MRI Generic Implant Safety Policy (GISP): Detailed review

Title: Intraorbital (eye) Lens

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 current review:

Date of next review: Annually/ pending new information.

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'

Implant Procedure and Clinical Cohorts where implant is typically used:

Cataracts causes the lens of the eye to become cloudy which eventually affects vision and can limit a patient's activities or daily life. A lensectomy with artificial intraocular lens (IOL) implantation (pseudophakia) is a surgical option for treating cataracts [1]. This involves the removal of the natural intraocular (crystalline) lens, via phacoemulsification, for an artificial lens which may be positioned anteriorly or posteriorly to the iris [1] (see Fig. 1). Posterior placement is more commonly performed given the high complication rates associated with anterior chamber IOL implantation. However, placement of the IOL in the ciliary sulcus or anterior chamber is sometimes required [2] – indications for the latter may include lens dislocation, loss of posterior capsular support during surgery, and selected cases of secondary implantation [1]. Patients may undergo piggyback IOL implantation where two or more artificial IOLs are implanted in one eye and used to treat high hyperopia (farsightedness) following cataract removal in which a single high-power IOL implant would not have provided sufficient power.

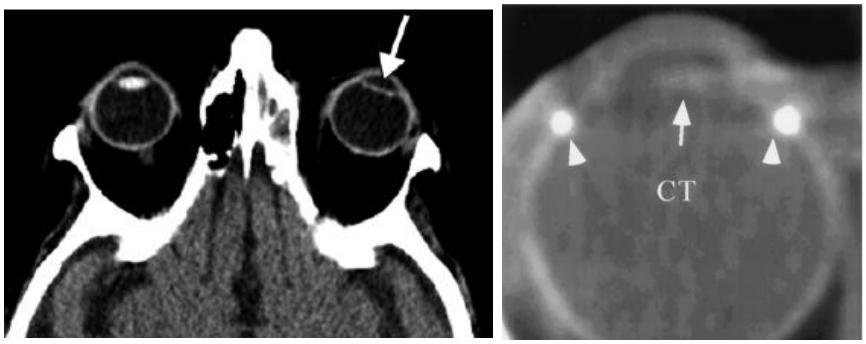


Figure 1. LEFT: Axial CT depicting posterior chamber artificial IOL (arrow) as a thin hyperattenuating linear structure. This may be compared to the other eye for which the native lens remains intact [1]. RIGHT: Axial CT depicting anterior chamber artificial IOL (arrow) and silicone band (arrowheads) [6].

Artificial IOL implantation may also take place during refractive lens surgery, but cataract surgery is the most commonly performed [3] [4]. In the case of refractive lens surgery, the procedure is similar to that for cataract surgery, but the patient does not have cataracts – instead, they have been diagnosed with myopia (near-sight1dness) or hyperopia (farsightedness) and require a refractive IOL for treatment [5]. Phakic IOL implementation describes the treatment offered for correcting myopia and involves securing an artificial IOL to the iris whilst preserving the native (crystalline) lens intact.

Implant Components and Materials:

The basic components of an IOL implant include the central optic portion and two haptics that hold the device in position (see Fig. 2, adapted from [1]) – the haptic loops maintain the position of the IOL and prevent the lens from dislocation and eventually become encased and secured by fibrous tissue [1]. Synonyms for haptics include footplates [2].

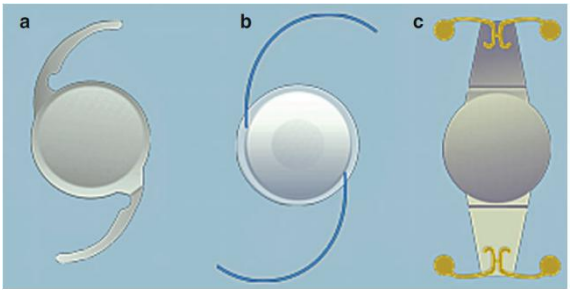


Figure 2. Schematic of different types of intraocular lens implants, including (a) Technis IOL, (b) ReZoom, (c) Crytalens..

The authors in [1] and [6] discuss the materials involved in IOL designs and from an MRI safety perspective, would be regarded as MRI Safe. These materials include: polymethyl methacrylate (PMMA), polypropylene (Prolene), silicone, water-compatible polyhydroxyethyl methacrylate (hydrogel), or polyethylene (Dacron). Most rigid IOL optics are composed of PMMA, and the haptics

are composed of either PMMA or Prolene, while flexible (foldable) IOLs are composed of either silicone or polyhydroxyethylmethacrylate (PHEMA).

