TECHNIQUE

Ab externo device for the treatment of glaucoma: direct flow from the anterior chamber to the ocular surface

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A new microinvasive glaucoma surgery device, the Beacon Aqueous Microshunt (BAM), drains aqueous humor directly from the anterior chamber to the surface of the eye vs draining to enclosed spaces within the eye, where outflow resistance, including the episcleral venous pressure, might limit drainage effectiveness. The BAM has a 0.030 mm × 0.048 mm channel and provides a fixed resistance. For implantation, a 1.40 mm wide transcorneal incision into the anterior chamber was created with a posterolimbal outer placement under topical anesthesia. The surgery was easy to execute and had a flat learning curve. Preliminary and early experience have shown success with lowering intraocular pressure immediately postoperatively. In conclusion, the BAM offers a promising minimally invasive surgical procedure.

G laucoma is one of the leading causes of irreversible blindness in the world. In most cases, lowering intraocular pressure (IOP) is the only and most effective treatment method to prevent disease progression. Because of the drawbacks of traditional glaucoma surgery, different devices for microinvasive glaucoma surgery (MIGS) were introduced. These devices drain aqueous humor from the anterior chamber and can be classified by their outflow destination. Outflow destinations have included the trabecular, uveoscleral, or subconjunctival spaces. Furthermore, most devices are implanted by an ab interno approach through a clear corneal incision with minimal damage to the surrounding tissue. The achieved pressure reduction was 29.3% compared with baseline with the XEN gel stent (Allergan, Inc.) in combination with cataract surgery or 40.2% with 2 iStent microbypass stent injects (Glaukos Corp.) in possible combination with topical therapy. Occasionally, the effect alone is not as high as needed to prevent progression of the disease, and effectiveness sometimes decreases with time. None of the currently available devices have prevailed. In this study, a MIGS stent that directly drains from the anterior chamber to the ocular surface of the eye is presented.

METHODS

The Beacon Aqueous Microshunt (BAM) (MicroOptx) is a new ab externo MIGS device for the treatment of glaucoma (width: 1.70 mm and length: 3.30 mm) (Figure 1). The device has a small hydrogel channel inside that guides aqueous humor from the anterior chamber to the surface of the eye. The channel is 0.030 mm × 0.048 mm and provides a fixed resistance. The BAM is engineered to achieve an IOP of 8 to 12 mm Hg regardless of the starting IOP. To prevent retrograde penetration of bacteria and pathogens, the channel is composed of a network of polymerized, superhydrophilic polyethylene glycol polymers. The antibiofouling properties of the polymers, combined with the shear stress of laminar flow, prevent adherence to the laminar walls and bacterial encroachment. The outer wall design is similar to barbs, which allow a fixed position after implantation.

Study Design

All surgeries were performed in patients with open-angle glaucoma between June 2018 and July 2018 at the Ruhr University Eye Hospital, Bochum, Germany. The surgeries were part of an ongoing clinical trial (ClinicalTrials.gov, NCT03634319) and were recorded with a high-definition video (Video 1, available at http://links.lww.com/JRS/A64). The trial was approved by the local ethics committee (Eudamed: CIV-17-09-021648). The study was performed in accordance with the tenets of the Declaration of Helsinki, and all participants provided written informed consent.

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Online Video
Eligibility Criteria
Inclusion criteria for the ongoing trial were age 22 years or older; mild, moderate, or severe open-angle glaucoma; same IOP-lowering medications for the previous 30 days; able and willing to comply with protocol requirements; and able to understand and sign the informed consent form. Exclusion criteria were active neovascular glaucoma in the study eye; corneal conditions in the study eye that might inhibit normal incisional healing (eg, Fuchs dystrophy) or impaired visualization of the implant inside the anterior chamber; anticipated need for ocular surgery within 1 year in the study eye; contact lens use in the study eye; clinically significant inflammation or infection in the study eye within 60 days before the preoperative visit; patients who had undergone surgery in the trial eye within the past 6 months (simultaneous cataract surgery was not an exclusion criterion); or angle-closure glaucoma.

