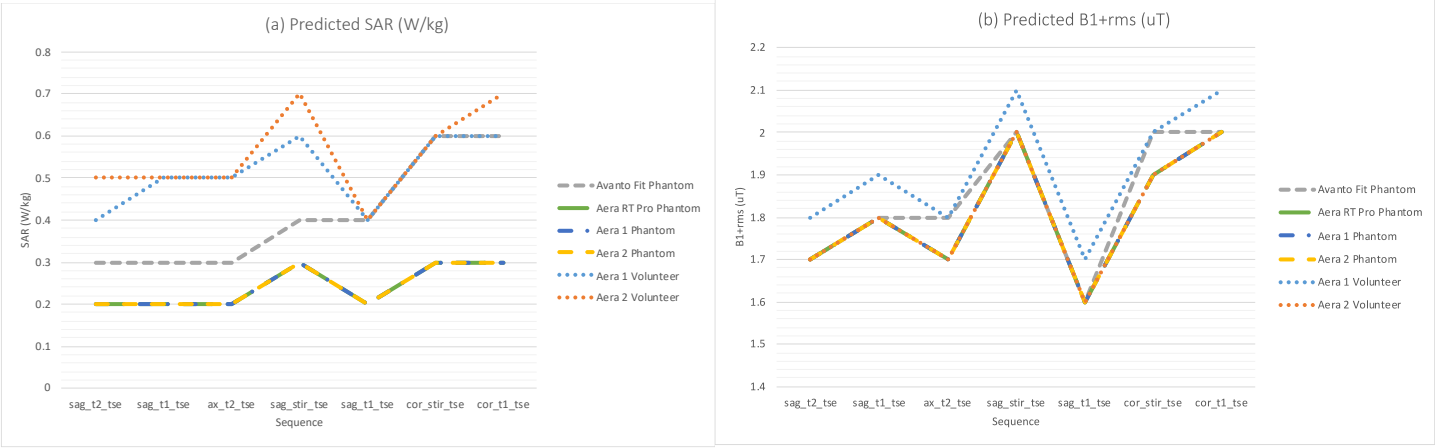

Figure 1 (a) Predicted SAR and (b) Predicted B1+rms in the phantom and volunteer.

Discussion. B1+rms was within 0.1 µT for all scanners and between phantom and volunteers. SAR values were up to 0.4 W/kg higher for the volunteer scans compared to the phantom, which might be partly due to differences in characteristics of the volunteer compared to the phantom, which may impact the SAR calculation but do not impact B1+rms. The Avanto Fit had up to 0.3 W/kg higher SAR compared to the other scanners. It has a narrower and longer bore compared to the other scanners, so the RF coil will be different, which is likely to be the cause of higher SAR. Future work will include investigating how B1+rms and SAR varies between other models and other vendors, other patient sizes, and other field strengths.

Conclusion. Given that B1+rms was within 0.1 µT for the phantom and volunteer, phantom scanning may be adequate for protocol testing with B1+rms limits. Additionally, protocols may not need to be re-tested when transferred between similar scanners for B1+rms limits. This is unlike SAR, which we found to have differences of up to 0.4 W/kg between phantoms and volunteers and up to 0.3 kg/W between scanners.

Key references.

[1] American Society for Testing and Materials (ASTM) International. F2503 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment. West Conshohocken: ASTM, 2020
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Mastering Medtronic Visualase Procedure: Practical MR safety considerations for the use of MRI and laser technologies in combination.

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Background. MRI-guided laser interstitial thermal therapy (LITT) is a minimally invasive procedure that has revolutionised the way healthcare providers treat patients with neurological disorders including medically intractable epilepsy [1,2,3]. The Medtronic Visualase system was purchased in NHS Lothian and used clinically in May 2023; the first treatment of its kind in Scotland. This state-of-the-art technology affords Neurosurgeons the ability to precisely navigate to regions of the brain through an incision as small as 3 mm. Laser output is regulated to deliver heat energy and ablate the epileptogenic zone, creating an irreversibly damaged thermal lesion without causing unintended harm to surrounding healthy brain tissue [4]. During the ablation therapy, the Visualase system receives images from the MRI scanner, and generates 2-dimensional temperature and thermal damage maps in real time to ensure clinical efficacy and minimise damage to healthy tissue [5]. The successful delivery of the first treatment was the culmination of many months of effort involving a range of multidisciplinary stakeholders. Multiple rehearsals were performed to refine safe workflows between theatre and the MR Environment, ensuring the safety of the patient and staff in the MR Environment.

