MRI Generic Implant Safety Policy (GISP): Detailed review

'Guidance in italics'

Title: Scleral Buckle

Executive summary:

Scleral buckling is a procedure used to repair retinal detachment. In most cases a silicone band is used with no metal, but occasionally a metal clip or tack might be used to secure the band. Any clips or tacks are usually tantalum, which is not ferromagnetic and is suitable for MRI. Several publications state that scleral buckles are safe for MRI and a recent consensus paper states screening for scleral buckles is not necessary. I would conclude that scanning a patient who has had a scleral buckle procedure is low risk.

There is one published example of an MR-unsafe stainless steel retinal tack (the Western European tack, tested in 1990). Several papers and MR safety groups recommend screening for retinal tacks and seeking information on make and model. I have found no evidence that this tack was used as part of a scleral buckling procedure. There is a 2017 experimental study performed on cadavers which used magnets as part of the scleral buckle. The risk assessment for scleral buckles should be reviewed yearly to check whether this sort of device is being developed.

'Insert implant/ device category'

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

'Generic text to be added, ignore for now' (This may come out of this document on webpage)

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

'Generic text to be added, ignore for now'' (This may come out of this document on webpage)

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
- Failing to identify a specific patient implant has the potential to mis-identify an implant due to some misunderstanding
- 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'

'Briefly outline the clinical use of the implant/device category. This might include but is not limited to: details of the function of the implant or device, implant procedure, implant materials commonly used, clinical cohorts where the device is typically used '

Scleral buckling is a procedure used to repair retinal detachment. In most cases a silicone band is used with no metal, but occasionally a metal clip or tack might be used to secure the band. Any clips or tacks are usually tantalum, although (rare) examples of other materials are detailed below. The band is usually left in place permanently. Any procedure that results in indentation of the eye wall is referred to as scleral buckling.

Dates used:

Scleral buckling was first used experimentally by ophthalmic surgeons in 1937. By the early 1960s, scleral buckling became the method of choice when the development of new materials, particularly silicone, offered surgeons new opportunities for improving patient care. Tantalum clips were first used with scleral buckles in the 1960s.

Appearance on imaging (from [Reiter, 2015] and [Lane, 2003]):

Solid silicone rubber devices are hyperattenuating at CT, whereas silicone sponge devices appear as a structure with air attenuation deforming the globe. In MR images, indentation of the eye may be the only clue to their presence. All current scleral buckle devices are MR imaging safe [Reiter, 2015]. Decades ago, the free ends of encircling elements were secured with small metallic clips, but now small silicone sleeves are used. These clips were composed of tantalum, a nonferrous metal, and are suitable for MRI. Tantalum clips are seen on radiographs and CT images as radiopaque structures, and they create susceptibility artefact at MR imaging.

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

'Briefly outline the challenge MRI units may face when patients present with these implants'

Hypothesis

'You may wish to make a statement here which you can later refer back to in regard to your initial impression on the general MRI safety status of this implant category'

Initial impression: scleral buckling usually uses a silicone band with no metal. Where a metal clip is used, it is very unlikely to be ferromagnetic. The hypothesis is that scanning a patient who has had a scleral buckle procedure is low risk.

MRI Generic Implant Safety Policy (GISP): Detailed review v10

Aim

The aim is to provide a detailed review from all available sources of the MRI safety status of *scleral buckling*. 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 of 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

On the MRIsafety.com "The list", accessed on 15/1/2020, a search for "scleral" gave no results. A search for "buckle" gave no results. A search for "ocular" gave 59 results. 36 of these are lens implants. 2 are eyelid springs. The others are:

- 4 tantalum clips by Mira (safe).
- 2 tantalum clips by Storz Instrument Co. (safe).
- Elastimide Silicone Aspheric LOL by STAAR surgical company (safe)
- Hydrus Aqiueous Implant by Ivantis (safe).
- MORCHER Capsular Tension Ring (not relevant, used at lens for cataracts, – safe)
- Retisert implant by Baush and Lamb (safe).
- Single tantalum clip (safe)
- Sensimed Triggerfish intraocular pressure monitor by Sensimed (unsafe, but not relevant for scleral buckling).
- 7 retinal tacks – one of these is unsafe made by Western European, material is martensitic stainless steel [Bakshandeh, 1993].
- Troutman magnetic ocular implant (unsafe).
- "Unitech round wire eye spring" (unsafe) – I do not know if it is an eyelid spring or used elsewhere in the eye. (I think this is Unitec corporation).