In 1982, Leonard and Rommel reported on 30 years of progress in lens implantation [7]. This highlights that the first IOL to be implanted and recorded was in 1797, with the introduction of modern lens implantation (made of fully polymerised methylmethacrylate (PMMA), <1cm in diameter) in 1948. Single material IOLs, optic and haptic parts made entirely of PMMA, include the Copeland lens, the Choyce lens, and the Pearce lens. Two material lenses include the Iris Clip Lens, the Sputnik Lens and the Medallion Lens (this list is not exhaustive). Here, the loops are made from Nylon and in some models, polypropylene. Three-material lenses include the Platinum Clip lens which has the optic made from PMMA, the loops made form Nylon, and the stave made from platinum. The authors also mention that stainless steel thread was used by surgeons as an intraocular suture material.

The authors in [4] and MRIquestions.com [8] also discuss the variety of IOLs on the market in which some contain different colours (blue-blocking IOLs or IOLs made with coloured haptics) whilst others may be classed as "clear". Consistent with Leonard and Rommel's report, there is mention of older models of IOLs containing metal and that metallic loops made of platinum, iridium or titanium may be attached to the lens for suturing purposes.

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'

A range of eye implants exist including retinal tacks, scleral buckles, eyelid weights/springs, and Glaucoma devices in addition to artificial IOLs. MRI units may face the challenge of recognising an artificial IOL on clinical images, e.g., CT, and distinguishing this from other eye implants, if unaware of what to look for. Additionally, artificial IOLs are not the same as contact lenses which may cause confusion during patient screening. The MHRA outline some ocular implants which may present risks to patients undertaking an MRI scan [9].

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 impressions on the general MRI safety status of this implant category are the majority of artificial IOLs are MRI Safe with the exception of those that contain metal materials and therefore would be classed MRI Conditional but with no real safety concerns.

Aim

The aim is to provide a detailed review from all available sources in regard to the MRI safety status of intraorbital lenses. 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 intraorbital lenses. 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

'Review the MRIsafety.com website for an overview of 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.

A review of MRIsafety.com highlights 96 results when using the search term "lens" under the safety topic "Ocular implants, Lens implants and Devices". Of these 96 results, the following makes and models have been labelled MRI Unsafe:

- Intraocular Lens, Models 12A, 12P, 12S, 24P, 31P, 42P, 61P, 71, 71B, 71M, 71P, 71PC, 71R, 75M, 75P, EXP D. Manufacturer: Bausch & Lomb.
- Precision Cosmet Lens, Models 3110, 3120, 5110, 5120. Manufacturer: Bausch & Lomb.

The MRI safety profile of these models have been investigated in this review process, the outcomes of which are considered in Section "Review of the MR Safety Facebook Page" of this Detailed Review.

The remaining implants on this list have been labelled MRI Safe and the following statement quoted from the website regarding eye lens implants: "many lens implants pose no hazard to the patient during an MRI procedure since they are not made from metallic or conducting materials".

No publications could be found that discuss incidents or injuries as a result of being scanned in MRI with an eye lens implant in-situ.

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.

Gwyneth A. van Rijn et al [4] tested 23 intraocular lenses (selection based on presence of dyes and metals and different geometric shapes) at 7 Tesla. IOLs tested included those from the following manufacturers: Advanced Medical Optics, Alcon, Bausch and Lomb, Carl Zeiss, Hoya Lens, Oculentis, and Ophtec. This study marks the first to have considered the MRI safety of IOLs at 7T and acknowledges previous MRI safety testing of IOLs at a lower field strength of 1.0T. Gwyneth A. van Rijn et al detected no significant displacement or RF-induced heating with a max temperature rise of 0.25 degrees Celsius measured for the dyed IOLs compared with a max temperature rise of 0.15 degrees Celsius for the metal-containing IOL (platinum clip lens). The temperature rises of all IOLs under testing did not significantly differ from that of the control gel in which the implants were placed during scanning and therefore suggests no extra contribution to temperature rise was invoked by the presence of the IOL. These findings are consistent with the ASTM findings which states that "*a device with deployed dimensions of less than 2 cm in all directions may not need to be tested with respect to RF-induced heating, as it is expected to generate ΔT of less than 2°C over 1 h of exposure at 1.5 T/64-MHz or 3 T/128-MHz frequencies*" [10]. RF-induced heating of dyed and metal-containing IOLs is therefore expected to be negligible given the size of the implant and its components under consideration. IOLs containing ferromagnetic components are at risk of movement or rotation due to

