MRI Generic Implant Safety Policy (GISP): Detailed review

Title: Sternal wires and fixation devices

Executive summary

Date detailed review completed: *'not important for now, these are placeholders as a reminder that this should be set. Will likely be recorded in document quality system if available or set by local board'*

Date of next review: *'as per comment above'*

Version code: *'as per comment above'*

Introduction

Generic benefits of generic implant safety policies for MRI

Ensuring the safety of patients undergoing MRI is of paramount importance. An appreciable portion of the population has medical implants or devices and in many cases an individual patient may have multiple implants. Identifying every patient implant can be difficult for a number of reasons and the purpose of the GISP's is to review specific categories of implants such that general statements of safety can be made. Key benefits of GISP's are as follows:

- Facilitates scanning when implant information is not readily available.
- Speeds up scanning when implant information takes some time to obtain.
- Avoids unnecessary cancellations.
- Reduces resources required to obtain and evaluate specific implant information

Generic risks of generic implant safety policies for MRI

It should be noted that generic implant safety policies and their use are not without risk. Some of the risks involved are listed below

- Newly developed unsafe implant
- Previously unrecognised unsafe implant
- As the implant make and model will not be identified when using a GISP, there is a risk that a patient implanted device may be incorrectly reported and attributed to a GISP that does not relate to the actual implanted device.
- Updated safety information that adversely changes the safety status of an implant might take some time to filter through to the GISP

Clinical context of the 'insert implant / device category'

Sternal (sternum) wires are used to close the breastbone after open heart or thoracic surgery. They are typically multiple wires made from stainless steel or titanium but some newer devices include clamps or talons.

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Outline the challenge / issue from a MRI unit context in dealing with the 'implant / device category'

The main challenges would likely be focused on determining what other implants may have been inserted during the surgery. With regards to sternal wires and fixation devices the main challenge may be confirming there are no abnormally large loops or twists of wires.

Hypothesis

Sternal wires are generally thought to be safe to undergo MRI but I am aware of more complex sternal fixation devices that may have stricter MR Conditions. I suspect there will be little to no evidence at ultra-high field strength.

Aim

The aim is to provide a detailed review from all available sources in regard to the MRI safety status of sternal wires. This is with a view to creating the basis to inform subsequent risk assessments on this topic. This will in-turn be used as the basis for guidance and safety policies to be used by Radiology staff to inform decisions on performing MRI scans on patients with these implants or devices.

Methods

A range of MRI safety resources will be reviewed with the aim of gathering as much information as possible in regard to the MRI safety status of the implant category under investigation. As far as possible, detail should be included on search terms used and time periods reviewed such as to allow provenance of the information to be established and if necessary, replicated or audited at a later date.

Results

Review of MRI implant safety databases (performed 29/10/20)

A search of mrisafety.com revealed that all implants under the subject category "Sutures" are MR Conditional 6, MR Conditional 8 or MR Safe. Using search terms "sternal", "sternum", and "suture" identified only implants that were listed as MR Conditional 5 (meaning check the manufacturer's website for MR Conditions), MR Conditional 6, MR Conditional 8 or MR Safe. Using the search term "wire" revealed a number of MR Unsafe wires but none were sternal wires. The MR Unsafe wires belonged to the subject categories: "Biopsy Needles, Markers and Devices", "Otologic Implants", "Ocular Implants, Lens Implants, and Devices", and "Miscellaneous Implants and Devices" (an external neurostimulation system).

The subject category for sutures states the following (accessed 29/10/20):

"Rec ID #226

Subject: Sutures

Article Text: A variety of materials, including nonmetallic and metallic materials, are used to make sutures. Various sutures with the needles removed have been tested at 1.5- and 3.0-Tesla because they have not been previously evaluated in association with the MR environment and there is confusion regarding the implications of these materials for patients undergoing MR procedures. At 1.5-Tesla, for the 13 different sutures evaluated, all were considered safe for patients.