Under safety topics, scleral buckle is safety infor ID# 274. The article acknowledges that most scleral buckles involve no metal, and in the rare cases that a metallic clip is used it is likely to be tantalum. Tantalum clips are acceptable for patients undergoing MRI procedures. However, the article states "Some metallic clips may pose a risk to patients undergoing MRI procedures".

'Review the MRIsafety.com website for an overview the safety status of the implant category of concern as well as recording publications discussing incidents or injuries as a result of the implant category under review.

Review of manufacturer implant information

'Include here information on manufacturer implant documentation such as the MRI safety statements from the instructions for use (IFU) documents.'

Review of the peer reviewed literature

'Review the peer reviewed scientific literature for evidence of publications relating to the MRI safety status of the implants of concern as well as publications discussing incidents or injuries as a result of the implant under review.

There are some well-known papers and relevant information in general MR safety literature. The go-to paper that is often cited in discussion of ocular implants is 'Postoperative Imaging of the Orbital Contents' [Reiter, 2015]. The paper states that "regardless of their composition, all current scleral buckle devices are MR imaging safe. In the past, tantalum clips were used to hold scleral buckle devices in place, although, currently, sutures alone are preferred. Tantalum is a nonferromagnetic metal and, thus, is considered MR imaging safe [Bakshandeh, 1993]." The table on pg 223 [Reiter, 2015] states "Scleral buckles: All types are safe, including titanium clips".

On 15/1/2020, a search on pubmed for 'scleral buckling mri' yielded 35 results. Two abstracts were unavailable, but study title did not indicate MRI safety relevant information. 32 abstracts were not related to MRI safety and were imaging studies or case reports. The one relevant paper [Bakshandeh, 1993] performed ex-vivo deflection testing of 7 tantalum clips and found none deflected in the magnetic field.

A search for 'magnetic resonance retinal tacks' in pubmed shows 2 studies in the Archives of Ophthalmology. In the first letter [Joondeph, 1987], a titanium retinal tack (Cooper-Vision) and a cobalt-nickel tack (Grieshaber) were shown to have no deflection in a 1.5T scanner. The second letter [Albert, 1990] shows the **Western European tack made from martensitic stainless steel**, displaced by 90° in the 1.5T field. The others (Norton staple, Ruby, Coopervision, Duke, BascomPalmerEye Institute) showed no movement. The Western European tack is given as an example of MR unsafe tack in several other papers, all referencing back to this 1990 study. I found no other examples of MR unsafe tacks in the literature.

A search for 'scleral buckle magnetic' on pubmed (any field) yields 45 results. Most relate to MRI for imaging and are not relevant for safety. Two experimental studies described the use of magnetic implants in retinal repair. The first study, in Germany, [Eckardt, 1984] used **magnetic implants for transscleral fixation of a detached retina** on 3 patients. A small metal pin is fixed on the surface of the retina and is held in position by an extraocular magnet. The second study, in Russia, [Kazimirova, 2017] described modified **scleral buckling using magnetic buckles** for additional fixation of the retina. The proposed device consists of an episcleral magnetic buckle and endovitreal magnetic buckles. The episcleral magnetic buckle contains one or more permanent magnets (neodymium-iron-boron powders). The endovitreal magnetic buckles are small elements made of silicone elastomer filled with magnetic particles. The technique was assessed on cadavers. No other examples of this were found in the literature search.

Scleral buckles and retinal tacks are covered in a recent consensus paper "MRI safety and devices: An update and expert consensus", [Jabehdar, 2020]. Recommendations were reached by a panel of 10 radiologists in U.S.A. and Canada. Following a literature review and review of manufacturer information by one author, several recommendations were generated. All authors reviewed the recommendations, and a Delphi method was used to evaluate the recommendations; those recommendations that did not reach 100% consensus were removed. For scleral buckles and retinal

tacks, consensus was achieved at Delphi round 2, following minutes of round 1 and structured discussion on any disagreements. The recommendations are:

1. With regards to MRI safety, screening for scleral buckles is not necessary.
2. With regards to MRI safety, screening for retinal tacks, including model and manufacturer should be sought as some retinal tacks are not safe to scan.