Methods. Here, we present an overview of the practical MR safety considerations for the use of MRI and laser technologies in combination. Multiple dry-run simulations were arranged, supported by the NHS Lothian Simulation Lead and Medtronic Case Support Specialist, to test the technology and refine safe workflows and associated procedures. A short-life working group was established to commission the MRI-guided laser ablation service, including appropriate MR safety governance frameworks. Specific Risk Assessments and Standard Operational Procedures were developed to identify and mitigate risks and outline contingency procedures. Quality Control procedures were designed to assess performance of the bespoke MRI coil arrangement on the 3 T Philips Ingenia MR-OR intra-operative scanner and ensure the accuracy of MR thermometry over the course of ablation therapy.

Results. A robust and effective MR safety program was developed and implemented to cover equipment safety checks, personnel training, patient transfer between theatre and MRI scanner suite and emergency preparedness. This included the creation of specific MRI safety briefings and checklists (Figure 1), adapted from processes in use for existing intra-operative MRI services within NHS Lothian and integrated with analogous laser safety processes.

Figure 1. MR Safety brief conducted in theatres prior to every case with all involved staff present.

In May 2023 the service was commissioned and saw its first clinical use. Feedback provided from multiple staff groups during the resultant debrief highlighted how workflows developed during rehearsals were found to work effectively in practice.

Discussion/Conclusion. The combined hazards presented by MRI and laser technologies required medical physics to work with radiology, anaesthetics, theatre, and neurosurgery teams to ensure patient and staff safety. Following the successful commissioning of the Medtronic Visualase LITT service in NHS Lothian, this therapy can now be delivered safely and effectively to patients via the Scottish Paediatric Epilepsy Surgery Service, representing an exciting advancement in the treatment options available to this patient cohort.

Key references. [1] LaRiviere *et al.*, Front. Surg. **3**, 64 (2016) [2] Tovar-Spinoza *et al.*, Childs Nerv Syst **29**, 2089 (2013) [3] Curry *et al.*, Epilepsy & Behavior **24**, 408 (2012) [4] Medtronic Visualase Product Brochure [5] Patel *et al.*, Operative Neurosurg **15**, 179 (2018).

Hard to Swallow? - An Audit of Safety Policies Following an Incident Involving a Pill Cam Retained for 5 years

A Goodall, L Clayburn, J Lister, S Powell, A Fry

Background Capsule endoscopy (CE) or "PillCam™" procedures are routinely used to diagnose small-bowel pathologies[1–10]. Capsule retention (CR, defined as the capsule not passing after 2 weeks from administration [9]) is the most common adverse effect[10] with a rate of up to 3% for all patients[1–3], increasing to up to 20% for those with Crohn's disease[3,10]. CR can be asymptomatic[3,5,7–10], leaving patients unaware if the capsule has passed. This can lead to attendance for MRI with a retained capsule in-situ.

Following an incident where a patient with CR (5 years post CE) underwent an MRI scan, it was decided to conduct a review of CE screening policies in use across NHS Trusts in the UK, to inform any changes to the local policy. The aim was firstly to determine what CE screening practices are in place, and secondly whether any practice would have been likely to prevent patient with CR from undergoing MRI.

Methods A survey was sent on the MRI and Medical Physics jiscmail mail-bases. Responses were aggregated and the resulting policies used to assess whether CR from literature[1–3,5] would have been noted before MRI.

Results Responses were received from 23 Trusts from around the UK. 87% of trusts explicitly screen for previous CE, and 60% have a CE policy. 83% require confirmation of the capsule passing before MRI, however, 39% use a waiting time as part of that confirmation (Mean time: 21.5 days, Mode: 14 days). Only 2 trusts screen for confounding factors that would increase the chance of CR. 10 of the 23 policies audited would lead to scanning a patient with CR from the literature.

Discussion For all cases in the literature, waiting time post-CE is not a sufficient marker for capsule passage, especially without consideration for confounding factors such as Crohn's disease, other GI motility issues, lesions, stenoses, or surgeries[1–5,7–10]. Retention times in the literature extend to 7 years[5] and may be asymptomatic. No reported retention occurred in the healthy gut, and all CR events > 6 months had Crohn's disease as a factor.