the presence of translational and torque forces in an MRI Environment. Physical movement of the IOL may cause damage to the eye. Whilst the metal-containing IOL tested by Gwyneth A. van Rijn et al was non-ferromagnetic (platinum component), the authors put forward the following argument which eases safety concerns relating to an IOL that may contain ferromagnetic components: "*…taking into consideration that in-vivo resistance is provided by ocular tissue, a maximum deflection angle of 1 degree due to the magnetic field is highly unlikely to result in any movement of the IOLs in-vivo; thus the risk of displacement caused by the magnetic force is smaller than the risk that is imposed by normal daily activity in the Earth's gravitational field.*"

Keizer et al [11] considered the MRI safety of IOLs with and without metallic loops, and of ocular steelwire sutures at 0.5T and 1.0T. With their work published in 1986, Keizer et al consider IOLs which were used at the current time, and these included: Binkhorst iridocapsular lenses with platinum-iridium or titanium loops, the Worst Platinum Clip lenses (also tested at 7T by Gwyneth A. van Rijn et al as previously discussed), and IOLs with steel wire suturing material. It was found that when MRI scanning was performed with the IOLs held in three different configurations (hanging on a long silk thread, placed on a Teflon surface, and placed on a donor eye emersed in water), there was no change in the position of the implants. It is therefore concluded that these IOLs pose no danger to the eye with respect to ferromagnetic risk.

Reiter et al [2] also consider the MRI safety profile of artificial IOLs (in addition to other implanted devices used by Ophthalmologists). The authors state that acrylic and silicone are the two most frequently used materials in IOL construction and that all currently used IOLs are MR Safe.

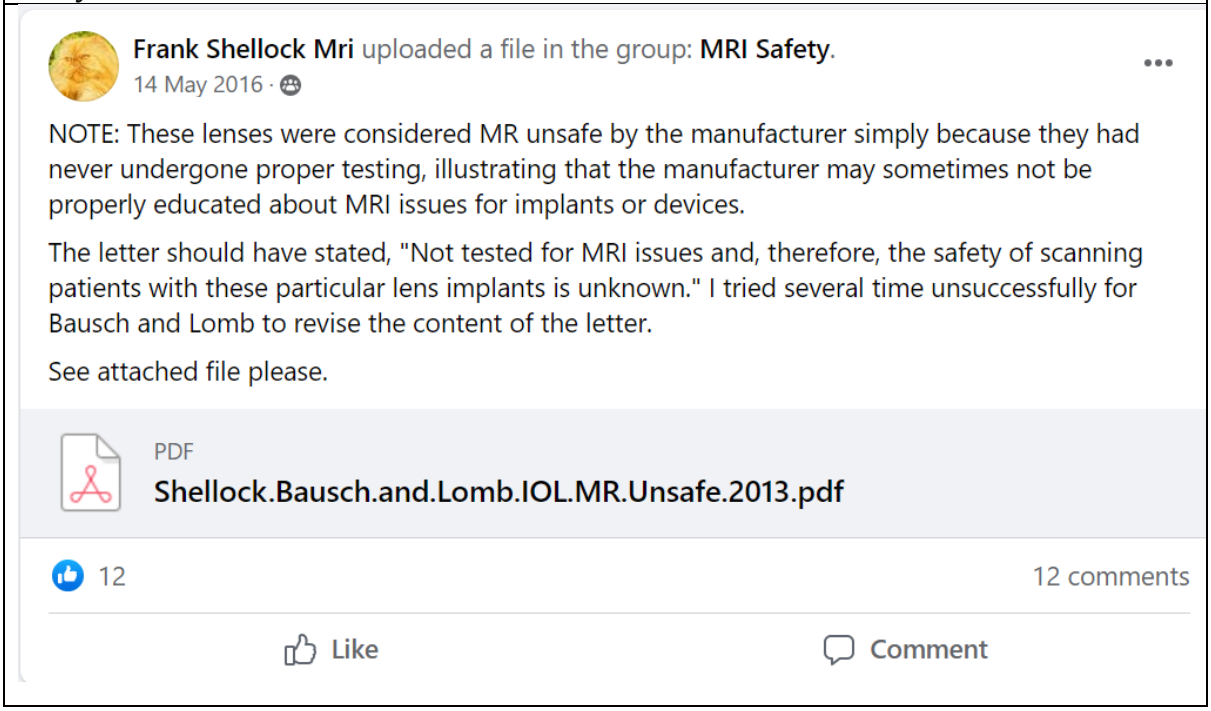
Review of the MR Safety Facebook Page

Search term: "lens"

