Off-label MRI scans of external fixators: a review of local practice and the literature

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Background. Patients with traumatic knee injuries may be fitted with an external fixator (ex-fix) across the knee joint, to immobilise the fracture [1]. These patients often need MRI to aid with treatment planning. Most models of ex-fix are MR conditional, provided that the ex-fix remains outside the bore of the scanner [1]. Therefore, MRI knee scans are off-label. At STH we have completed several off-label MRI scans of patients with ex-fixes, following the MHRA guidelines [2]. In all cases the Stryker Hoffman 3 ex-fix was used. The aim of this work was to evaluate adverse events in off-label scans of patients with an ex-fix, locally and in the literature.

Methods. A list of patients who had an ex-fix fitted between July 2015 and July 2020 was cross-referenced with Radiology records to identify off-label MRI scans. Further patients were added between July 2020 and June 2023 when the MR Physics team received safety queries about them. Radiology records were checked to see if the scan was completed successfully and average SAR values were calculated from the DICOM files. A literature review of off-label MRI scans of patients with ex-fixes was completed and the number of abandoned scans recorded.

Patient ID	Scan Date	Scan Type/Body Part	Average SAR (W/kg)	Scan Completed (Y/N)?
1	16/08/2016	MRI Knee Left	0.63	Y
2	11/12/2018	MRI Knee Left	1.12	Y
3	26/06/2019	MRI Knee Right	0.72	N - Scan abandoned as patient felt something 'pop' in their leg
	03/07/2019	MRI Knee Right	1.22	Y
4	01/05/2020	MRI Knee Right	0.82	Y
5	19/12/2017	MRI Knee Left	0.87	Y
6	14/05/2018	MRI Knee Right	1.10	Y
7	24/07/2019	MRI Knee Right	0.05	Y
8	11/10/2021	MRI Knee Left	0.36	Y
9	28/09/2021	MRI Knee Right	0.0038	N - Scan abandoned after localiser as patient felt leg was heating up.
10	10/09/2022	MRI Knee Right	0.73	Y
11	23/11/2022	MRI Lower Leg Right	0.93	Y
12	28/05/2023	MRI Knee Left	1.22	Y

Table 1: Summary of the results of the audit of local practice.

Results. Table 1 summarises the 13 off-label scans carried out on 12 patients locally. Average SAR of 0.75 ± 0.39 W/kg. 11/13 scans (85%) were completed without incident. Patient 3's first scan was abandoned as they felt something "pop" in their leg, but was repeated later without issue. On discussion a consultant surgeon reported that several ex-fix patients had previously reported popping sensations, likely due to the inherently unstable injuries. Patient 9's scan was also abandoned as they felt their leg was heating up. The clinical team reported the patient's leg was hurting and they felt scared. The results of the literature review (Table 2) showed 171 out of 173 scans (99%) were completed without issue.

Authors	Journal	Year	Patient Scans	
			Scans carried out	Scans abandoned
Ballard et al [3]	Emergency Radiology	2021	22	0
Gillig et al [4]	Journal of Orthopaedic Trauma	2018	57	2
Javidan et al [5]	Journal of Knee Surgery	2015	19	0
Lo et al [6]	Current Problems in Diagnostic Radiology	2021	63	0
Hayden et al [7]	Orthopaedic Trauma Association Annual Meeting 2016	2016	12	0

Table 2: Summary of the results of the literature review.

Discussion. This review shows it is possible to complete off-label knee MRI scans of patients with an ex-fix in situ, provided an appropriate policy for off-label scanning is implemented. The off-label scans at STH show a low adverse event rate, and discussion with the clinical teams following each abandoned scan suggests that the patient's discomfort was unlikely to be caused by the MRI. All scans have relatively low SAR values that fall below the upper limit for normal mode SAR. There are no specified SAR values for off-label ex-fix scans, only that SAR should be kept as low as possible. The literature review showed a similarly low rate of adverse events, however SAR values were not provided so it is not possible to compare directly to our study.

Conclusion. Provided that an appropriate off-label procedure is followed, and a low SAR protocol is used, it should be possible for most patients with an ex-fix to have knee MRI.

Key references.

