MRI Generic Implant Safety Policy (GISP): Detailed review

Title: Eyelid Weights

Executive summary

Date of current review: June 2022

Date of next review: June 2023

Version code: *V1.0*

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 sscanning 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
- 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'

Eyelid weights are used in patients with facial nerve palsy. They are typically made of gold and platinum although other non-ferrous materials are used (e.g. iridium). They can easily be identified on x-ray and MRI [Greenwood]

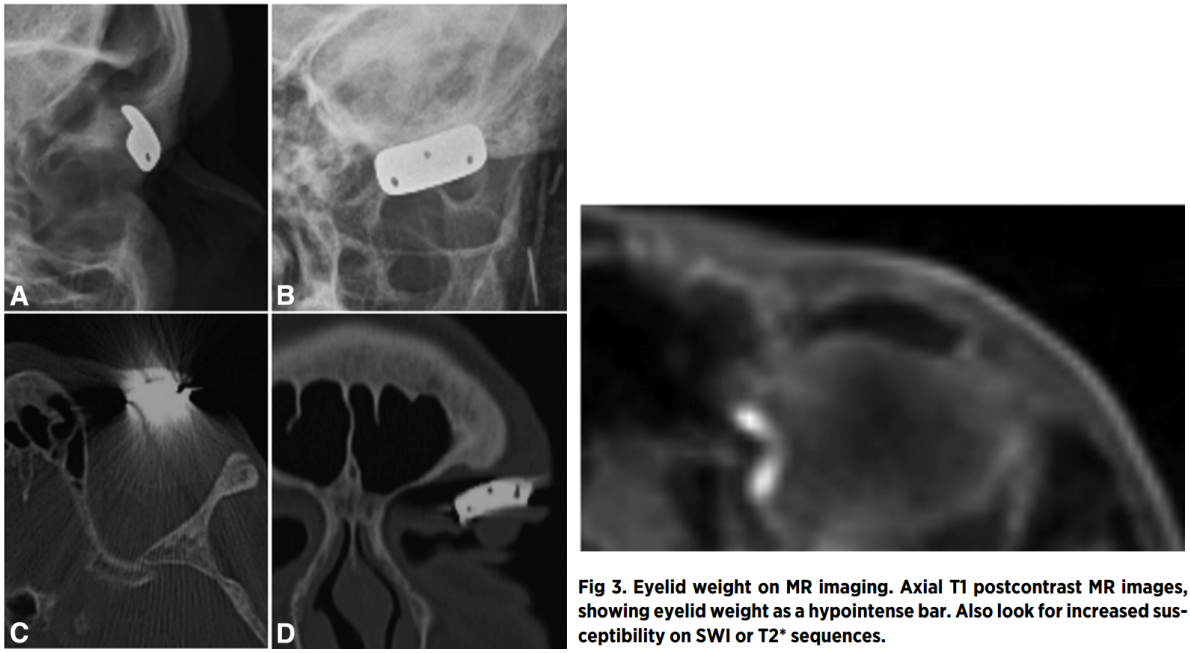
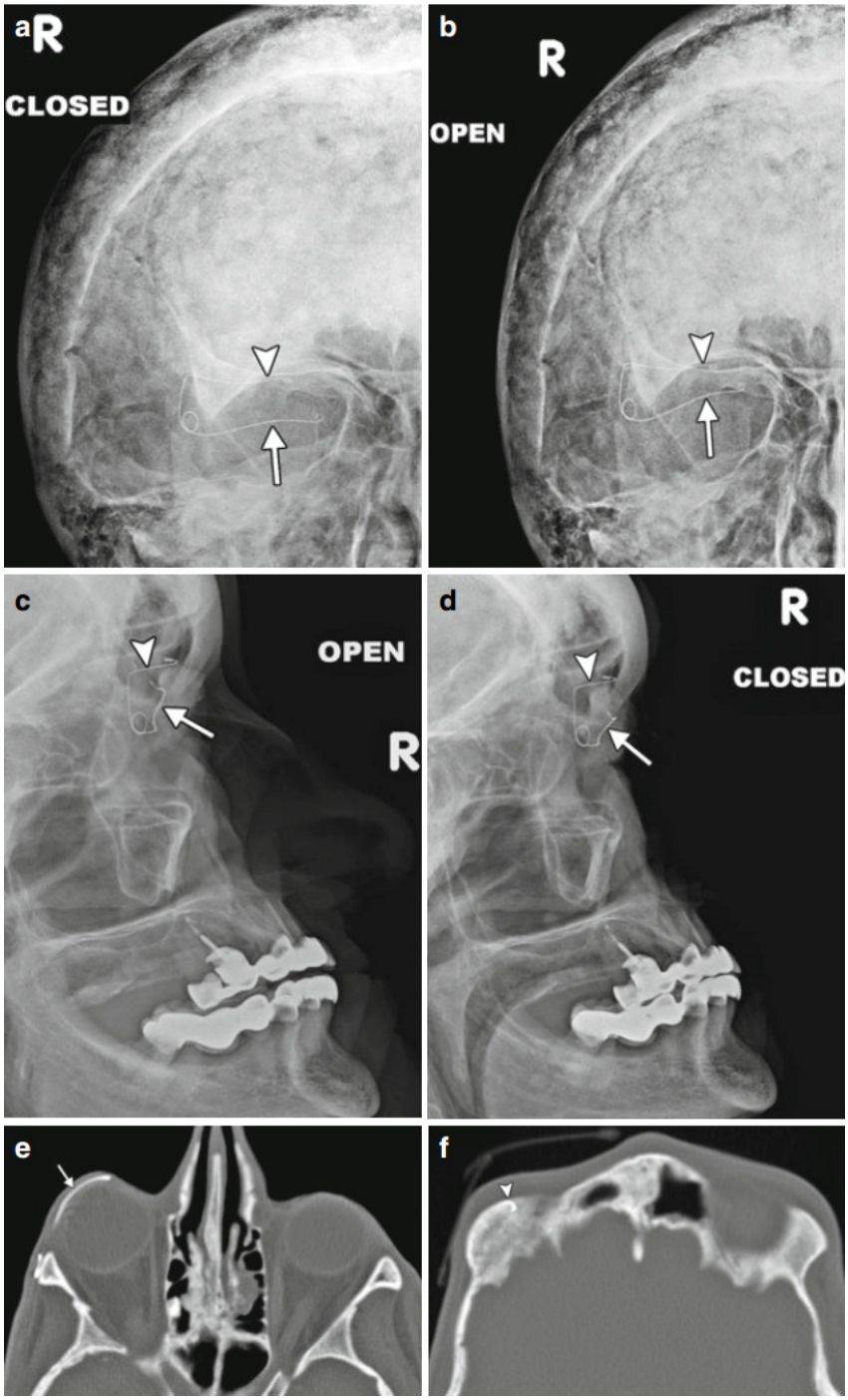