For retinal tacks, due to the limited number of studies, these should be considered MR Unsafe and patients should be screened to identify MR Unsafe models. It was also concluded that retinal tacks for the Argus II retinal prosthesis system are MR Conditional at 1.5T and 3T [da Cruz, 2016 and Weiland, 2012]. The paper states 'No reports on the use of metallic nontantalum clips for scleral buckling were found in the literature'. The [Kazimirova, 2017] study which used magnets is not mentioned.

Review of the SMRT MR Technologist mail base

'Review the SMRT MR Technologist mail base for evidence of incidents or injuries as a result of the implant under review and also any information on the MRI safety status of this implant type'

On 15/1/2020, search of "scleral", search of "buckle", search of "buckling" in smrt-mr-technologists google group yielded no results. A search for "retinal tack" yielded 2 results, neither was relevant.

Review of the UK MRI mail base

'Review the MRI Physics JISCMAIL mail service for evidence of incidents, injuries as a result of the implant under review and also any information on the MRI safety status of this implant type'

Scleral – no results

Buckle – no results

Retinal – 3 matches, none safety related.

Ocular – 6 results: December 2016 eyelid weights. One physicist mentioned Postoperative Imaging of the Orbital Contents paper by Reiter et al.

Internet Search

'Summary of information found as a result of a general internet search, please record search terms and web browser used'

A search for "scleral" in the UK MRI safety facebook group on 15/01/2020 gave no results. A search of "scleral" in the MRI Safety facebook group on 15/01/2020 showed posts with comments from several concerned MR technologists but no examples of specific implants that are unsafe. Several MR technologists stated they have seen unsafe ones, but no further information was given. The level of safety knowledge within the group is very variable, and without further details of the unsafe implants I suspect the comments reflect some confusion. Some technologists suggest an x-ray is required to confirm there is no metal, and if there is metal, further information on the surgery is required or a risk benefit decision by the radiologist. Experts in the group (Frank Shellock and Tobias Gilk) comment that any metal should be treated as unknown metallic implant and risk/benefit performed accordingly.

Summary of locally implanted devices *'Optional section'*

'The aim of the generic implant safety policies is to be exactly that, generic. That is, the policy should hold true throughout the world. However, in some circumstances, it may be desirable to insert a local caveat or to capture information on a local context. For example, if a notable exception is recorded for a particular device in general terms, one may wish to record information on local implants alone such as to form the basis of a locally defined decision making pathway. On the other hand, some health boards (perhaps the larger ones) may find it difficult to get a handle on locally implanted devices and to establish robust processes for ongoing assessment of such devices, thus, this section may be deemed undesirable '

Empirical evidence

'This section is included to capture data and experience from real world use and knowledge of clinical MRI in patients with these implants i.e. whilst a formal documented policy may not have been in place previously, sites and persons may have considerable experience in scanning patients with these devices. This real world, practical experience should not be ignored. The expectation here is that MRI modality leads may be able to contribute a great deal of useful information in this section. '

Anecdotal data

'This section is included to capture data from any resource which does not have a strong scientific basis, this might include but is not limited to: anecdotal patient or radiography reports, unverified statements e.g. as noted on safety message boards or mailing lists. The expectation is that MRI modality leads may be able to contribute information in this section. '

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

'From the evidence gathered above, summarise the perceived risks of the implant category in the context of the MRI hardware'

The main risk is from the static magnetic field: if a ferromagnetic component has been used to secure the buckle to the retina, there is a risk of deflection (rotation or translation). The likelihood that a magnetic component has been used seems very low. If a magnetic component has been used the likelihood that it will deflect is quite high. The likelihood that this deflection will cause damage to the eye is more difficult to assess – in the single study that looked at an MR-unsafe retinal tack [Albert, 1990], the deflection caused the tack to move out of the eye.