MR Safety at 3.0-Tesla and Sutures

At 3-Tesla, most of the sutures evaluated displayed no magnetic field interactions, while two (Flexon suture and Steel suture, United States Surgical, North Haven, CT) showed minor deflection angles and torque. For these two sutures, the in situ application of these materials provides sufficient counter-forces to prevent movement or dislodgment. Therefore, in consideration of the intended in vivo use of these materials, all of the sutures with the needles removed tested to date are regarded to be acceptable at 3-Tesla.

REFERENCE

Shellock FG. Reference Manual For Magnetic Resonance Safety, Implants, and Devices: 2010 Edition. Biomedical Research Publishing Group, Los Angeles, CA, 2014.

Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. J Magn Reson Imag 2002;16:721-732."

Review of manufacturer implant information (performed 23/07/21, updated 27/9/22)

Of the 25 sternal wires and fixation devices identified, none were explicitly labelled as MR Unsafe in their IFU. However, two manufacturers, Medicon and Teleflex, have listed their sternal fixation devices as MR Unsafe in the FDA's AccessGUDID database. Medicon did not respond to the request for further information and so all the information that could be found about their sternal fixation devices are that they included titanium sternal locking plates, ladders and screws. The Teleflex locking plate is made from stainless steel but they confirmed in their IFU that it is "non-magnetic". However, they include the following warning in their sternal locking plate IFU:

"*Although sternal locking plates are made from non-magnetic stainless steel, heating and movement may occur under magnetic resonance imaging (MRI) conditions. Therefore, magnetic resonance imaging (MRI) should not be used in combination with implanted sternal locking plates.*"

The IFU does not explicitly label it as MR Unsafe but this is perhaps implied. However, the MRI safety statement does not use standard MRI safety terminology and does not present any results from MRI safety testing. If we assume that the manufacturers meant that the stainless steel is non-ferromagnetic rather than non-magnetic, this contradicts the later sentence suggesting there is a risk of movement. Nonetheless, the risk of movement and heating is taken into consideration in this review.

Furthermore, 7 manufacturers stated they had not undergone MR safety testing and 6 provided no MR safety statement. I contacted Zimmer Biomet about their Sternalock device range as the Sternalock 360 is MR Conditional but the Sternalock Blu states it has not been tested and received the following response:

"*Our Sternalock product Family has two systems within it, one tested and one waiting on regulatory approval, even though both Sternalock 360 and Sternalock Blu are made of the same material and utilise the same screws we have to test every product brand separately.*

Sternalock Blu has been tested but we are waiting on regulatory approval before we can promote it as MRI tested.

Sternalock 360 is a newer to market product as as part of it's market release and validation it was subjected to MRI testing which why the IFU you sent states some MRI conditions.

Sternalock Blu has been available to the market since 2011 so has a strong history of clinical use and I am unaware of any MRI issues, but until we have regulatory clearance we have to state untested."

This demonstrates that the manufacturers that have stated devices are untested or those that do not provide an MRI safety statement are not necessarily MR Unsafe.

Review of the peer reviewed literature (performed 26/07/21)

Search terms used in Google Scholar included: "sternal wires MRI" and "MRI safety sternal wires". Further papers were identified through the references found during the literature review and internet search. 15 articles were investigated, all of which discussed MRI safety of sternal wires or other sternal fixation devices.

No reports of injuries or safety concerns from sternal wires or other sternal fixation devices in the MR Environment were reported. Symons and colleagues (2019) reported one case of a paediatric patient reporting discomfort during MRI performed 2 days after cardiac surgery. The discomfort stopped following the discontinuation of the MRI examination. Due to the similar symptoms, it is unclear whether the pain was due to the sternal wires or anxiety.

All of the literature found stated that sternal wires/sutures are safe to scan, with most stating up to 3T (Baikoussis et al (2011), Levine et al (2007), Shellock (2002) and Zheng et al (2019)). Baikoussis and colleagues (2011) added that these can be scanned immediately after implantation. Diken and colleagues (2016) also mentioned screws, adjustable clips and nitinol clips used for sternal closure are usually made from titanium and nitinol and therefore do not represent a contraindication to MRI. Levin and colleagues (2010) report that the KLS Martin Sternal Talon (Figure 1) is "magnetic resonance imaging compatible" but provide no MR Conditions. Thermoreactive nitinol clips were also reported to be "compatible" with MRI, suggesting these are MRI Conditional devices (Negri et al, 2002).