Fig 3. Eyelid weight on MR imaging. Axial T1 postcontrast MR images, showing eyelid weight as a hypointense bar. Also look for increased susceptibility on SWI or T2* sequences.

Their appearance is vastly different to eyelid springs as shown below [Ginat 2012]



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

The main challenge would be ensuring the patient has eyelid weights and not to get confused with springs for which there are known MR Unsafe models.

Hypothesis

Eyelid weights of known certain material compositions can be scanned in MRI without identifying make and model. The risk associated with this scenario is low enough that a GISP can be put in place.

Aim

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

A review of www.mrisafety.com using the search term "eyelid" highlights the following:

- Number of MR Unsafe eyelid weights: 1
- Number of MR Conditional eyelid weights : 4
- Number of MR Safe eyelid weights: 2

The MR Unsafe eyelid weight is the Fatio eyelid spring/wire. IT should be noted when searching under the general category of "Ocular implants, Lens Implants and Devices" Mrisafety.com also highlights another device the "Unitek round wire eyelid spring" as having positive magnetic field interactions. Hence it appears the number of MR Unsafe eyelid implants is 2. Both of these devices however appear to be able to be differentiated from "weights" given they are wires/springs.

A review of GUDID database using the search term "eyelid" highlighted the following

- Number of MR Unsafe devices = 2
- Number of MR Conditional devices = 5
- Number of MR Safe devices = 8

The MR Unsafe devices are external eyelid weights (Brand: Oculid) or TearCare system (localised heat therapy for Meibomian gland dysfunction). For the MR conditional devices, one device was not an eyelid weight. For the other 4 devices their details are in the table below.