There have been numerous discussions on the MR Safety Facebook page regarding MRI scanning of IOLs and whether a blanket policy to scan all makes and models is appropriate. There is an overall consensus that the majority of IOLs are safe to scan with most being manufactured from acrylics and plastic polymers. As such, many sites will happily scan all IOLs without obtaining make and model. Others in the MRI community exercise caution given the known MRI Unsafe Bausch and Lomb IOLs on MRIsafety.com and require make and model of all IOLs (or perform orbital screening if this information cannot be obtained) or apply a blanket policy after a certain time period.

A document, published by Bausch and Lomb regarding their MRI Unsafe lens implants, was uploaded to the page on Oct 8th, 2020, and has been appended to this detailed review. This confirms comments on the MR Safety Facebook from members including Frank Shellock that the Bausch and Lomb IOLs were labelled MRI Unsafe on mrisafety.com because they had not been regulatory tested. Furthermore, Bausch and Lomb state the materials from which these IOLs were manufactured include platinum and iridium and were in circulation in the 1970s and 1980s until 1991 at which time there discontinued.

Some comments from the MR Safety Facebook page have been captured in Table 1 to summarise the overall opinions and attitudes of members towards the MRI scanning of artificial IOLs. One of the comments make reference to an eye lens in the early 19080s which is held in place by a magnet – no reference can be found in the literature or elsewhere regarding such an eye lens. It is possible that the Facebook member is confusing eye prosthesis implants with IOLs here for which some are held in place with a magnet.

I called Bausch & Lomb and they emailed me a letter saying the lens are safe to scan on a 1.5T.
Our safety person checked on that and apparently the unsafe ones were implanted in the 80's from what she found. If you find anything else though let me know. I'm not sure if she is getting OP reports unless it was in 80
Says unsafe because it's not been tested.
Most, if not all, IOLs are MR Safe. (Frank Shellock).
The reason that those were indicated as MR Unsafe, to my understanding, is because they never underwent testing for MRI issues. (Frank Shellock)
Recently discovered some Bausch and Lomb cataract lens implants that are Unsafe (1.5T). According to the manufacturer these lens were discontinued in 1991 but had a 3 year shelf life. Wondering how other facilities are handling patients without documentation for lens implants 1994 or prior? There was a lens implant in the early 80s that was held in place by a magnet but orbit X-rays can clear this.
 **Frank Shellock Mri** uploaded a file in the group: **MRI Safety**. 14 May 2016 · NOTE: These lenses were considered MR unsafe by the manufacturer simply because they had never undergone proper testing, illustrating that the manufacturer may sometimes not be properly educated about MRI issues for implants or devices. The letter should have stated, "Not tested for MRI issues and, therefore, the safety of scanning patients with these particular lens implants is unknown." I tried several time unsuccessfully for Bausch and Lomb to revise the content of the letter. See attached file please. PDF **Shellock.Bausch.and.Lomb.IOL.MR.Unsafe.2013.pdf** 12 12 comments Like Comment

Melissa Maluegge 3 April 2013 · 16 baush and Lomb cataract lens implants unsafe in 1.5. Called company and they say all there's are safe. Not according to our safety book. What a pain! And the ones that two of our patients have aren't in the book. 1 comment Like Comment
ok lenses are replaced but i always assumed they are fine. where I work we don't check anything for cataracts.
We get orbit xrays for anyone implanted prior to 1990 if no other imaging on file due to possible metal used in the 1980's lenses

Table 1. Comments from members of the MRI Safety Facebook from 2015-2020, capturing the opinions and attitudes towards the MRI scanning of artificial IOLs.

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'

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'

Internet Search

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

Web Browser: Google Chrome

Search terms: intraorbital lens MRI Safety, intraocular lens MRI, eye lens MRI

MRIquestions.com: Additional Orbital Safety Issues [12]

MRIquestions.com highlights a relatively new IOL (see Fig. 3) – the implantable miniature telescope (VisionCare) [13] – which is MRI Conditional due to the incorporation of a small stainless-steel component. The implantable miniature telescope is an FDA-approved telescope prosthesis which is surgically implanted to improve the visual acuity in patients with end-stage age-related macular degeneration (AMD). The procedure involves removal of the natural eye lens, and the implant is held in position by haptic loops The manufacture MRI Conditions allow for the implant to be safely scanned using MRI up to 3T in Normal Operating Mode.