Figure 1: KLS Martin Sternal Talon

One paper by Leitgeb and colleagues (2013) stated that, from a heating perspective, "metallic sutures as used to fix the sternum after thorax surgery are no contraindication for MRI with static magnetic flux densities up to 7T". Furthermore, a single break in a sternal wire does not increase the risk of heating. However, as Shellock noted on the SMRT mailbase: "the investigators only performed numerical anatomical and thermal modelling in this study and did not include actual temperature measurements to confirm their findings. Regardless, the information is interesting and included work up to and including 7T".

Review of the SMRT MR Technologist mail base (performed 27/07/21)

There have been a few discussions of sternal wires and fixation devices on the SMRT mailbase, with Dr Kanal and Dr Shellock the most prominent contributors. In one thread relating to a sternal talon by KLS Martin (Figure 1), Dr Kanal expresses his concern for the potential for heating or dislodgment or arrhythmogenesis but Dr Shellock reported that they tested this as a single device in 2010, which resulted in MR Conditional labelling. However, the manufacturer's documentation states that it has not been tested in the MR Environment and there remained concern about multiple sternal talons presenting an MR safety issue. Interestingly, mrisafety.com no longer hold information about the KLS Martin sternal talon.

In this discussion, it was suggested that the sternal talon is an example of a fixed, passive, internal orthopaedic implant and that these are generally not considered a contraindication for MRI. Dr Kanal was strongly opposed to this argument:

"I firmly disagree with any generalization that would suggest that any orthopedic hardware firmly attached bone would not present an MR safety issue. I also don't believe that I ever heard anyone promulgate it, so this might actually be a bit of a misunderstanding. In any case, ferromagnetic large spine rods could experience extremely high rotational and/or translational forces in today's 1.5T and 3T systems (let alone the recently FDA approved 7T systems). Further, I am personally aware of significant burns suffered at the tips of screws from bone-anchored orthopedic hardware. I would be exceedingly uncomfortable relying on such a generalization and of course would not accept nor permit my own institution to accept or follow such a "rule" for our patients."

Later adding:

"I continue to repeat that the incessant drive we all seem to have to find and use absolute universal always applicable "rules" and "generalizations" is almost never in the best interest of safety but rather in the interest and pursuit of convenience. I continue to maintain that thoughtful prospective patient implant review is indicated for ALL implant patients."

And:

"Generalizations do exist. Rarely. I personally tend to oppose the ones that are potentially dangerous, or unfounded, or unnecessary, and embrace the ones - the few - that work just about all the time."

However, in a conversation earlier that same year about sternal ties, Dr Kanal appeared to suggest he does not check the approach used for sternal closure:

"I am not aware of any of them presenting MR-specific problems other than artifact potential. There is of course always a theoretical concern of possible heating, but I am not aware of confirmed

reports of these having heated to a point of patient injury to date (even if they contain breaks in the ties, which as you are probably well aware is exceedingly common)."

Dr Shellock replied "I would not make general recommendations regarding the lack of MRI issues for those devices" and gave examples of single wire sternotomy designs that he thought had the potential to be an MRI safety concern.

Dr Kanal then made his approach to sternal wires clear in the following two statements:

"I personally do not hesitate to accept sternotomy sutures for MR scanning (even if they may have a break in them after several years of having been implanted in that patient, as it moderately common), and do not review what material was used or the type of closure utilized or the shape or "make or model" of the suture(s) closure(s) used. My rationale is as I have previously explained in this post-interchange - I am not personally aware of any type in use to this day that would present a significant MR risk."

"TO reiterate, in my practice (and that of any and every MR site in the world of which I am aware) I do not review the type of sternotomy closure used in a given patient before permitting them access to an MR scanner to undergo a requested clinical MR examination. Maybe some could argue that we should! But this would certainly represent a massive shift in the standard of care being utilized to date. Should a given sternotomy closure system appear tin our collective futures that would make this a true clinical concern such as (I believe) Frank is suggesting from the "single wire" scenario posted below, this could of course be revisited in the future."

