

Management protocol

Prospective study to evaluate the results of a proactive management in eyes with certain types of serious ocular trauma

General description

The goal of the study is to evaluate a new treatment method (“proactive management”), developed and introduced by the Principal Investigator for the treatment of **perforating** injuries (see *Klinische Monatsblätter für Augenheilkunde* 221: 622-628, 2004). Two other types of serious trauma (posterior **ruptures** and certain types of **IOFB** [intraocular foreign body] injuries) also have a high rate of scar-related complications, leading to very poor anatomical and functional outcome. In this prospective, multi-center, international study - to our knowledge the first such trial in the field of ocular traumatology - we intend to compare the results achieved with this new, proactive method to those published in the literature using traditional methods of treatment.

The most important aspect of the proactive management is a prophylactic retinectomy around the exit/rupture wound/IOFB impact site to prevent retinal incarceration and to remove the intravitreal blood/disconnect the intravitreal tract. To be effective, these steps must be taken no later than 100 hours postinjury.

Injury types included in the study (see BETT for definitions)

- perforating injuries (corneal or scleral entrance wound + scleral exit wound);
- IOFB injuries with impact deeper than the retina (choroidal or choroidoscleral involvement);
- ruptures with scleral extension posterior to extraocular muscle insertion.

Cases to be excluded

Infection (endophthalmitis) at any time during the treatment/follow-up period.

Endpoints

Primary: Occurrence of proliferation (at any time during follow-up):

- proliferative vitreoretinopathy;
- full- or partial-thickness retinal folds.

Secondary:

- anatomical failure (enucleation, evisceration, phthisis);
- visual acuity;
- lens status;
- retinal attachment;
- silicone oil in eye;
- intraocular pressure (IOP).

Management protocol:

Primary (emergency) surgery

- Close wound (if it can be safely reached) as soon as possible;
- clear anterior segment opacity (hyphema, cataract etc.) as necessary (*surgeon's decision*);

- in eyes with a perforating or IOFB injury, it is preferred, although not mandatory, to perform limited indirect ophthalmoscopic vitrectomy with/without anterior chamber infusion to cut the intravitreal traction pathway; no indirect ophthalmoscopic vitrectomy in eyes with rupture;
- in eyes with an IOFB, it is the *surgeon's decision* whether the IOFB is removed now or delayed until the secondary surgery;
- do not use scleral buckle.

If the patient is referred with the primary surgery already performed elsewhere, skip to "post-operative care" section.

Postoperative care

- Heavy topical steroids (systemic corticosteroids: *surgeon's decision*);
- other topical/systemic medications as needed (*surgeon's decision*);
- intravenous/intravitreal antibiotics: (*surgeon's decision*).

Secondary¹ (reconstructive) surgery, whether following no primary surgery, own primary surgery or referral after the primary surgery has been performed elsewhere

Must be performed no later than 100 hours² postinjury; surgery between 48 and 96 hours is preferred.

- **Pars plana vitrectomy:** complete removal of all vitreous, including posterior cortical vitreous and vitreous base:
 - use triamcinolone to stain posterior cortical vitreous if necessary (*surgeon's decision*);
 - use scleral indentation to assure complete removal of peripheral vitreous;
 - remove lens, even if clear, if this is felt necessary to get access to vitreous base;
 - pay especially close attention to cut/remove incarcerated vitreous around wounds/IOFB impact site;
- removal of the IOFB if still present;
- pay close attention to the intraoperative IOP: avoid high IOP values to prevent retinal extrusion into the orbit through a previously not closed posterior wound.
- **Judicious retinectomy** around the retinal incarceration into exit³/rupture wound or IOFB impact site:
 - deep diathermy (involving choroid, not just retina; use a diathermy setting far exceeding that used for retinotomy);
 - destroy retina and choroid so that a 1 mm "ring" of bare sclera

¹*In certain cases, primary surgery is not necessary (e.g., the wound is too small to require closure and no anterior segment pathology requiring surgical intervention is present). Although in such cases the secondary surgery is the primary surgery by strict interpretation, for data entry and analysis purposes, such intervention remains to be called secondary surgery with no primary surgery performed.*

²*The 100 hours is not a magic number; we extended the originally planned 96 hours [4 days] to allow for Monday morning surgery of eyes that were injured on Thursday morning.*

³*In those rare cases when the entrance wound is also scleral, it is the surgeon's decision whether this is treated similarly to the exit wound.*

around the incarceration site remains;

- if wound is too close to fovea, appropriately reduce the width of the ring juxtafoveally but keep it 1 mm elsewhere;
 - no need to trim proliferative tissue plugging the exit/rupture wound;
 - use forceps to gently lift the remaining retina, verifying that the retinal edge is free of any tissue bridge to the developing scar;
 - perform laser cerclage around the retinectomy and in the periphery;
 - use silicone oil or gas for tamponade;
 - inject 4 mg triamcinolone/400 μ g dexamethasone intravitreally at the end of surgery, unless contraindicated (glaucoma).
- Do not use **scleral buckle**.
 - If the **lens** was removed, it is the *surgeon's decision* whether the posterior capsule is also removed, although this is preferred.
 - **IOL** implantation: *surgeon's decision*; delayed implantation is preferred.

Postoperative care

- Heavy topical steroids; systemic corticosteroids: *surgeon's decision*;
- other topical/systemic medications as needed (*surgeon's decision*);
- intravenous/intravitreal antibiotics: *surgeon's decision*.

Follow-up length

Minimal follow-up of 6 months (final visit/report to Study Center), whether or not the silicone oil has been removed. One year follow up encouraged.

Follow-up visit schedule

Surgeon's decision; visits at 1 month and 3 months post secondary surgery preferred.

Documentation

- Videotaping of all surgeries requested.
- Copy of surgical notes requested, with schematic drawing on sclera/cornea of wound/s.
- Photographs of posterior pole at all postoperative visits requested.
- Macular OCT at the final visit (6 months) requested.

Data entry to database

- Fill out initial report form no later than 1 week after injury;
 - submit interim and final reports within 2 weeks after then examination.
- All requested details must be reported on.