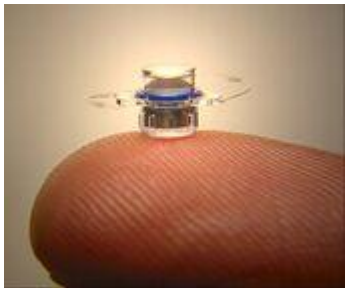


Figure 3. The implantable miniature telescope (VisionCare).

Ento Key – Fastest Otolaryngology & Ophthalmology Insight Engine – Intraocular lenses [14]

This webpage provides an extensive overview of the history and evolution of artificial IOLs since the first implantation in 1949. Materials, designs, makes and models of IOLs are covered. This has highlighted older models of IOLs incorporated metal in their design (as suggested by the peer-reviewed literature, the MR safety Facebook page and MRIquestions.com), specifically platinum is mentioned. Early designs involved metal haptics and metal used in iridocapsular fixation IOLs. This source suggests that IOL designs involving metal were phased out after the 1980s. Regarding their size, schematics are shown illustrating total lengths of IOLs to be no more than 2cm.

Radiopaedia Intraocular Lens Implant [15]

This webpage clarifies ophthalmology terminology where the presence of a lens implant is known as pseudophakia (literally, "artificial lens").

The webpage explains that the presence of an IOL can be seen on both CT and MRI where the optic manifests as a thin linear hyperdense structure on CT and a thin hypointense structure on T1-weighted and T2-wieghted MRI (see Fig 4).

The webpage also reiterates findings considered elsewhere in this detailed review: a few of the older IOLs had platinum in their haptics which can produce magnetic susceptibility artefact on MRI. Furthermore, these IOL designs were generally not used after the 1980s and that all intraocular lens implants are considered MRI safe up to 3T.

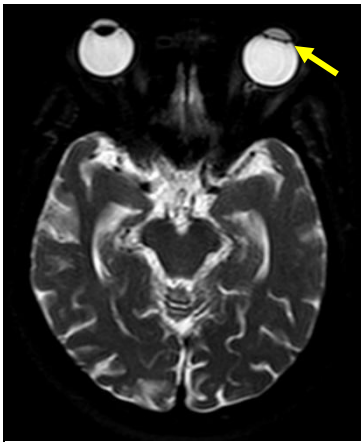


Figure 4. axial T2-w MRI showing presence of IOL in left eye (yellow arrow). Case courtesy of Dr Daniel J Bell, Radiopaedia.org, rID: 62328.

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.'

IOLs currently implanted in NHS Highland

Make/Model	Materials	MRI Safety Status
Rayner Rayone Aspheric Lenses	hydrophilic acrylic	MRI Safe
Alcon AcrySof IQ	hydrophilic acrylic	MRI Safe
Alcon MA60AC	soft acrylic material, PMMA	MRI Safe
Iris Fixated Artisan Lenses (By Ophtec)	PMMA	MRI Safe
Rayner Toric Lens	hydrophilic acrylic	MRI Safe

Table 2. Artificial IOLs currently implanted in NHS Highland.

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.'

Current implant safety policies for NHS Greater Glasgow & Clyde (GG&C) [16] and InHealth (Mobile MRI Van company) include the generic MRI scanning of all artificial eye lens implants at 1.5T and 3T. NHS GG&C note that there have been no reports of adverse events arising from the MRI scanning of patients with eye lens implants and add that, according to Shellock (2011 reference manual), no lens implant that has been tested has been shown to be MRI unsafe. It is therefore recommended scan patients all patients in NHS GG&C with such implants without the need to perform an orbital X-ray first.

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, including considerations for different magnetic field strengths up to and including 7T'

With regards to the static magnetic field, the perceived risks of scanning IOLs containing ferromagnetic material includes serious injury to the eye due to translation and/or rotation of the object. The forces involved in this movement of the implant will be greater at higher field strengths and therefore the perceived risk will be greater.

With regards to the RF-field, the perceived risks of scanning IOLs containing dyes (i.e., iron oxide) or metal include serious injury to the eye due to RF-induced heating.