This directly contradicts Dr Kanal's later statements on generic policies and concerns around the sternal talon. He argues that a generic policy cannot encompass all situations and scenarios but that this is acceptable in the practice of medicine:

"if we ever get to the point where the widespread usage - or even initiation of usage - of closure devices that seem to present practical and real MR safety risks, we can start defining new screening practices if/as needed.

We so commonly hear people attempting to reduce a risk to zero. That is simply not always possible or practical. If you have ever taken a new medication, you should recognize that there is a small but finite risk that you could have died an anaphylactic death from so doing. Zero is not necessarily the only acceptable objective in the real world. Reasonable practices must be defined - by the industry and its experts - and by definition that might be sufficient for the vast majority of patients.

NOTHING in the above precludes ANY site from deciding to go far above and beyond any reasonable approach and exercising whatever additional steps they choose prior to accepting a patient into an MR study. Just recall that canceling a scan or significantly delaying it in urgent or emergent situations is also accompanied by its own risks - and liabilities.

This is the practice of medicine. We don't attempt to issue guarantees, but rather excellent and reasonable practices to the best of our abilities in real world settings."

When reviewing the archived SMRT mailbase emails, one conversation reported a patient complaint of burning below the diaphragm while undergoing a T spine MRI. The patient had cardiac surgery 4 years before the MRI (which included sternal wires) and had some vascular clips visible on a chest x-ray. The patient had safely undergone previous MRIs without incident. The scan had a peak SAR above Normal Mode (2.9 W/kg in the sequence where the patient said it changed from a warming sensation to pain). Respondents questioned whether the MR coil was heating and recommended a

field engineer tests the coil. It was also questioned why the patient wasn't changed into a gown or scrubs but the original poster insisted the patient had no metal on their person. Dr Kanal concluded the conversation stating:

"To date I have not heard any confirmed reports of any patient injuries as a result of sternal wires. Recall that man of these are actually broken (i,.e., they split open over time), with small gaps between them. This would be a theoretical almost worst case scenario for RF-related thermal heating. Yet, for whatever reason, I am not aware of any alleged injuries related to sternal wires. Presumably the cross sectional area of these loops is quite small and (relative to the power being transmitted) insufficient to generate enough heat per time for tissue injury to occur. However, this is purely conjecture, and I must admit that frankly I am mildly surprised that no injuries have been reported/confirmed related to sternal wires to date."

Another conversation from the SMRT archive highlighted than neither Dr Kanal nor Dr Shellock had concerns about scanning a research patient with sternal wires at 3T, despite the lack of clinical benefit to the patient. Dr Shellock highlighted that, at the time of writing in 2014, less was known at 7T.

One post raised the issue that active implants often state they have not been tested with other implanted devices. The specific example was sternal wires alongside a Medtronic REVEAL device. Tobias Gilk suggested the use of a T/R head coil to eliminate the risk from RF but acknowledged he would not have a concern about the combination of these implants provided they cleared individual MR safety checks.

Review of the UK MRI mail base (performed 27/07/21)

Using the search term "sternal" produced two conversations. One highlighted the possibility of nitinol sternal clips. No conditions could be found for these clips but they were reported in the literature to be "MR compatible". The other related to scanning MR Conditional pacemakers/ICDs and the fact that some implant conditions state that no implant must be present – meaning cardiac devices and sternal wires may strictly make the scan off-label.

No search results were returned for "sternum" or "suture".

Internet Search (performed 27/07/21)

The only other GISP from another site was reviewed in this section:

<u>Kings College Hospital (KCH) – 03/03/2016</u>

The outcome of the KCH GISP is that "Sternal wires and other sternal closure devices can be scanned immediately at 1.5T and 3T". The generic conditions summarised for this GISP were:

- Field Strength: Up to 3T
- Spatial gradient: <720 G/cm (Position patient centrally on table and avoid area near covers at entrance to magnet)
- Time since implantation: Immediately

- SAR: Normal mode (< 2 W/kg whole body) - Can scan at first level (<4 W/kg whole body) for head scan
- dB/dt: First level
- Total active scanning time: No restriction

As would be expected, there is a strong overlap in the information identified and the conclusions drawn in the KCH GISP and this detailed review. There is a reference that were not previously identified in the current detailed review (American College of Cardiology Foundation Task Force (Hundley et.al 2010)) but the findings ("Sternal wires associated with cardiac surgery/valve replacement are not considered to be a contraindication to CMR examination") are in agreement with the rest of the literature identified.