Surgical Technique
All surgeries were performed by 1 experienced surgeon (H.B.D.). After the patient was positioned on the surgical bed in the aseptic operating room, regular disinfection with povidone–iodine solution 5% was performed. Next, the eye was sterile draped, and the surgical microscope was positioned above the eye. An angled microsurgical slit knife (Unique Technologies, Inc.) was used to create a posterolimbal incision (width: 1.40 mm and length: 1.0 mm). In cases of combined surgery, routine cataract surgery was first performed from the temporal side. After hydration of the cataract incisions and creation of a new posterolimbal incision, the BAM was removed from its sterile packaging with microforceps. Next, the device was carefully implanted, accordingly through the angle of the incision. If necessary, the device was cautiously pressed into the final position. To check the tightness and function, trypan blue dye (Vision Blue, D.O.R.C.) was dripped on the device (Figure 2). In case of a normal function, a continuous trickle was seen in the middle of the trypan blue stain (Figure 3). Finally, antibiotic and steroidal drops were applied, and the eye was covered with a patch.

RESULTS
The BAM was implanted in 5 eyes of 5 patients: 1 woman and 4 men. The mean age of the patients was 78 years (±4.7 [SD]). Three were left eyes and 2 right eyes. In 1 patient, the implantation was combined with cataract surgery. The incision was performed with amid width and length. Extensive conjunctival bleeding did not occur in any case. The angle of the incision was always aimed at the middle of the anterior chamber. In all patients, the BAM was easily removed from its packaging and positioned correctly in the cornea. After staining with trypan blue, all patients showed a continuous central outflow of aqueous humor. Paraxial leakage was not seen in any eye. Immediately postoperatively, the IOP was reduced. Intraoperatively and immediately postoperatively, there was no severe complication, such as endophthalmitis, and no unexpected loss of visual acuity or pain occurred. All patients reported a pleasant feeling of the surface of the eye.

DISCUSSION
This article describes a new generation of MIGS devices. Based on the microengineering and nanotechnology used, the stent drains 1-way aqueous humor directly from the anterior chamber to the surface of the eye. In comparison with most of the established traditional MIGSs, the implantation was easy to accomplish and quickly executed within a few minutes. The procedure can be performed in a simple setup under sterile conditions. Furthermore, the integration seems to be effortless and the learning curve flat. In all 5 eyes, the IOP was efficiently lowered and regulated immediately postoperatively. Because of the fixed continuous outflow of the BAM stent, the individual target pressure independent of the preoperative IOP was achieved.
without additional topical medication. Most likely, the small diameter of the inner lumen helps avoid uncontrolled IOP drops, and the outcome might be predictable. In the conducted case series, no severe complications, especially no endophthalmitis, occurred. In addition, no paraxial outflow on the edge of the device was observed. However, this needs to be confirmed with a larger patient number and a longer follow-up. Moreover, the long-term performance of the stent needs to be investigated, especially the corneal reaction, including dellen formation and corneal melting. Unexpected complications such as trauma or inflammation might occur postoperatively and needs to be investigated in the future. Of interest, the risk for a conjunctival overgrowth seems to be low, because of the continuous flow of aqueous humor. All patients were asked postoperatively whether they experienced a foreign-body sensation or any change compared with preoperatively. Of interest, all patients reported a more pleasant, comfortable feeling of the surface of their eye postoperatively. It is possible that the BAM device might also be beneficial in dry-eye diseases.

In conclusion, the BAM device was an easy-to-apply procedure. A larger number of patients need to be investigated over a longer period, including endothelial cell analysis, before drawing any conclusions. We will continue to report on this clinical trial after more eyes have been operated over a longer period.

**WHAT WAS KNOWN**

- New devices for the minimally invasive surgical treatment of patients with glaucoma are summarized with the name microinvasive glaucoma surgery.
- Already known devices provide outflow to the trabecular, uveoscleral, or subconjunctival spaces.

**WHAT THIS PAPER ADDS**

- The Beacon Aqueous Microshunt drained aqueous humor directly from the anterior chamber to the surface of the eye.
- Effective intraocular pressure regulation was reached without additional therapy in the performed cases.

**REFERENCES**


Disclosures: None of the authors has a financial or proprietary interest in any material or method mentioned.