[1] Milby JN, et al. External Orthopaedic Implants in the Magnetic Resonance Environment: Current Concepts and Controversies. JAAOS. 2020;28(4). **[2]** Medicines and Healthcare Products Regulatory Agency. "Safety guidelines for magnetic resonance imaging equipment in clinical use." (2021). **[3]** Ballard, DH., et al. "Safety and image quality of MR-conditional external fixators for 1.5 Tesla extremity MR." Emergency radiology 28 (2021): 581-588. **[4]** Gillig, JD., et al. "Safety and complications associated with MRI-conditional external fixators in patients with tibial plateau fractures: a case series." Journal of Orthopaedic Trauma 32.10 (2018): 521-525. **[5]** Javidan, P. et al. "How do spanning external fixators on knee dislocation patients affect the use of MRI and knee stability?." The Journal of Knee Surgery (2014): 247-254. **[6]** Lo, L. et al. "MRI of traumatic knee Dislocation: a study to evaluate safety and image quality for patients with knee-spanning stabilization devices." Current Problems in Diagnostic Radiology 51.3 (2022): 317-322. **[7]** Hayden, BL., et al. "Magnetic resonance imaging of trauma patients treated with contemporary external fixation devices: a multicenter case series." Journal of Orthopaedic Trauma 31.11 (2017): e375-e380.

Development of an MRI Generic Implant Safety Procedure (GISP) for eyelid weights

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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). These are procedures which allow for immediate scanning of implants within a certain category without identifying implant make and mode. 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 eyelid weights.

Methods. The detailed review included examination of MRI implant safety databases (mrisafety.com, GUDID), 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.

Results. Our review found no reports of incidents relating to eyelid weights in the literature and no devices labelled as MR Unsafe. The literature highlighted that most implants are made from gold or platinum although older implants have been known to be made of stainless steel. The risk of heating was considered to be negligible given eyelid weights are < 2cm, the length requirement under which implants does not need to be tested according to the ASTM standards [1]. The primary risk associated with eyelid weights is the potential confusion with eyelid springs which are known to have been constructed from ferromagnetic materials. If there is confusion between these implant types, an x-ray could easily identify the nature of the device (figure 1). It was also found that there were MR Unsafe external eyelid weights. These are easily identified during screening.

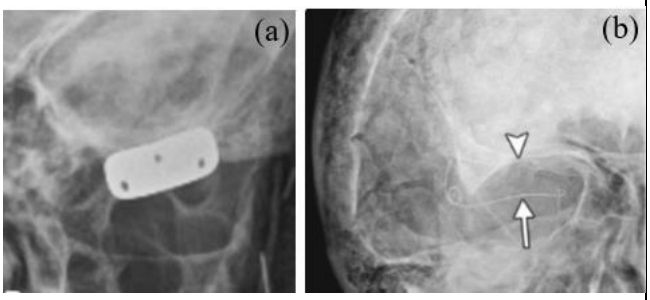

Figure 1: Xray images of (a) Eyelid weight (b) Eyelid wire

Discussion. Our evidence showed there to be no MR Unsafe or MR Conditional eyelid weights (with limiting conditions) either currently on the market or historically implanted. As such we developed a GISP allowing all eyelid weights to be scanned in MRI immediately after implantation without the need to identify the make/model or metallic composition of the device.

Conclusion. An eyelid weight GISP was approved for use throughout NHS Scotland[2].

Key references.

[1] https://www.fda.gov/media/74201/download
[2] https://www.mriphysics.scot.nhs.uk/implant-safety-policies/

Implant Safety Procedure: MRI scanning of patients with MR Conditional Spinal Cord Stimulators

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Background. Spinal Cord Stimulators (SCS) are active implanted devices that treat chronic pain, such as neuropathic, schemic pain syndromes (3). They consist of electrodes and an implantable pulse generator (IPG), that delivers electrical pulses to the spinal cord via the electrodes (2). In the past, SCS were considered MR Unsafe. However, the increased need for safe MRI scanning of patients with SCS (1, 4, 5) has recently led to the manufacture of MR Conditional SCS. The manufacturers of these devices provide detailed conditions and instructions for safe scanning. Therefore, a safety procedure was developed facilitating the safe MRI scanning of patients with MR Conditional SCS considering the manufacturers guidelines and the MRI department practices.