Conclusion The most common causes of CR are not considered by 91% of the policies audited, and 43% would lead to scanning patients with CR.

CR is commonly diagnosed through X-ray; however, it would not be advisable for all patients due to the risk of radiation exposure and possible delays to MRI. Greater consideration for X-ray screening should be given to patients with confounding factors that may increase the incidence of CR, such as Crohn's disease.

Where patients with CR have inadvertently undergone MRI[1,2] there have been no adverse outcomes indicating the risk to patients is likely low.

Key references

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Off-label scan of a NeuroControl FREEHAND® peripheral nerve neurostimulator in a tetraplegic patient

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[1] The Christie NHS Foundation Trust; [2] Bolton NHS Foundation Trust; [3] Southport and Ormskirk NHS Trust

Background. The NeuroControl FREEHAND® system is a peripheral nerve neurostimulation system that returns simple hand function to patients following traumatic spine injury, suitable for patients with level C5 to C6 tetraplegia only [1,2]. The neurostimulator is implanted in the shoulder region with leads running the length of the arm to eight electrodes in the forearm and hand (Fig. 1). Movement is controlled by a sensor implanted in the opposite shoulder region and an external control unit is attached by external leads to this sensor and the neurostimulator. Approximately 250 of the systems have been implanted worldwide and 19 of these were implanted at centres in the United Kingdom [3]. The system was FDA approved in 1997, but production ended in 2001 and NeuroControl went out of business soon after [3]. The majority of implanted systems are now inactive. Despite the complexity of the system, it is labelled as MR Conditional and can be scanned on a 1.5 T MR system, but MR conditions include functional testing of each electrode prior to MR to ensure lead integrity [2]. Unfortunately, functional testing cannot be performed on inactive systems and therefore any MR scan would be off-label. The main risk factor is heating in the leads if there is a lead fracture. Here we describe the successful off-label scanning of a patient with an inactive NeuroControl FREEHAND® system who was referred for an MR scan of the pelvis to assess soft tissue involvement following chronic groin ulcer and suspected osteomyelitis.

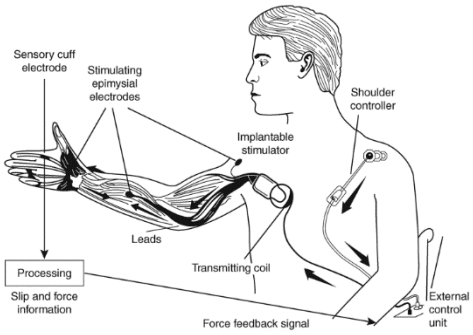


Fig. 1 Overview of the NeuroControl FREEHAND® system

Methods. A risk assessment was performed following a local standard operating procedure (SOP) based on guidance provided by the MHRA [4]. Four of the seven manufacturer conditions were satisfied; one condition could not be met (functional testing) and for the remaining two (dB/dt and patient reporting of unusual sensations), it was indeterminate whether the conditions could be met. X-rays were acquired prior to MRI and demonstrated no lead fractures, serving as a surrogate for functional testing. Following completion of the risk assessment a multi-disciplinary team including the MR Safety Expert, a consultant radiologist and a spinal injuries surgeon assessed the risk *vs* benefit of proceeding with the MR scan and the decision was taken to proceed. Written informed consent was obtained from the patient. A low SAR protocol was used with the minimum sequences required to answer the clinical question, as vetted by a consultant radiologist. Gradient slew rates were minimised in order to satisfy the gradient magnetic field limit of 20 T/s.

Results. The MR scan was completed without incident. Maximum sequence SAR for the examination was 1 W/kg (mean 0.75 W/kg (SD 0.15 W/kg)) and total acquisition time was < 10 minutes. The patient tolerated the scan well and did not report any unexpected sensations during the scan.

Discussion. Despite the complexity of the system and the inability to interrogate the system to confirm lead integrity, we have demonstrated that the NeuroControl FREEHAND® system can be scanned off-label by following a minimal sequence, low SAR protocol. The patient has subsequently been scanned on three more occasions without incident, in one instance at another Trust but under the same risk assessment, with the imaging playing an essential role in diagnosis and surgical planning.

Conclusion. We describe the incident-free off-label scanning of a NeuroControl FREEHAND® system.