Review of manufacturer implant information

Manufacturer	Model	Most stringent conditions
Meddev-corp	Contour Thin profile	Max Field strength =3T, Max spatial gradient = 40T/m, Max SAR = 4W/kg See: https://meddev-corp.com/wp-content/uploads/2021/03/15-10005-A-with-bookmarks01.pdf
Meddev-corp	Blink-eze	MR Unsafe (External eyelid weights) See: https://meddev-corp.com/wp-

		content/uploads/2021/03/15-10005-A-with-bookmarks01.pdf
Kurzmed	4001002-4001010 4007002-4007010	Max Field strength = 7T, Max spatial gradient = 100T/m, Max SAR = 2W/kg See: https://www.kurzmed.com/en/mr-information
FCI	Gold and platinum tapered eyelid weight	Max Field strength = 3T, Max spatial gradient = 16T/m, Max SAR = 4W/kg, max gradient strength 20T/m See:www.accessdata.fda.gov/cdrh_docs/pdf20/K203569.pdf
FCI	Oculid	Max Field strength = 3T, Max spatial gradient = 16T/m, Max SAR = 4W/kg, Max gradient Strength 20T/m Personal correpodance from FCI to J Ashmore
Spiggle & Theis Medizintechnik	Lid implant (lid chain)	Max Field strength = 3T, Max spatial gradient = 129T/m, Max SAR = 2W/kg https://www.spiggle-theis.com/images/PDF/zertifikate/englisch/WEB-Text_LID_englisch_210728_TN.pdf

Review of the peer reviewed literature

In the 2006 article of Schrom et al. They considered eyelid implant made from pure gold pure platinum and a platinum iridium alloy [Schrom]. They concluded that none of the implants demonstrated a risk of heating or dislocation at 3T.

In a letter to the editor from 1991 Seiff et. al. highlight that the Unitek wire used for an eyelid spring is ferromagnetic and aligned itself with the magnetic field [Seiff]. They did scan 2 patients with these springs in place for 3 months without incident and the authors highlight that fibrosis can securely fix the wire/spring into place and that imaging prior to one month is not recommended.

In the 1995 article from Marra et.al. they tested gold and carbon steel implants in a rat model. They noted no displacement, heating or adverse tissue effects [Marra].

In the 2016 article by Greenwood et.al. they highlight that early materials for eyelid weights include stainless steel, tantalum, hyaluronic acid gel, and autologous cartilage [Greenwood2016]. Because these materials had higher complication rates modern eyelid weights are either platinum or gold. The article states that eyelid weights can be deemed safe at 1.5T. The article references Marra et.al as the source for this statement.

In the 2022 article by Ginat they suggest that “MR imaging is safe” in eyelid weights and springs [Ginat2022].

In the 2012 book by Ginat et.al. they suggest that Gold eyelid weights are MR compatible [Ginat 2012]. They do not discuss eyelid weights of other material compositions and in the section on eyelid springs they do not make any reference to MRI compatibility.

Review of the mrtechnologist list, facebook MRI safety page, MR physics mailbase and other anacedotal sources of information

Grey Naughton
October 7, 2020 ·

Tobias Gilk Emanuel Kanal, wondering if I could please get your comment on a question we have had in our MRI department for quite a while now. Should we research all intraocular implants or all eye surgeries? What intraocular implants or surgeries are actually known to be a hazard?

For context, let's look at the topics discussing this category of implants on MRI safety.com. Ocular Implants, Lens Implants, and Devices appears to discusses this category in the broadest way. It refers to 4 (and only 4) intraocular implants that pose a concern due to magnetic attraction:

"Of the different ocular implants, lens implants, and devices that have undergone MRI testing, the Fatio eyelid spring, the retinal tack made from martensitic (i.e. ferromagnetic) stainless steel (Western European), the Troutman magnetic ocular implant, and the Unitek round wire eyelid spring demonstrated positive magnetic field interactions in association with 1.5-Tesla MR systems."

The list does confirm that these aforementioned implants are MR unsafe, but I read the previous paragraph as stating that *only* these intraocular implants are known to be unsafe, right?

However, the Scleral Buckle (Scleral Buckling Procedure) topic makes it sound like things may be more complicated:

"In rare instances, a metallic clip may be used. Some metallic clips may pose a risk to patients undergoing MRI procedures."