It is noted that the detailed review has not highlighted any incidents or adverse events associated with the MRI scanning of patients with artificial IOL implantation. Furthermore, a first of its kind study conducted by Gwyneth et al [4] confirms a range of IOLs (non-metallic, metallic and coloured) are safe to scan up to 7T with no significant displacement or RF-induced heating observed. Older models of IOL that contain metal have been highlighted by the detailed review to be non-ferromagnetic except from those IOLs with steel-wire sutures that are potentially ferromagnetic. However, testing at 1.0T indicated no significant displacement [11] and the authors in [4] put forward the argument the risk of displacement caused by magnetic forces us smaller than the risk imposed by normal daily activity in the Earth's gravitational field. Hence, altogether, the risks imposed by the static magnetic field and RF field are considered to be extremely low, if not 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'

There is a risk that a patient will report that they have a lens implant when in fact they have contact lenses, or a retinal tack, or an eyelid spring. Some retinal tacks and eyelid springs are contraindicated for MRI. Coloured contact lenses may contain metal which may be ferrous and may cause image artefacts, so contact lenses are recommended to be removed prior to the patient entering the magnet room at some MRI sites. Additionally, there is an implanted contact lens which could be mistaken for an IOL – the SENSIMED Triggerfish is labelled MRI Unsafe and is a continuous ocular monitoring system that has an embedded micro-sensor. It is implanted for a 24-hour period in glaucoma patients [17].

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'

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'

This detailed review of the MRI safety profile of artificial IOLs has confirmed that the majority of such implants are MRI Safe. A select few older models incorporate metal in their design (platinum, iridium, titanium, and steel wire for suturing purposes) and therefore would be deemed MRI Conditional without any restrictive conditions posed. It is thus recommended, given the extremely low risk of scanning patients with IOLs, to impose a generic implant safety policy which supports the MRI scanning of all artificial IOLs up to 3T.

Appendix

Letter from Bausch and Lomb concerning the IOLs they acquired which are labelled as MRI Unsafe on MRIsafety.com.

BAUSCH+LOMB

Bausch + Lomb Surgical
Customer Service

50 Technology Drive
Irvine, CA 92618
T 800.338.2020

To Whom It May Concern,

Thank you for your inquiry regarding the Bausch + Lomb intraocular lenses (IOLs) and Magnetic Resonance Imaging (MRI) technology.

All currently manufactured Bausch + Lomb IOLs contain no metal components, therefore, should pose no anticipated risk to patients undergoing MRI.

The lenses listed below, that contain platinum and iridium metal components, have not been tested under MRI conditions; therefore, remain on the Unsafe 1 list indicated by the MRIsafety website.[1]

IOLAB intraocular lenses, manufactured in the late 1970s and early 1980s, contained platinum or iridium metal components and may not be MRI compatible. Reference model numbers listed below:

12A	24P	71B	75M
12P	31P	71M	75P
12S	42P	71P	EXPD
24A	61P	71PC	
24S	71	71R	

The IOLAB brand lenses were not commercialized outside of the United States. These lenses were discontinued in 1991 and have a three (3) year shelf life.

The following Precision Cosmet lenses contain platinum or iridium metal components and may not be MRI compatible. Reference model numbers listed below:

[1] Information retrieved on March 5, 2013 from: http://www.mrisafety.com/list_result.asp?list_description=&list_status=2&manufacture_name=&object_category=43&rows_returned=25&sort_by=list_description&submit_search.x=52&submit_search.y=10http://www.mrisafety.com/list_result.asp?list_description=&list_status=2&manufacture_name=&object_category=43&rows_returned=25&sort_by=list_description&submit_search.x=52&submit_search.y=10

Rev. August 2014

BAUSCH+LOMB

3110, 3120, 5110, 5210

The Precision Cosmet brand lenses were not commercialized outside of the United States. These lenses were discontinued in 1991 and have a three (3) year shelf life.

We appreciate your continued commitment to Bausch + Lomb and look forward to partnering with you in providing quality of care and products to your patients.

Please let us know if I can provide any additional information.