All internet searches were performed on Google Chrome. Search terms included "Sternal wires MRI", "Sternal MRI safety", "MRI safety sternal wires" and specific products identified during the review of manufacturer implant information.

The mriquestions.com website described sternal wires as "safe to scan", noting that they are "tightly affixed to chest wall and have no risk of movement or untoward effects on the heart". However there is an acknowledgement of potential to undergo eddy current-induced heating and thus patients should be "advised to notify the technologist if any discomfort develops during the MR procedure".

Another page on mriquestions.com states that sternal wires "can be scanned immediately after placement at all field strengths up to 3T. This is true even if the wires are broken." The potential for heating up to 10 °C was mentioned, particularly at higher field strengths and more complex wire designs (not simple loops).

The same page mentioned some examples of sternal fixation devices and noted "As these metallic devices are tightly adhered to the sternum, there are no concerns about displacement in the magnetic field. In that they are conductive implants with a relatively large amount of metal close to the skin surface, they are considered MR Conditional and justifiable concern exists that significant RF-heating may occur. Caution is advised to limit SAR-intensive sequences and to warn the patient to report heating or discomfort. To my knowledge no injuries serious injuries have occurred, but some patients have reported twitching of the chest muscles due to local tissue eddy currents during rapid gradient stimulation."

The Pectus (Nuss) Bar is also mentioned on the Sternal wires, fixators and implants page of mriquestions.com. This is a metallic bar across the chest which is anchored to the ribcage and (usually) passing under the sternum, used to treat patients with anterior thoracic wall deformities. The author reports that a single company make these and that they are MR Conditional up to 3T. However, we have not included these in the scope of the GISP as these are quite different devices and the Pectus (Nuss) Bar is unlikely to be confused with sternal wires and other fixation devices.

In the advanced section of this page, the author highlights that there is a potential future device for treating pectus excavatum called the Magnetic Mini-Mover. "The system consists of a titanium-encased rare earth magnet implanted subcutaneously onto the lower sternum together with an external removable brace containing another magnet. The system is considered MR Unsafe at all field strengths."

A chapter by Nazarian and coleagues (2009) from the book 'Novel Techniques for Imaging the Heart: Cardiac MR and CT' reported a patient that had "chest discomfort that was classified as "possibly" related to sternal wires; the MRI in this case was discontinued with the resolution of symptoms and no further complications."

The remaining information found in the internet search suggested that patients with sternal wires are safe to undergo MRI.

Summary of locally implanted devices

No local information provided at this time.

Empirical evidence

A search of the implant safety queries received by the NHS Greater Glasgow and Clyde MRI Physics group since the introduction of a generic shared email (~November 2017-July 2021) highlighted 4 cases specifically involving sternal wires. All 4 of these cases were recommended to scan without knowing the make or model of the sternal wire. In one case the sternal wire was known to be made from stainless steel and in another case the patient also had a pacemaker implanted. We are not aware of any issues arising from these scans.

Anecdotal data

Review of Facebook MRI safety groups (performed 30/7/21):

UK MRI Safety Group:

Search terms included "sternal", "sternum" and "talon". Talon was included as Dr Kanal reported concerns about the sternal talon in the SMRT mailbase. No posts were identified that were relevant to this GISP.

MRI World:

Search terms included "sternal", "sternum" and "talon". No posts were identified that were relevant to this GISP.

MRI Safety Group:

Search terms included "sternal" and "talon" and identified 73 posts. It is worth noting that some of the older comments have been deleted (including some from Dr Shellock), which hinders interpretation.

Generally, posters had little concern around the safety of sternal wires, including immediately post-implantation. Dr Shellock suggests that these should be treated like any other metallic implant, e.g. check make and model, orientation of wires, MR safety labelling etc., but others suggest it is impractical and unnecessary to do this given the low risk of heating. There was more concern around other sternal fixation devices but this is primarily around the lack of formal MR safety testing/labelling rather than anything known to be inherently unsafe.