Key references. [1] Hobby, J, et al., J Hand Surg Br 2001, 26(5):459-464

[2] Shellock, Frank G, JMRI 2002, 16:485–496

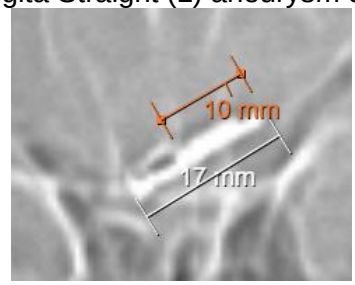
[3] https://www.technologyreview.com/2015/04/09/168424/paralyzed-again/ [accessed 2023-06-07]

[4] Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, MHRA 2021

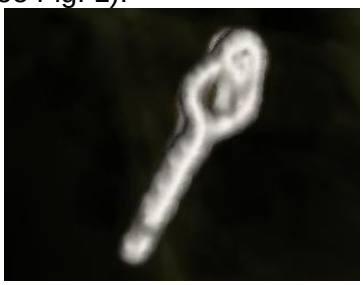
Using 3D CT Reconstructions to Widen Access to MR for Patients with Aneurysm Clips

James Harkin[1], Samuel Curley[1], Steven Jackson[1], Suzanne Phenna[2], Michael Hutton[1]
[1]The Christie NHS Foundation Trust, [2]Northern Care Alliance NHS Foundation Trust

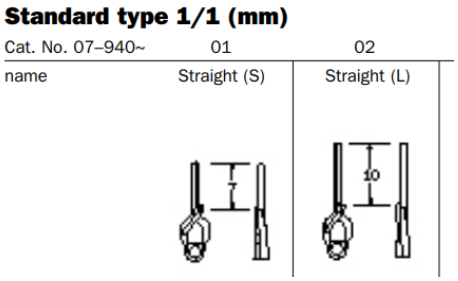
Background: Some models of older aneurysm clip are ferrous and classified as MR Unsafe, in particular many implanted pre-1990 [1]. The consequences of scanning a patient with an MR Unsafe clip could be catastrophic [2] and, given this, historically an extremely conservative approach has been adopted.
Prior to this work, for Trusts supported by Christie Medical Physics and Engineering (CMPE), patients with aneurysm clips were only scanned if it could be verified that the clip was non-ferrous; either through the patients' surgical notes, or a blanket statement from the implanting centre. This limits access to MRI for many patients, where MR would have been beneficial to their care. When investigating the make and model of clip, it is common to be unable to find this information, especially for those implanted >15 years ago. Some NHS Trusts provide blanket statements which specify a date after which all clips implanted were non-ferrous. However, these statements are conservative, with the likely date of the last ferrous aneurysm clip (if any) implanted at a Trust being much earlier than the date in the blanket statement.
Recently, a Netherlands working group issued guidelines [1] stating that: for clips implanted in 2000 or later in the Netherlands, or a comparable healthcare country, MRI can take place up to 3 T. They also list MR Unsafe clips and the likelihood that a clip is ferrous, depending on the implantation date.
CMPE has well established procedures for scanning MR Unlabelled devices, including a patient specific risk assessment. We aim to use these to increase access to MR for patients with aneurysm clips.
Methods: At the Salford Care Organisation, the only known aneurysm clips implanted are from Sugita and Aesculap/Yasargil, though historically other models may have been used. We hypothesised that we could use existing 3D CT reconstructions to identify the design of clip and compare this to literature evidence, to determine if the clip is ferrous or not [1,3,4,5].
Results: CMPE have incorporated 3D CT reconstructions into their safety checking process, providing strong assurance of the clip model. Two patients have been scanned successfully using this procedure with no adverse incidents. The first patient had an implant date of 2000 and the second of 2003. For both patients we were able to conclude with a high degree of confidence, that the clips were non-ferrous Yasargil clips. For an upcoming patient we were able to conclude, with a high degree of confidence, that the clip is a non-ferrous Yasargil/ Sugita clip (implanted 1996). The most likely model is believed to be a Sugita Straight (L) aneurysm clip (see Fig. 1).



(a) CT scout



(b) Helical CT 3D reconstruction



(c) Sugita aneurysm clip design [6]

Figure 1 Sugita Straight (L) aneurysm clip scheduled to be scanned at Salford.