Any metallic components are small and therefore risks from RF heating are negligible. There are no active components or long wires or components large enough to induce eddy currents, so risk from imaging gradients are negligible.

Consideration of risks, specific to this implant category

'Here we record information on risks specific to this implant category, this may include but is not limited to notable exceptions, the potential for misunderstandings between the implant category under consideration and other devices and the potential for new unsafe devices of this type to be released'

Potential for misunderstandings: Scleral buckling could perhaps be confused with other types of retinal repair, which may be more likely to use retinal tacks.

Potential for new unsafe devices: One proposed device involving magnets, from a study in Russia [Kazimirova, 2017]. Only performed on cadavers so far, no clinical trials found, no manufacturer for the device.

Discussion (optional)

'If there are points worthy of discussion, in particular, matters pertaining to limitations of the review process or method, these may be included here. However, this section may be surplus in many instances'

All literature searches have indicated that scleral buckles are usually MRI safe with no metal, and in those cases where a metal tack is used to secure the buckle the vast majority are tantalum and are safe for MRI.

There are several papers that cover the MR safety of scleral buckles and retinal tacks, which may give the impression that there is a lot of original independent evidence. However, they all reference [Bakshandeh, 1993] as evidence of safety of tantalum clips, and [Albert, 1990] as evidence of an MR-unsafe retinal tack.

There is one example given of a MR-unsafe stainless steel retinal tack (the Western European tack, tested in 1990).

There are two examples of experimental devices using magnets to secure the band. These were published in 1984 (implanted in patients, in Germany) and 2017 (experimental studies on cadavers, in Russia). I have not found evidence that these were more widely used and there are no further publications.

Conclusion

'Summarise the above into a concise closing statement. You may wish to refer back to your hypothesis at this point. You may also wish to highlight the conclusion and any notable exceptions or salient points from empirical experience. The conclusion here will likely be very close to the executive summary at the beginning of the detailed review'

All literature searches have indicated that scleral buckles are usually MRI safe with no metal, and in those cases where a metal tack or clip is used to secure the buckle the vast majority are tantalum and are safe for MRI. Several publications state that scleral buckles are safe for MRI and further screening is not necessary. I would conclude that scanning a patient who has had a scleral buckle procedure is low risk.

There is one published example of an MR-unsafe stainless steel retinal tack (the Western European tack, tested in 1990). I have found no evidence that this tack was used as part of a scleral buckling procedure. There is a 2017 experimental study performed on cadavers which used magnets as part of the scleral buckle. The risk assessment for scleral buckles should be reviewed yearly to check whether this sort of device is being developed.