Dr. Shellock then goes on to list no examples of unsafe clips. Is this statement to be read as a hypothetical, in the sense that we just can never know the safety status of every single implant ever made in any category, or are there some known unsafe buckles/clips that he is not explicitly listing here?

Dr. Shellock does specifically address Tantalum clips, stating "Because tantalum is a non-ferrous metal (non-magnetic), these clips are considered to be acceptable for patients undergoing MRI procedures." I am assuming 'acceptable' means MR conditional?

There are no results returned when searching for 'scleral buckle' in The List. This may be because:

"The application of a scleral buckle (note, this is a procedure not an implant) or "scleral buckling" is a surgical technique used to repair retinal detachments and was first used experimentally by ophthalmic surgeons in 1937."

Which I am guessing means that the implant itself is not called a scleral buckle, but rather that the procedure causes the sclera to buckle, or 'bend and give way under pressure or strain'.

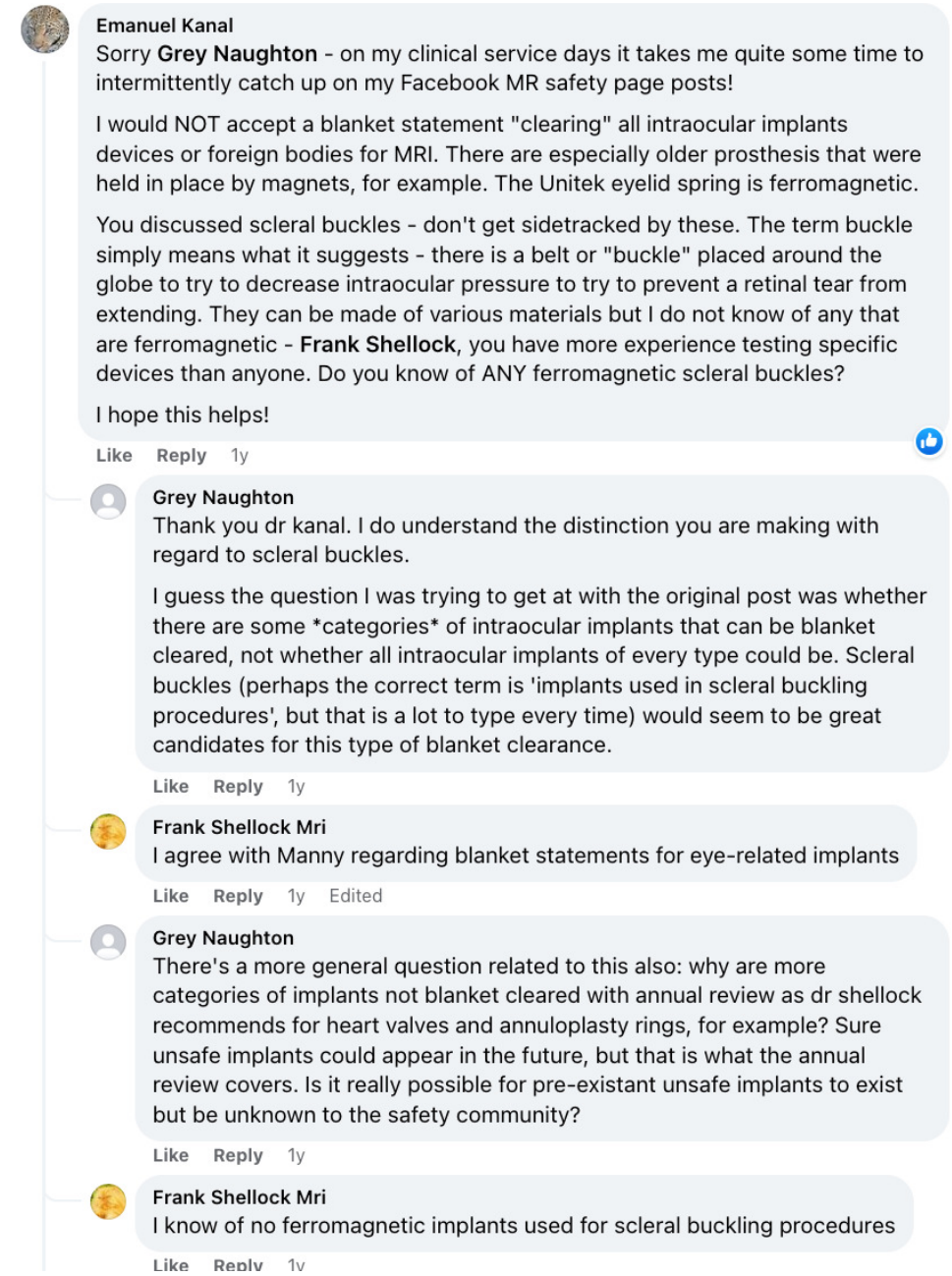
However, I also cannot find any relevant entries for either 'sponge' or 'band' which the components of the buckling system are sometimes referred to as. At any rate, no components used in a scleral buckling procedure that I have ever researched using manufacturer provided info have ever been MR unsafe.