Discussion: All clips identified so far have a helical coiled, cross action, alpha design. This is a strong indication that a clip is likely to be non-ferrous, with only early (<1970) models from McFadden being manufactured from austenitic stainless steel [5]. Given the potential consequences of introducing an MR Unsafe clip into the MR Environment, CMPE currently adopts a more conservative approach than recommended by Hofman et al [1]. The expansion in the aneurysm clip scanning procedure currently only applies if there is some supporting information that the clip is non-ferrous (e.g. previous MR scans, or indication that all the clips known to be used at the time by the implanting centre were non-ferrous). All evidence from CT imaging must corroborate this supporting information. Also, there should be no alternative imaging modality which could answer the clinical question and the MR scan must have the potential to have a significant effect on the patient's management. It is recognised that under this procedure many patients with non-ferrous clips will be refused MR.
Having high quality imaging of all MR Unsafe aneurysm clips would provide increased confidence in expanding this procedure. In future, we also hope to assess our ability to identify (in particular MR Unsafe) clips from CT imaging, where the model is known.
Conclusion This procedure, of utilising 3D CT reconstructions to assist in identifying aneurysm clips, widens patients' access to MR. However, there is still scope for expansion in future.
References [1] Hofman, M.B.M et al. Guideline Use of MRI in patients with implants. 2021 [2] Johnson, G.C. Caution during MR, aneurysm clips. 1993 [3] Olsrud, J. et al. MRI artifacts caused by aneurysm clips. 2005 [4] Fox, J.L. Vascular clips for the microsurgical treatment of stroke. 1976 [5] Mcfadden J.T. MRI and aneurysm clips, 2012 [6] Sugita Aneurysm Clips Brochure, https://www.kebomed.dk/files/30/sugita_elgiloy_clips_brochure.pdf

Why Are We Waiting? – Balancing MRI Safety Investigations with Achieving the New Cauda Equina Syndrome Guideline Scanning Timeframes

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Aims and Background:

In February 2023, NHS England published the National Suspected Cauda Equina Syndrome (CES) Pathway [1]. Alongside this document, IPEM, SoR and RCR published a document detailing recommendations for the provision of MRI for the CES Pathway [2]. This guidance recommends that acute Trusts should provide 24/7 access to MRI and that imaging should be undertaken within four hours of referral.

The University Hospitals of North Midlands (UHNM) NHS Trust provides an acute service that aims to achieve the four-hour target for inpatients with suspected CES. This review explores the impact of investigating patient safety on achieving the targets set by this new guidance.

Methods:

Using a RIS download, in-patient data was taken from the 1st January to the 30th June 2023. The data measured the time between the initial referral and the attendance of the patient to the MRI department. The RIS comments were used to determine if the patient had an implant that required investigating and cross-referenced with the MRI screening form.

Results:

A total of 173 patients with suspected CES were scanned at UHNM over the six-month review period, of which 154 (89%) attended the MRI department within the four-hour target window. From these, 7 patients (0.5%) had implants that were noted to have contributed to delays. Despite this, scanning was facilitated within the four-hour window.

Of the 19 patients scanned outside of the four-hour target, 4 patients (21%) had implants that were noted to have caused delays to their MRI scan. These implants were either pacemakers or implantable cardiac defibrillators (ICDs).

Discussion:

The impact of investigating safety for patients can have a varying effect on the delays to MRI. A greater proportion of patients scanned outside of the four-hour target had implants that caused delays. Based on these results, delays in scanning due to safety were more likely caused by active implants such as pacemakers or ICDs that require additional support during scanning. UHNM has a range of generic implant safety policies developed by the MRI Physics Team which have been used to make efficient and safe decisions on safety by the MRI team.

Conclusions:

Patients experiencing delays in receiving MRI for the CES pathway increases the risk of long-term neurological damage to patients [1]. Minimising delays resulting from safety investigations will help to achieve the four-hour target and provide the best care for patients.

