MIMS - minimally invasive micro-sclerostomy: A new filtering surgical procedure.

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Glaucoma surgery in recent years has been characterized by a variety of new procedures. The focus is on minimally invasive or microinvasive glaucoma surgery (MIGS). Also in fil- tration surgery, after more than 50 years of trabeculectomy, innovations are available which, as in glaucoma surgery as a whole, do not represent new surgical principles but modifications of existing surgery. A new filtration procedure has now been added to the four existing ones.

Filtration surgery includes all procedures that drain the aqueous humor into the subtenon space, thus bypassing all resistances of the draining system located in the actual eye wall. In this respect, this surgery leads in principle to the lowest postoperative intraocular pressure values, corresponding to the pressure in the subtenon space, which is generally equated with the episcleral venous pressure. Currently, four different fil- tration procedures are available: ab externo trabeculectomy with its variants including ex- press [1] and ologen implant [2], the episcleral implants (so-called "Molteno principle") [3] as well as the Pre- serflo [4], ab interno the XEN gel implant [5]. In the following article, another new filtering procedure, the so-called minimally invasive micro sclerostomy (MIMS®, Sanoculis) [6], will be presented.

Implant-free drainage into the subtenon space

MIMS is an implant-free procedure that uses a micro drill to create a 90 µm sclerostomy ab interno to filter aqueous humour into the subtenon space. The system consists of a reusable touchscreen unit with the electric motor integrated into the handpiece, the foot pedal (Fig 1) and a disposable drill attachment (Figures 2a and 2b). The procedure has the CE mark, but no FDA approval to date.

The intraoperative steps of MIMS

The operation is performed after antiseptic preparation with povidone-iodine under topical anesthesia (drops and gel), if necessary in combination with analgo-sedation. Preferably, a na- sal placed Lieberman eyelid retractor with open valves is used as eyelid retractor. Immediately before surgery, the pu- pill can be constricted by administration of pilocarpine 2%. The three main surgical steps are a) injection of MMC, b) subconjunctival injection of viscoelastic (OVD), and c) placement of the sclerostomy (MIMS).

MMC injection: 0.1 ml of MMC at a concentration of 0.3 mg/ml is prepared with 0.1 ml of Scandicaine 2 % in an insulin syringe with a 30-gauge needle. The injection is performed temporally, so that the Needlepoint comes to rest about 5 mm behind the limbus in the nasal upper quadrant. The MMC-Scandicaine mixture is then spread with a swab. The ocular sur- face is then rinsed with BBS and apraclonidine 0.1% is applied.

Fig. 1: MIMS equipment Fig. Sanoculis

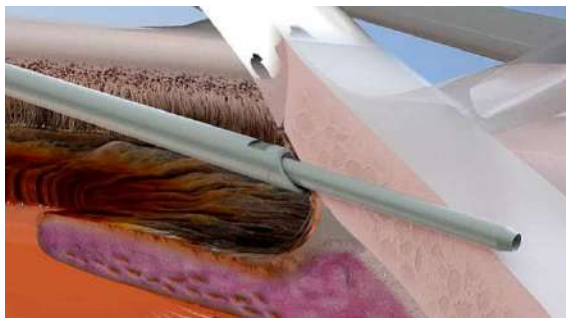
Subconjunctival **OVD injection:** 0.1-0.2 ml of OVD is injected subconjunctivally with a 30-gauge needle. The OVD is intended to cause visco-dissection of Tenon in the area of the planned exit site of the sclerostomy. The OVD injection can be performed before or after placement of the paracenteses and filling of the anterior chamber with OVD.

Fig. 2a and 2b: Drill attachment as a single use instrument

Fig.: Sanoculis

The creation of the sclerostomy (MIMS) (▸Figures 3a and 3b): First, a 1.5 mm para-
tese is applied temporally below with sufficient distance to the limbus to avoid bleeding from the limbal vascular network. The anterior chamber is then completely filled with OVD until the bulb is toned (approximately 20-25 mmHg). In the
The next step is to test the MIMS system under the operating microscope. After actuating the foot switch, the micro-drill must emerge from the injector with a clockwise rotational movement of 2.7 mm.