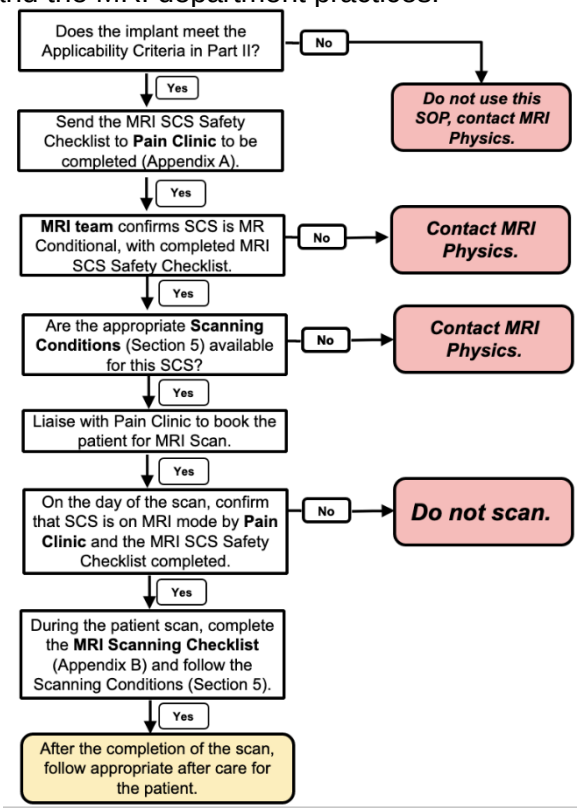

Figure 1: Flowchart describing the workflow from the scan request to the scanning of the conditional device.

Methods. The safety procedure was prepared considering the MRI guidelines of four SCS manufacturers, Abbott, Boston Scientific, Medtronic and NEVRO. Their latest guidelines for MRI scanning were consulted from each manufacturer website. The devices of these manufacturers would be scanned only on a 1.5T GE Healthcare Signa Artist MRI Scanner. Initially, the implant safety procedure was prepared by the MRI Physics team outlining each step and the associated actions from the scan request to the scanning of the conditional device. Secondly, the MRI Safety committee of the trust, consisting of a multi-disciplinary team reviewed and approved the procedure.

Results. A flowchart (Figure 1) was developed starting from: i) the device eligibility, ii) the MR Conditional assessment of its components, iii) the determination of the scanning conditions, iv) the scan booking and the device set-up for the MRI scan, v) the required practices for the safe scan, and vi) the patient after care. An MRI SCS safety checklist for each device manufacturer was produced for the identification of the device components and the implant configuration information.

The scanning conditions were defined for each one of the eligible combinations of the device components of each manufacturer considering the MR scanner characteristics. Moreover, an MRI Scanning Checklist was prepared describing the final verifications for: i) the device, ii) the device set-up, iii) the scanner, iv) the patient status and information, v) the patient set-up, vi) the scanning set-up, and vii) the patient and device verification after the scan. This procedure was originally developed for one site but aimed to be extended to the others of the trust with a 6-month review timeline.

Conclusion. For the safe MRI scanning of patients with MR Conditional SCS, a framework of practices was developed. This procedure describes and summarises all the necessary actions before, during and after the completion of the scan ensuring patient safety.

Key words: MRI Conditional, Spinal Cord Stimulators, Implant Safety Procedure.

Key references. [1] De Andres J et al. *Pain Med;* 2014,15:1815-9. [2] Moens M et al. *Clin Neurol. Neurosurg*; 2012, 114:135-41. [3] Moeschler SM et al. *Neuromodulation*; 2015, 18:285-8. [4] Rubino S et al. *Stereotact. Fun*; 2016,94:254-8. [5] Ragukonis T. *J Pain Res; 2022,*3625-38.

Towards a generic safety policy for scanning patients with Silver Wound Dressing

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Background. The use of antimicrobial dressings containing silver has become routine in the care of burns and wounds. In current practice, silver dressings are often removed prior to MRI due to safety concerns for radiofrequency (RF) induced tissue heating and the potential for image artefacts. However, MR safety information from manufacturers is variable and there is a lack of evidence to support this recommendation. The need to remove dressings for MRI may increase anxiety, pain and the risk of infections. Hence, we investigate the safety of silver containing dressing and develop a policy to scan patients whose silver dressing can safely remain in place during MRI.