Appendix

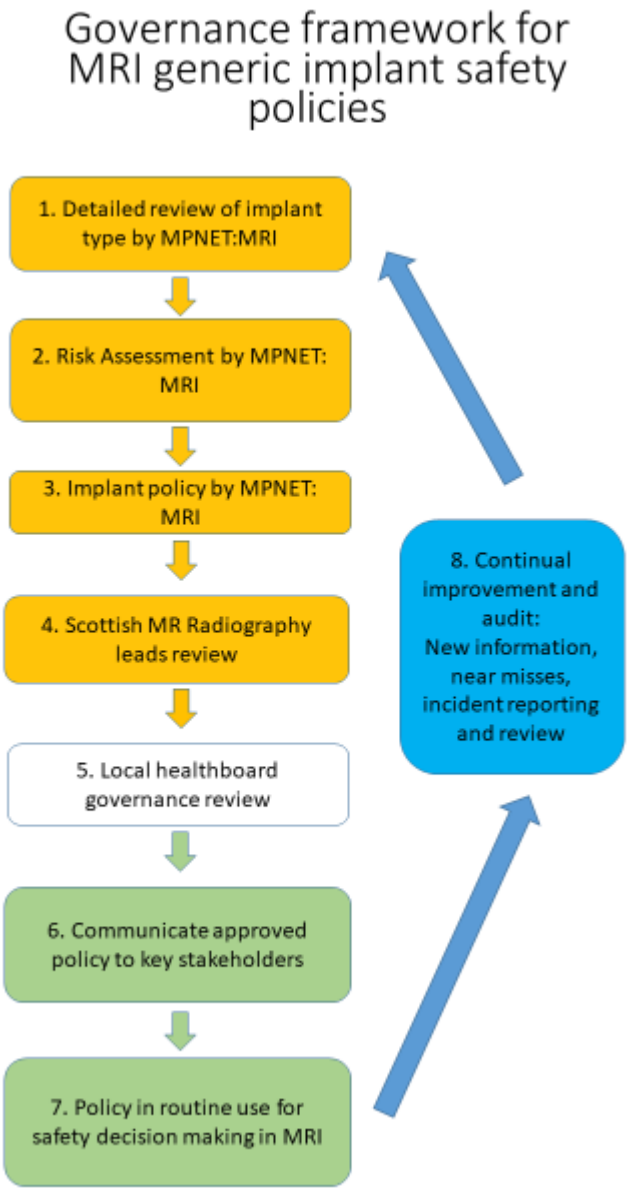
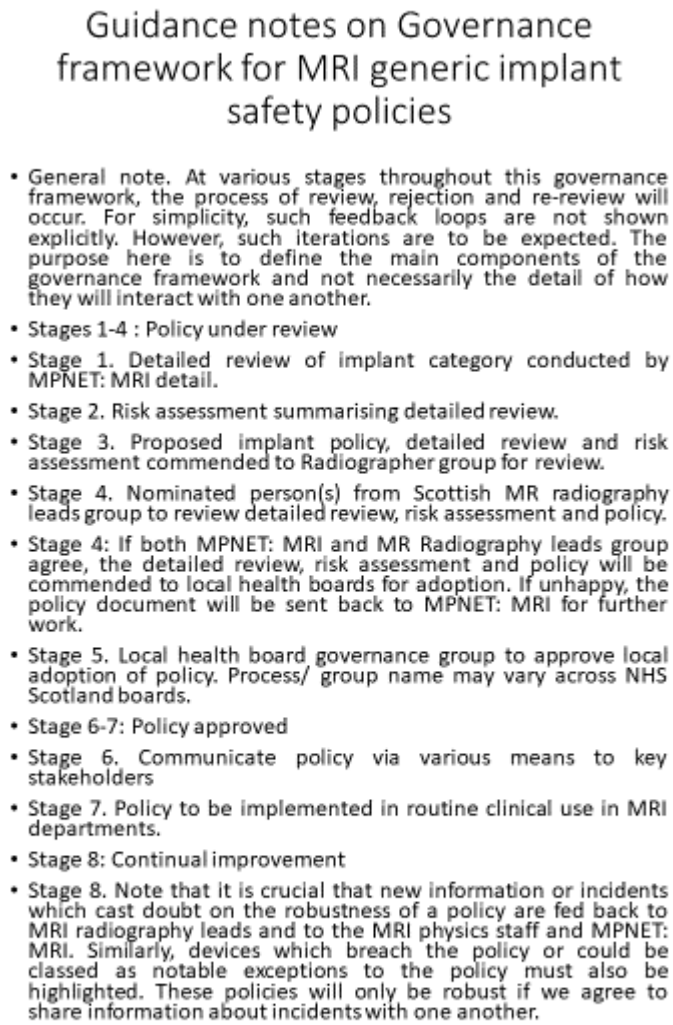


Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment



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. Detailed review of implant category conducted by MPNET: MRI detail.
- Stage 2. Risk assessment summarising detailed review.
- Stage 3. Proposed implant policy, detailed review and risk assessment commended to Radiographer group for review.
- Stage 4. Nominated person(s) from Scottish MR radiography leads group to review detailed review, risk assessment and policy.
- Stage 4: If both MPNET: MRI and MR Radiography leads group agree, 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 MPNET: MRI for further work.
- Stage 5. Local health board governance group to approve local adoption of policy. Process/ group name may vary across NHS Scotland boards.
- Stage 6-7: Policy approved
- Stage 6. Communicate policy via various means to key stakeholders
- Stage 7. Policy to be implemented in routine clinical use in MRI departments.
- Stage 8: Continual improvement
- Stage 8. 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 MPNET: 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

References

'Include any relevant references used throughout this detailed review here'

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