(Figures 2a and 2b), in order to
then again completely with rotation
The MIMS system is placed with its tip in the nasal upper ridge angle via the temporally inferior para-centesis. The MIMS system is placed with its tip in the nasal upper ridge angle via the temporal lower para- centesis, so that the marking on the injector can be seen at the limbal edge. From the outside, open forceps are used above and below the injector to indent the bulb wall close to the limbus and thus stabilize the eye. The drilling procedure is then triggered via the foot switch. After complete retraction of the drill, the MIMS system is removed from the eye. The cylinder of scleral tissue removed during the drilling process measures 90 µm in diameter and 1200 µm in length. After rinsing out the OVD, the functionality of the scleral tissue can be checked intraoperatively by means of trypan blue through the passage of the vital dye into the subtenon space. This can also be seen by placing the Filter pad (Figures 4a and 4b) during rinsing of the OVD.
under slight positive pressure. At the end of the operation, the paracentesis is stromally hydrated and, after local application of a steroid-antibiotic combination free of preservatives, a perforated pad dressing is applied.



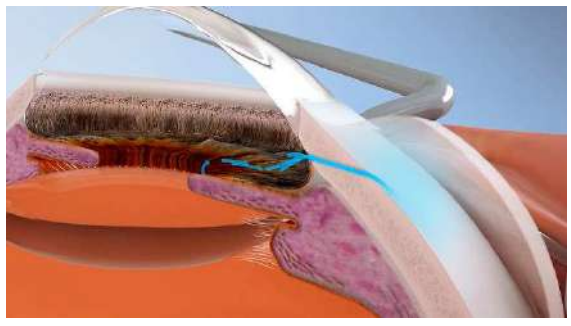


Fig. 3a and 3b: Creation of the sclerostomy in the scheme a) Microdrill in the sclerostomy canal; b) aqueous humor outflow through the sclerostomy. Fig.: Sanoculis

Preoperative management

Avoiding revisions in filtering surgery begins with preparation for surgery. Every local antiglaucomatous therapy leads to chronic
blepharokeratoconjunctivitis. This is often not noticed in the clinical routine, especially in the mild forms, because the glaucoma patients have been coming regularly every four months for years for follow-up or intraocular pressure measurement with their familiar face, and because they always have bilateral drips and therefore there are no lateral differences.

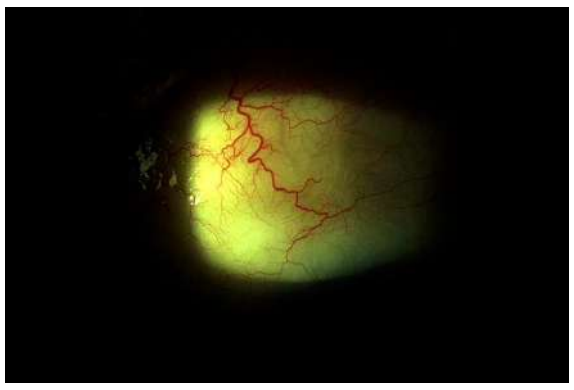
The resulting conjunctival changes may contribute significantly to the postoperative fibrosis reaction [7]. Thus, treatment duration and the number of previous topical glaucoma treatments are crucial for the success of trabeculectomy [8]. Discontinuation of topical therapy and concurrent topical steroid therapy reduces inflammatory cell infiltration in the tenon and conjunctiva and "whitens" the eye. Intraocular pressure (IOP) can be counter-regulated by systemic carbonic anhydrase inhibitors(CAIs) such as acetazolamide. However, regulation of IOP by systemic CAI is not possible in all patients, so IOP control and local IOP lowering may be necessary. In principle, benzalkonium chloride (BAC)-free drugs should be used. A local steroid therapy for one month preoperatively reduced fibroblasts and inflammatory cells and improved the success rate after trabeculectomy [9, 10]. A preparatory phase of four weeks is often impractical in everyday life, but should be carried out over at least one week. Longer periods make additional IOP measurements necessary because of a possible IOP increase. Despite sufficient knowledge about the positive effect of pretreatment on the outcome of trabeculectomy and thus the revision rate, a survey among glaucoma specialists in England revealed that only 40.6% prescribe preservative-free eye drops, 29.7% discontinue eye drops preoperatively and only 50% prescribe topical steroids [11].