The RTI surgical sternal cable (figure of 8 system) was mentioned in 2016. Dr Shellock said he was in the process of testing it but there doesn't appear to be anything on the manufacturer or Dr

Shellock's website. He mentioned the multiple configurations the implant could be implanted with so perhaps that caused an issue with the MR safety labelling. In any case, Dr Shellock seemed sufficiently concerned with heating to indicate a T/R head coil may be advisable for the specific research participant.

Broken sternal wires are discussed a few times. Often, the use of a T/R coil is suggested to minimise the risk. However, many posters reported previous MRI scans of patients with broken sternal wires and others questioned how often these would have been scanned without knowing they are broken given they are often scanned without checking a chest x-ray. One poster said one patient's wires had "exploded" but that they were all retained in the chest wall (not in the heart or lungs) and the patient was able to be scanned safely after Radiologist sign off.

A poster asked if there were any concerns scanning sedated patients with sternal wires at 3T. The general consensus seemed to be that this is safe but Dr Shellock was keen to know the type and configuration of the wires first.

In 2017, a contributor reported that a patient with sternal wires reported burning in their chest and had to stop the MRI scan but the patient's chest did not feel warm to the radiographer. Dr Shellock suggested this is likely to be rapid vibration from the metallic implants. Another poster suggested it might have been a claustrophobic patient. A further responder said that they had been scanning sternal wires since 1988 and only ever had two patients report "stinging and burning along the skin over their sternum", and only these two patients no longer get MRI. In other posts, two more contributors reported that a patient of theirs with sternal wires reported pain during their MRI scan.

Mr Gilk has said on a few occasions that sternal wires represent low risk of potential harm and that there should not be any wait post-implantation of sternal wires.

There were a few posts discussing the KLS Martin Sternal Talon (Figure 1). Dr Shellock suggests that they should be treated as MR Unlabelled and therefore a Radiologist should perform a risk vs. benefit decision whether to scan. He points out that whilst the article by Levin and colleagues (2010) states it is "MRI compatible", the article does not provide proper MRI testing information to support this statement. It was reported in 2016 that Dr Shellock had tested them previously and listed them as MR Conditional 6 on his mrisafety.com website but this has since been removed. All links to the KLS Martin website do not work any longer but a screenshot of part of the guidance has been copied below which mentions "irritating artifacts" and "MRIs are not permitted unless potential patient injury can definitely be ruled out" (Figure 2). Furthermore, one contributor mentioned that their department received a memo from KLS Martin that their "FDA testing was obsolete due to revised FDA guidelines".

NOTICE

Potential misinterpretation of examination results!

Implant systems can cause irritating artifacts in CT scans and MRIs.

⚠WARNING

Danger of burns or accidental implant movement when using magnetic resonance imaging (MRIs)!

Due to the further development and increasingly higher energy density of MRI systems, an adverse effect on implants cannot be ruled out in the future. Therefore, MRIs are not permitted unless potential patient injury can definitely be ruled out.

Due to the magnetic field, MRIs pose a danger of heating up or dislocating potentially susceptible implants.

Figure 2: Extract from KLS Martin's Sternal Talon MRI guidance document

Dr Shellock states that the main concern for the KLS Martin Sternal Talon is MRI related heating and that the "magnetic field interactions (force and torque) are non-issues". A few contributors reported that they have scanned this device on a 1.5T system, totalling four patients, following Radiologist approval, and no adverse effects were noted during or post-scan. Another few contributors had known of a patient scanned with this device but provided no further details. A T/R coil was suggested to reduce the risk.

A patient with sternal talons reported heating when undergoing an MR knee scan. Dr Shellock said that this was impossible if a T/R knee coil was used but suggested gradient induced vibration could have been perceived as heating.

The Waston Medical sternal fixation system was identified through this search. It appears to be MR Unlabelled but I sent an enquiry to the company for an update. The response from Waston Medical confirmed that it is MR Unlabelled but that they are currently performing the MRI tests and expect it to be "safe in MRI" as it is pure titanium. I highlighted the risk from RF heating in my response and asked to be updated once the MRI safety testing was complete. Until this time, it must be considered MR Unlabelled.