Methods: We collated a list of the silver dressings used at our Trust, sought MR safety information from the manufacturers and performed a literature review of studies assessing MR safety and compatibility of silver wound dressings. Silver concentrations were identified and compared against other dressings not tested in the literature. In addition, the UrgoTul Ag dressing, which is routinely used in our trust, was assessed for RF related heating and image artefacts on a 3T Siemens Skyra System (using a transmit/receive knee RF coil). The MRI protocol was selected to generate a high level of RF energy within the imaged region, while the scanner fan was turned off during the experiments. Three identical saline bags were used to test three conditions: (a) no dressing, (b) dry dressing and (c) moist dressing. Temperature was recorded using an infrared thermometer immediately before and after the MRI scan.

***Table 1**: Details of silver containing wound dressings.*

Product	Manufacturer	Manufacturer Advice	Ag concentration	Study	B_0
Mepilex Ag Mepilex Border Ag	Mölnlycke Health Care	MR safe	1.2mg/cm^2	1	3T
Aticoat™	Smith & Nephew	Remove	0.841.60mg/cm^2	2	
Silverlon™	Argentum Medical	MR Unlabelled	0.55mg/cm^2		
AquaCel Ag™ AquaCel Ag+ Extra	AQUA-CEL Corp	Remove	0.08-0.09mg/cm^2	2,3	3T 7T
Tritec™ Silver	Milliken Healthcare	MR Unlabelled	0.5mg/cm^2	4	3T
ULTRA Silver		MR Unlabelled	Unknown		
Assist™ Silver		MR Safe	Unknown		
InterDry Ag	Coloplast	MR Unlabelled	Unknown		
Granufoam Silver	3M	MR Conditional	10% content		3T
UrgoTul SSD	UrgoMedical	Remove	0.14mg/cm^2 (3.75%)		3T
UrgoTul Ag			0.35mg/cm^2		
UrgoClean Ag			0.39mg/cm^2		
UrgoCell Ag			0.35mg/cm^2		
Atrauman Ag	Hartman	Remove	8.4-9.4% weight		

Results: Table 1 shows details of the manufacturer recommendations, the Ag concentration of silver containing dressings investigated, including references for those which were tested according to ASTM Standards F2052-15 and F2213-06. These studies provided the following findings; No significant magnetic deflection or torsion was exerted on any of the tested dressings[1,3-4]; No significant heating[2-4] of tissue was generated for any of the tested dressings, or MRI-related heating effects were at the same levels[1] as the background temperature rises; The tested dressings did not create noticeable artefacts in the MR images at 3T[3-4] or only low levels of distortions (for some of the sequences) at 7T[2] and 3T[1]. Similarly, no conspicuous artefacts were observed for UrgoTul Ag dressing in either dry or moist test conditions. The temperature increase after 15 min MRI (with an average effective RF B_1+rms of 3.3μT) was 0.3ºC and 1ºC for the dry and wet silver dressing respectively, compared to a 0.6ºC increase in the absence of silver dressing.

Conclusion: No evidence was found in the literature to support safety concerns associated with MRI scanning of patients with silver dressings. Our non-standard tests of the UrgoTul Ag showed minimal temperature rises in line with previous studies using silver containing dressings with a higher silver content, such as Aticoat[1] or Mepilex Ag[2]. These results taken together indicate that these silver-containing wound dressings do not pose additional hazards or risks to patients undergoing MRI scans. Taking into account the risks associated with unnecessary dressing changes, we conclude that for the silver containing dressings investigated (or others with similar or lower Ag concentration), it is reasonable for dressings to be left in place when a patient undergoes MRI.

Key References: [1] Escher & Shellok. Ostomy Wound Manage, 2012, 58(11):22-7 [2] Chaudry et al. Burns, 2009, 35(8):1080-5. [3] Nienhuis & Duan. J Am Coll Radiol, 2009, 6(7):500-5 [4] Bailey et al. Burns, 2009, 44(8):1940-1946

A generic implant safety procedure for managing patients with non-ocular metal fragments

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Background. The presence of embedded metal fragments presents risks for patients undergoing MRI. While there are examples of guidance for how to manage patients with intraocular foreign bodies [1], there is limited guidance on how to manage the main risks of migration and heating of metal fragments in other anatomical areas. The aim of this work was to create a workflow for managing patients with non-ocular metal fragments.