Have any such unsafe buckling components ever existed?

And then there are glaucoma drainage devices. No unsafe devices are discussed in the safety topic "Glaucoma Drainage Implants (Shunt Tubes)", nor does a search for 'glaucoma' on The List return any unsafe devices. This again raises the question of whether any unsafe devices in this category exist.

Also, is there any reason to think that intraorbital hardware (say, to repair a blowout fracture) would ever be a concern? The only real concern I have about such hardware is, if it was stainless steel, would the extremely thin bones that form the walls of the orbit provide enough retaining force to ensure it was not torn loose?

19 31 Comments



Emanuel Kanal
Sorry **Grey Naughton** - on my clinical service days it takes me quite some time to intermittently catch up on my Facebook MR safety page posts!

I would NOT accept a blanket statement "clearing" all intraocular implants devices or foreign bodies for MRI. There are especially older prosthesis that were held in place by magnets, for example. The Unitek eyelid spring is ferromagnetic.

You discussed scleral buckles - don't get sidetracked by these. The term buckle simply means what it suggests - there is a belt or "buckle" placed around the globe to try to decrease intraocular pressure to try to prevent a retinal tear from extending. They can be made of various materials but I do not know of any that are ferromagnetic - **Frank Shellock**, you have more experience testing specific devices than anyone. Do you know of ANY ferromagnetic scleral buckles?

I hope this helps!

Like Reply 1y

Grey Naughton
Thank you dr kanal. I do understand the distinction you are making with regard to scleral buckles.

I guess the question I was trying to get at with the original post was whether there are some *categories* of intraocular implants that can be blanket cleared, not whether all intraocular implants of every type could be. Scleral buckles (perhaps the correct term is 'implants used in scleral buckling procedures', but that is a lot to type every time) would seem to be great candidates for this type of blanket clearance.

Like Reply 1y

Frank Shellock Mri
I agree with Manny regarding blanket statements for eye-related implants

Like Reply 1y Edited

Grey Naughton
There's a more general question related to this also: why are more categories of implants not blanket cleared with annual review as dr shellock recommends for heart valves and annuloplasty rings, for example? Sure unsafe implants could appear in the future, but that is what the annual review covers. Is it really possible for pre-existant unsafe implants to exist but be unknown to the safety community?

Like Reply 1y

Frank Shellock Mri
I know of no ferromagnetic implants used for scleral buckling procedures

Like Reply 1y

Kimberly Thorsen
Had a lady who swore her weight was gold. Scanned her and she complained of heating we quit but it burned her eye. Apparently not pure gold was what the rad said. Scarey

Like Reply 50w 2

The final comment above regarding an incident of patient burn from an eyelid weight doesn't appear to have any real theoretical basis. Eyelid weights are less than 2cm in size, which is the limit outlined within the ASTM standard and FDA guidelines for which heating testing is not required due to heating being insignificant.

References

[Schrom] Effect of 7.0 Tesla MRI on Upper Eyelid Implants (2006)

[Seiff] Eyelid Palpebral Springs in Patients Undergoing Magnetic Resonance Imaging: An Area of Possible Concern. (1991)

[Marra] Effect of Magnetic Resonance Imaging on Implantable Eyelid Weights (1995)

[Greenwood2016] Imaging Characteristics of Common Postoperative Orbital Devices (2016)

[Ginat2022] Imaging of the Postoperative Eye and Orbit (2022)

[Ginat2012] Atlas of Postsurgical Neuroradiology Imaging of the Brain, Spine, Head, and Neck (2012)