[1] Spinal Surgery: National Suspected Cauda Equina Syndrome (CES) Pathway, NHS England (2023)

[2] MRI Provision for Cauda Equina Syndrome, Royal College of Radiologists (2023)

Update on a national MRI safety e-learning programme

G Charles-Edwards[1], M Greenrod[8], S Shinde[2], C Mills[3], J Thornton[4], M Graves[5], A Papadaki[1], P Wright[1], D Wilson[1], C McGrath[1], J Macfarlane[1,13], M Westwood[6], A Lipton[7], J Guy[8], S Gibbons[8], D Grainger[9], B Nugent[10], S Wilson[11], M Radon[12]

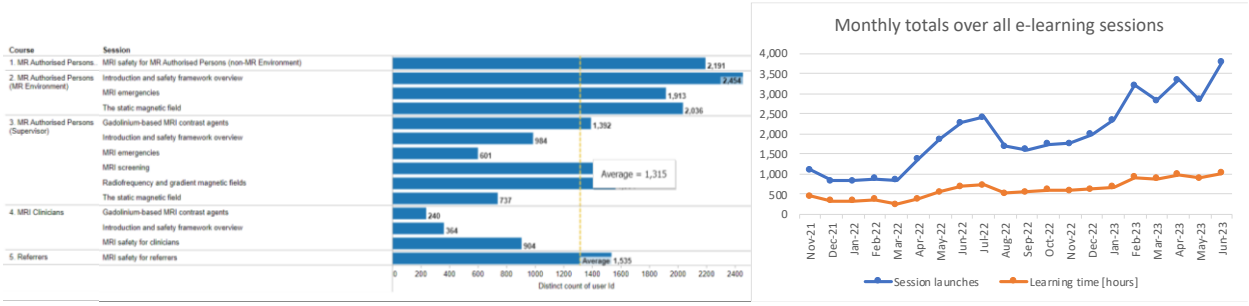
Representing the following organisations: [1]IPEM, [2]Association of Anaesthetists of Great Britain and Ireland, [3]British Association of Magnetic Resonance Radiographers, [4]British and Irish Chapter of the ISMRM, [5]British Institute of Radiology, [6]British Society of Cardiovascular Magnetic Resonance, [7]College of Radiographers, [8]Health Education England e-learning for Healthcare, [9]Medicines and Healthcare products Regulatory Agency (MHRA), [10]MRI Safety Matters, [11]Neuroanaesthesia and Neurocritical Care Society, [12]Royal College of Radiologists, [13]Scottish Imaging Network: A platform for Scientific Excellence (SINAPSE)

Background. A national e-learning programme for MRI safety is freely available to anyone working in the NHS or at a UK academic institution via a number of routes [1-3] and to others via the e-integrity platform [4]. A description of how this programme was developed with some early usage data has been described previously [5]. The purpose of this work was to provide an update on usage and feedback.

Methods. Data were extracted from separate systems capturing usage data via the elfh website, ESR and AICC links. No data were available on usage via the e-integrity website.

Results. There has been access to the e-learning sessions via all 4 access options. The majority of this has been via the elfh website, although there are now 20 organisations linking to the content from their local learning management systems via AICC links. The number of completed e-learning sessions via the elfh website and AICC links between 1st Nov 2021 and 13th July 2023 was 14807 and 1685 respectively with corresponding total learning times of 12650 and 1116 hours. These learning time figures include the duration of non-completed sessions. The average feedback score (elfh website only) was 4.5 out of 5.0 (from 1968 responses) and was either 4.5 or 4.6 for all the different sessions. Figures for the number of individuals accessing the different sessions over the same period (data for access via the elfh website only) demonstrate the most popular courses were those supporting MR Authorised Persons (non-MR Environment), MR Authorised Persons (MR Environment), and MRI safety for referrers.

Monthly totals (website access) show a steady increase in both the number of e-learning sessions launched and the total learning time. In June 2023 the total learning time via the elfh website across all sessions topped 1000 hours for the first time.



Since going live, a small number of suggestions to modify the content were received. These generally highlighted a few typos that have been corrected. A recent suggestion to update the content with regards advice on sedation to make it more consistent with national guidelines was approved. Another suggestion that the sensation of metal taste is the mouth is a common mistake and should be removed was not upheld since this is a well-documented phenomenon [6].

Conclusion. Utilisation of this MRI safety e-learning resource continues to grow. Together with high feedback scores this demonstrates this is well-received training resource.

Key references. [1] e-learning for healthcare, https://www.e-lfh.org.uk/programmes/mri-safety/ [2] from NHS electronic staff record https://my.esr.nhs.uk/ [3] AICC links from organisations' own learning management systems, https://portal.e-lfh.org.uk/home/aiccreport [4] e-integrity platform, https://www.eintegrity.org/healthcare-course/mri-safety/ [5] Charles-Edwards G, *et al*. ISMRM workshop on MR safety (2022) 8. [6] Cavin I, *et al*. JMRI (2007) 26(5):1357-61