

RADIOLOGY PHYSICS (AUSTRALASIA) LIMITED

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Molteno Ophthalmic Ltd.,
Box 6322
Dunedin
Attention Janine Hunter, General Manager.

21st August, 2015

Dear Ms Hunter,

Effects of the Molteno Implant Glaucoma Drainage Device in MRI Imaging

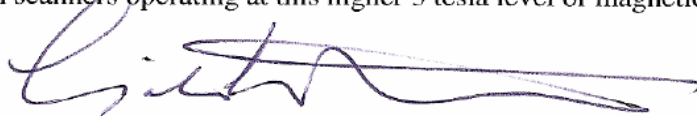
A Molteno Implant Glaucoma Drainage Device, of similar type to those evaluated for structural integrity in July 2009, was installed in an MRI head phantom and imaged at Dunedin Hospital Radiology using a GE "Signa HDxT" 1.5 tesla MRI scanner.

Phantom images were acquired using standard MR sequences as used for ophthalmology and of the orbit and have been evaluated for the possible presence of any artefacts which could be attributable to the Molteno Device.

For all MR sequences used, no significant artefact was detected and the device in all acquired images was essentially non-visible.

It is the opinion of Dunedin Hospital Radiology that, at 1.5 tesla and using typical ophthalmology MR imaging sequences, the Molteno Device produces no significant image artefacts. The Molteno Device is also considered to be MR-safe.

It is also concluded image artefacts are not likely to be produced by the Molteno Device when it is MR-imaged using 3 tesla. The Molteno Device is considered to be MR-safe in scanners operating at this higher 3 tesla level of magnetic field.



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Refer to MRIsafety.com for references and disclaimer details.

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Glaucoma Drainage Implants (Shunt Tubes)

Glaucoma Drainage Implants (Shunt Tubes)

A glaucoma drainage implant or device, also known as a shunt tube, is implanted to maintain an artificial drainage pathway to control intraocular pressure for patients with glaucoma. Intraocular pressure is lowered when aqueous humor flows from inside the eye through the tube into the space between the plate that rests on the scleral surface and surrounding fibrous capsule. The implantation of a glaucoma drainage device is used to treat glaucoma that is refractory to medical and standard surgical therapy. These are usually cases where standard drainage procedures have been unsuccessful or have a poor prognosis including failed trabeculectomy, juvenile glaucoma, neovascular glaucoma and glaucoma secondary to uveitis, traumatic glaucoma, cataract with glaucoma and high risk cases of primary glaucoma.

Importantly, for certain glaucoma drainage implants, radiographic findings may suggest the diagnosis of an orbital foreign body if the ophthalmic history is unknown, as reported by Ceballos and Parrish (2002). In this case report, a patient was denied an MRI examination for fear of dislodging an apparent "metallic foreign body." In fact, the patient had a Baerveldt glaucoma drainage implant that was mistakenly identified as an orbital metallic object based on its radiographic characteristics (i.e. due to the presence of barium-impregnated silicone).

At least one glaucoma drainage implant, the Ex-PRESS miniature glaucoma shunt (Optonol Ltd., Neve Ilan, Israel) is made from 316L stainless steel which, according to De Feo, et al. (2009), may affect MRI examinations of the optic nerve. Geffen, et al. (2010) reported that the Ex-PRESS glaucoma shunt is acceptable for patients undergoing MRI at 3-Tesla or less.

Many other glaucoma drainage implants are made from nonmetallic materials and are safe for patients undergoing MRI procedures. Commonly used devices that do not contain metal include, the following:

- Baerveldt glaucoma drainage implant (Pharmacia Co., Kalamazoo, MI)
- Krupin-Denver eye valve to disc implant (E. Benson Hood Laboratories, Pembroke, MA)
- Ahmed glaucoma valve (New World Medical, Rancho Cucamonga, CA)
- Molteno drainage device (Molteno Ophthalmic Ltd., Dunedin, New Zealand)
- Joseph valve (Valve Implants Limited, Hertford, England)