Yours truly,

Bausch + Lomb Surgical
Customer Service

Rev. August 2014

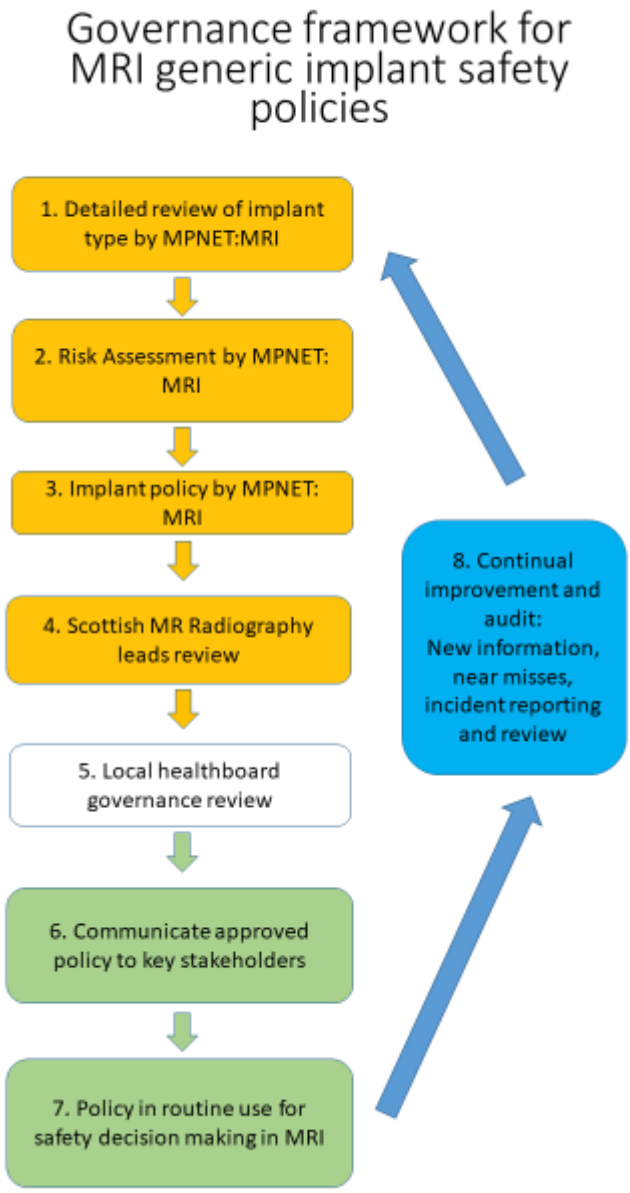
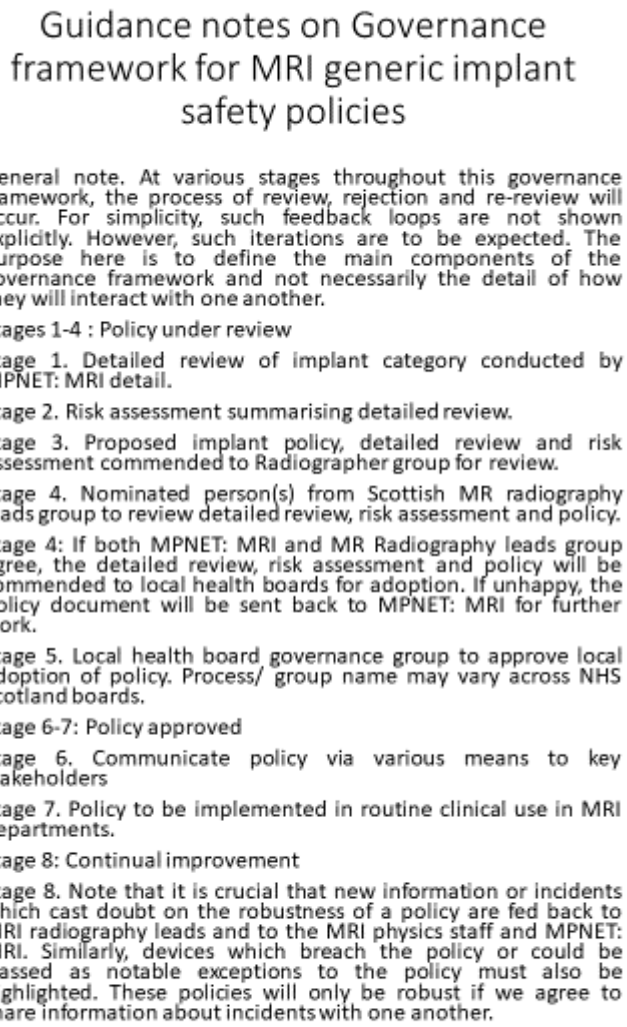


Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment



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