Methods. A literature search of the MAUDE/MDR databases using the keywords "MRI" and "unknown bodies"/"bullets"/"shrapnel" was performed to identify the prevalence of adverse events due to metal fragments in patients undergoing MRI scanner. The ability to induce injury depending on their ferromagnetic properties, location and time since implantation was assessed after reviewing previous incidents. Following consultation with clinicians, review of the current MHRA guidelines [2], policies [3,4] and relevant literature [5-7], a 3-level risk classification system was developed based upon the anatomical location of any metal fragments. This was used to develop a local workflow for managing these patients. Major considerations for the workflow included the geometry, object dimensions, field strength, and spatial field gradient of the MR system. Additionally, expectations that passive devices with dimensions <2 cm (and when any replicas are >3 cm apart) will experience a temperature rise of <2°C over 1 hour of exposure at 1.5T or 3T [8] were considered.

Results. In the last 3 years, 0.5% (n=68) of the total MRI-related incidents were linked to foreign bodies. The locally defined anatomy-based 3-level risk classification and workflow are shown below. A number of scenarios were identified as appropriate for managing via the standard individual risk assessment and clinical need/risk decision on whether to scan. The lowest risk group were deemed appropriate to proceed straight to scanning with a number of locally defined MR conditions that included a minimum time of 6 weeks since implantation (to allow for endothelisation to counter any potential attractive force), Normal operating mode for SAR to mitigate against the potential risk of heating). No additional limit for spatial field gradient was deemed necessary.

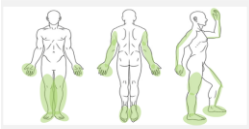
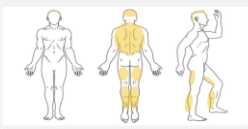
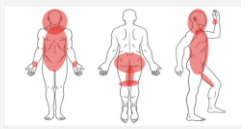
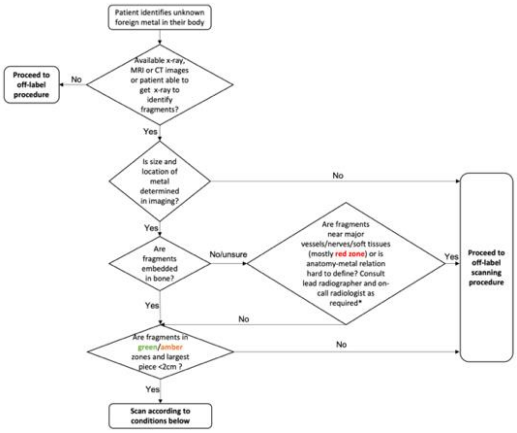
Green Zone - Lowest Risk	Amber - Low Risk	Red Zones - Medium/High Risk
		
Outer Arms (including outer wrist)	Back of the legs (excluding inner thigh and back of the knee)	Head (except top and back of skull) and neck
Hands and fingers	Upper Inner Arm	Spine, Knee (posterior of knee cap), Wrist (Excluding superficial outer wrist)
Front and lateral legs	Top and back of skull (subdermal)	Thoracic cavity and Superficial Chest
Feet	Superficial Back (above muscle wall and spine)	Abdominal cavity and Superficial Abdomen
		Genitals, Buttocks

Table 1: Traffic light system for identifying the high-risk anatomical regions.



Conclusion. A generic implant procedure for managing patients with non-ocular metal fragments has been developed, utilising a traffic light based system for recognising the varying risk levels associated with different anatomical locations where such metal fragments may be embedded. This work may be helpful for sites considering establishing their own workflows for these patients.

Key references.

[1] https://www.bamrr.org/safety/ [2] MHRA MRI safety guidelines (2021). https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use [3] University or Wisconsin Radiology dept, MRI clearance of patients with metallic implants of uncertain identity (2016). https://www.radiology.wisc.edu/wp-content/uploads/2017/10/MRI-clearance-of-patients-with-metallic-implants-of-uncertain-identity.pdf [4] UC Davis Imaging Research Center MRI Safety Manual. (2023) https://health.ucdavis.edu/irc/content/pdfs/IRC_MRI_Safety_Manual.pdf [5] Fujimoto, K. et al., 2018. Radio-frequency safety assessment of stents in blood vessels during magnetic resonance imaging. [6] Eshed, I. et al. Is magnetic resonance imaging safe for patients with retained metal fragments from combat and terrorist attacks. (2010) Acta Radiol. 2010 Mar;51(2):170-4. [7] Semple, T. et al., 2018. Button battery ingestion in children—a potentially catastrophic event of which all radiologists must be aware. [8] ASTM F2182-19. Standard Test Method for Measurement of RF Induced Heating On or Near Passive Implants During MRI.