Postoperative management

Postoperative management for MIMS is similar to that after XEN gel stent implantation. Preservative-free steroids five times daily, then reduced monthly to three times, twice, and once. Prophylactic antibiotics with preservative-free antibiotics for one week is common.

MIMS allows successful IOP lowering

MIMS procedures have been performed in Israel, India, Armenia and in Europe. In a study in Armenia on 120 eyes with open-angle glaucoma (100 MIMS stand-alone, 20 phaco-MIMS)



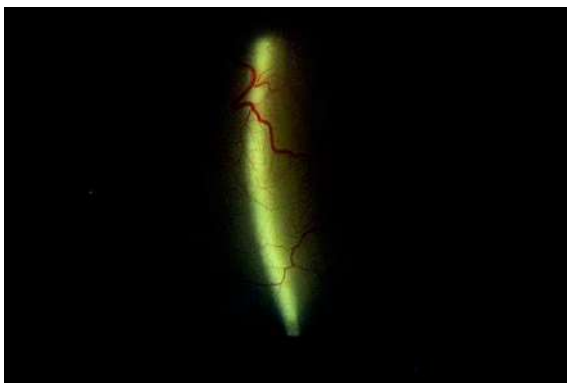


Fig. 4a and 4b: Filter cushion according to MIMS in overview (a) and slit (b)

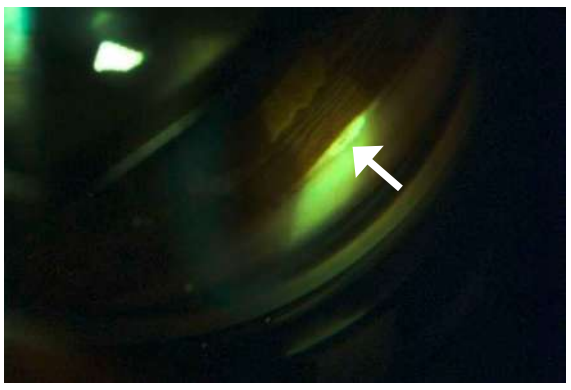


Fig. 5: Ostium internum according to MIMS

All Fig.: Authors

(Data on file at Sanoculis) at a mean age of 69±10.1 years, the mean pressure reduction one year postoperatively was 38 percent or 10.5 mmHg. There was no significant difference between stand-alone and combined surgery. The number of medications was reduced by 85 percent (from 1.8±0.8 to 0.27±0.7). Qualified success (IOP <21 mmHg and >20% IOP lowering, without or with medi- cants) was achieved in 72 (75.8%), and complete success (IOP <21 mmHg and >20% IOP lowering, without medi- cants) was achieved in 62 (65.3%) of 95 patients one year postoperatively. In a case series in India on 21 eyes, pressure reduction at 24 weeks averaged 47.4% or 14.8 mmHg. Medication was reduced by 58 percent (from 1.16±0.97 to 0.5±0.76).

Conclusion for practice

- MIMS is a promising minimally invasive filtering surgical procedure.
- It is an implant-free filtering surgery ab interno.
- MIMS requires the applica- tion of MMC.
- As with any filtering procedure, MIMS requires preoperative and postoperative management.

The sclerostomy was successfully created in all eyes. There were no malfunctions of the MIMS system or intraoperative complications. Postop- ratively, iris adhesions to the ostium internum (Figure 5) of the sclerostomy with early pressure- peaks were observed in five patients (16%) in the case series in India.

Keywords:
Minimally invasive micro-scleros- tomy - MIMS - Filtrating opera- tion - Microdrill drill

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Conflict of Interest:
The authors declare that there was no conflict of interest in the sense of the recommendation of the Inter- national Committee of Medical Journal Editors when the article was first published.

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