Summary of risks from implant associated with static field, RF and imaging gradients

Static magnetic field

All implants were found to be either MR safe materials, non-ferromagnetic (titanium or nitinol) or weakly ferromagnetic stainless steel. Sternal wires and other fixation devices are, by design, held firmly and would not be expected to move in a static magnetic field up to 3T. There is little information with respect to 7T testing.

RF field

Sternal wires form loops and have increasingly complex configurations and therefore might be expected to pose a heating risk. However, in practice, there is strong evidence that sternal wires can be scanned safely without any adverse effects. A small number of anecdotal reports of potential heating have been identified in this review but there has been no burns reported as all scans were stopped and heating subsided. Dr Shellock has previously suggested that this perceived heating may actually be due to the rapid vibration of the metallic implant. It is important to note that these reported potential heating incidents are very low compared to the number of sternal wires scanned. This review did not identify any concerns in respect to scanning patients that are unable to report heating (e.g. those under general anaesthetic).

Sternal wires have been known to break, which has the potential to increase the risk of localised heating and burns. However, in practice, and in modelling identified in the literature review, this has not been observed.

Other sternal devices are a greater concern with respect to heating, many are MR Unlabelled and have theoretical concerns of heating due to implant designs. However, given most centres do not check sternal closure method, it is likely these devices have been scanned many times without incident.

Risk of stimulation of adjacent tissue (e.g. cardiac stimulation)

This was mentioned as a theoretical possibility by Dr Kanal on the SMRT mailbase. There has been one report of "twitching of the chest muscles due to local tissue eddy currents during rapid gradient stimulation" but cardiac stimulation has never been reported. The risk of stimulation of adjacent tissues due to the gradients is thus considered low.

Consideration of risks, specific to this implant category

Typically, when sternal closure is required, the patient has undergone major surgery. It is important to check whether there are any other implants added during this surgery.

It is important to make it clear that this GISP relates only to passive wires used to close the sternum and not any active wires that may be implanted close to the sternum.

Many MR Conditions state that the conditions only apply when the needle has been removed from the sternal wire. As this is common practice, this is not expected to present a problem.

There is a small risk that pectus (Nuss) bars and pectus excavatum devices are assumed to be included in this GISP.

Sternal fixation devices appear to be a developing field and thus the potential for new unsafe devices may be greater.

Conclusion

MRI Generic Implant Safety Policy (GISP): Detailed review v11

This detailed review suggests that sternal wires and sternal fixation devices are suitable for a GISP. The proposed exceptions and policy statement is detailed below.

Notable exceptions:

This GISP relates only to passive sternal wires and sternal fixation devices and thus active wires (e.g. pacing wires) are excluded from this GISP.

Pectus (Nuss) bars and pectus excavatum devices are not covered in this GISP.

Policy statement:

Patients with sternal wires or fixation devices are more likely to have other implanted devices. Check for other implanted devices and follow any conditions relating to those.

Sternal wires or sternal fixation devices can be scanned immediately after implantation in Normal Operating Mode on 1.5T or 3T scanners. Where possible, please ask the patient to press the buzzer if they feel any heating or unusual sensations.

When the sternum is in the imaging field of view, look to keep the SAR as low as reasonably practical, particularly if the implant is known to be a sternal fixation device such as the sternal talon. This can be done by only running sequences that are required and interleaving low SAR sequences with any high SAR sequences that are required.

Appendix

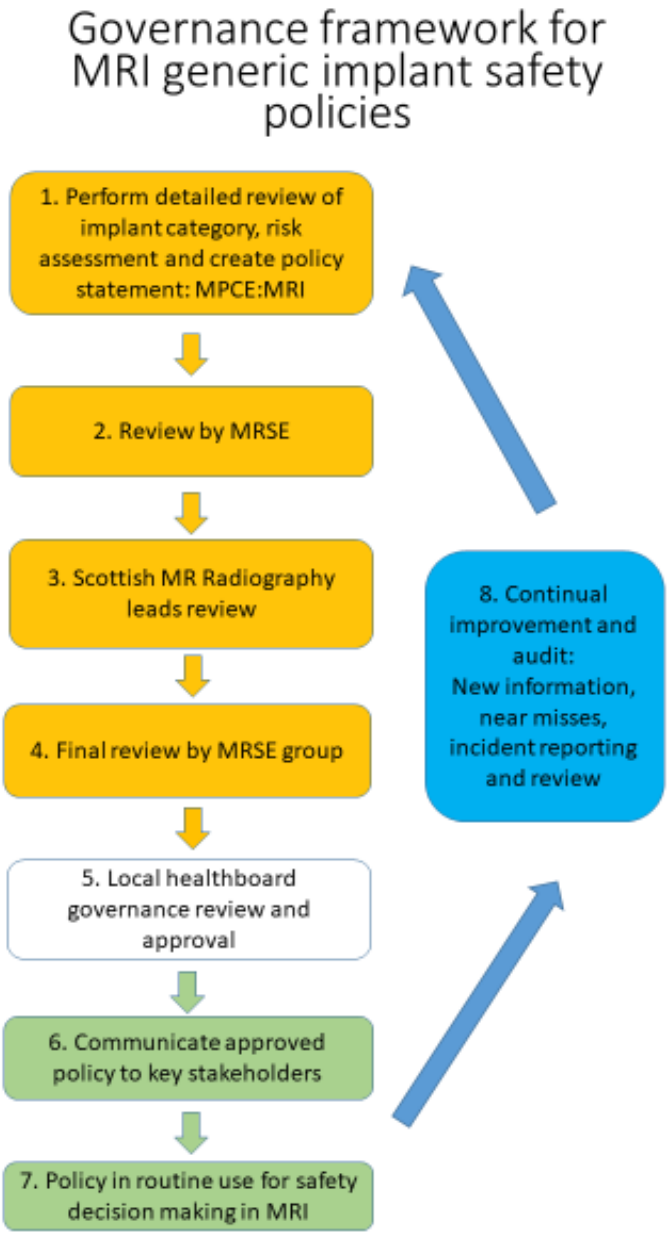

Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment

Guidance notes on Governance framework for MRI generic implant safety policies

- General note. At various stages throughout this governance framework, the process of review, rejection and re-review will occur. For simplicity, such feedback loops are not shown explicitly. However, such iterations are to be expected. The purpose here is to define the main components of the governance framework and not necessarily the detail of how they will interact with one another.
- Stages 1-4 : Policy under review
- Stage 1. MPCE: MRI to perform detailed review of implant category, risk assessment summarising detailed review and define implant policy statement. Policy statement may be accompanied by a work flow / decision tree where appropriate.
- Stage 2. Review all of above by MRSE
- Stage 3: (optional) Review by Clinical Subject Matter Expert. In some circumstances it may be advantageous to include a review of a clinical subject matter expert. This is likely someone who is involved with implanting or managing devices and has a deep knowledge of the devices practical use and historical use.
- Stage 4. Nominated person(s) from Scottish MR radiography leads group to review detailed review, risk assessment and policy. Report back to author and MR leads Chair with recommendation.
- Stage 5: Author to review MR radiography leads additions and amendments. Then progress to MRSE group for final review.
- Stage 6: If both MPCE: MRI MRSE group and MR Radiography lead representatives are in agreement, the detailed review, risk assessment and policy will be commended to local health boards for adoption. If unhappy, the policy document will be sent back to MPCE: MRI for further work or will be not be progressed.
- Stage 7. Local health board governance group to approve local adoption of policy. Process/ group name may vary across NHS Scotland boards.
- Stage 7-8: Policy approved
- Stage 7. Communicate policy via various means to key stakeholders e.g. radiographers, radiologists , MRI physics
- Stage 8. Policy to be implemented in routine clinical use in MRI departments.
- Stage 9: Continual improvement
- Stage 9. Note that it is crucial that new information or incidents which cast doubt on the robustness of a policy are fed back to MRI radiography leads and to the MRI physics staff and MPCE: MRI. Similarly, devices which breach the policy or could be classed as notable exceptions to the policy must also be highlighted. These policies will only be robust if we agree to share information about incidents with one another.

Figure AY: Notes on Governance Framework for Generic Implant Safety Policies

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