

Gold drainage device in glaucoma patients

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Interim results with the Gold Micro-Shunt suggest good short-term outcomes comparable with the Ahmed valve

Interim results from a gold drainage device are showing comparable results to trabeculectomy and the Ahmed valve, say the study investigators.

"Historically, the Ahmed valve has been used in patients who have undergone multiple failed surgeries," said Iqbal (Ike) K. Ahmed, M.D., assistant professor, University of Toronto, and clinical assistant professor, University of Utah, Salt Lake City. He added that the device is part of a new non-penetrating blebless treatment system for patients with glaucoma.

The Gold Micro-Shunt (GMS, SOLX, Boston) consists of two layers of electroplated gold that contain internal micro-channels to facilitate aqueous outflow, according to the company. The channels work by draining the fluid from the anterior chamber into the suprachoroidal space. Both the GMS and GMS + are single-use, sterile, miniature, multi-channel, valveless, flat drainage devices for implantation in the eye. The devices measure 5.2 mm in length and 3.2 mm wide at the tail; the GMS has a nominal thickness of 40 microns, the GMS + a nominal thickness of 60 microns.

"Medical quality gold is well-tolerated and biocompatible, so the thinness of the GMS is not a real issue," Dr. Ahmed said.

Because the device communicates from the anterior chamber to the suprachoroidal space and drains fluid from inside the eye to inside the eye, it avoids bleb creation.

"The GMS avoids some of the major issues we have with traditional surgery," Dr. Ahmed said. In European studies, the GMS gives patients an average of 6 mm Hg to 8 mm Hg of IOP reduction, while the GMS + may give patients IOP reductions in the 10 to 12 mm Hg range. Both the GMS and the GMS + have been granted CE approval.

FDA trial

The Food and Drug Administration (FDA) trial in the United States led to 145 patients receiving the device, with 60 receiving the Ahmed glaucoma valve, 60 the GMS, and 25 the GMS +. (After the initial FDA review, an additional 35 patients were approved to receive the GMS +, bringing the total enrolled patient population to 180, according to company information.) To date, 55 patients have been enrolled with follow-up through six months: 16 patients have received the Ahmed valve, 24 the GMS, and 15 the GMS +. Results of the interim analysis were discussed at the American Academy of Ophthalmology's (AAO) annual meeting last fall.

The U.S. study is a randomized, controlled, multicenter, outpatient study to compare the IOP-lowering ability and safety profile of the GMS with the Ahmed valve, with a follow-up of at least one year. Among the inclusion criteria are a diagnosis of primary open-angle glaucoma or refractory glaucoma, an IOP of > 21 mm Hg on medications, and a failed prior incisional glaucoma surgery. Patients must also have a detectable visual field defect. Patients are excluded from the study if they have the following: a visual acuity worse than counting fingers in either eye, a recent angle-closure glaucoma episode, secondary glaucoma or any other significant ocular disease (except cataract), an active ocular infection, planned ocular surgery within 12 months of baseline, a suitable quadrant for implantation cannot be found, or the patient is on systemic corticosteroid therapy greater than 5 mg/day of prednisone. Pregnancy is also an exclusionary criterion.

Interim results of the FDA study found a 40% or greater reduction in IOP at the six-month follow-up compared with the 50% or greater IOP decrease in patients implanted with the Ahmed valve. Dr. Ahmed said the GMS results are favorable.

The FDA requires IOP levels under 21 mm Hg to be considered a success; those implanted with the GMS had an average IOP of 16 mm Hg at six months post-op. Those implanted with the Ahmed valve had average IOP rates of 18 mm Hg at that same time period. Patients in both groups were on about 2.75 glaucoma medications at baseline. By the six month follow-up, those implanted with the GMS were on an average of 0.5 medications, while those implanted with the Ahmed were on an average of 1.0 medications.

More clinical results

A pilot clinical study in Europe of 94 patients found IOP reduced by more than 30% after 24 months. The average baseline IOP in that group was 28.29 mm Hg, which fell to an average of 19.21 mm Hg at the six-month follow-up, 19.75 mm Hg at the 12-month follow-up, and 17.83 mm Hg at the 24 month follow-up, according to the company.

“To date, this device has shown a 75% to 90% success rate, which is a very good, if not better than expected, result in this type of patient with ‘end-of-the-road’ eyes,” Dr. Ahmed said.

There were complications, mostly reported on days two and seven post-op. Among the complications were a significant visual acuity loss in patients in both groups that resolved by the one-month follow-up and a greater than trace sign of hyphema in both groups, reported on days zero and two and resolved by day seven. Bleeding was reported with the GMS implant group on or after day seven, and corneal complications occurred in both groups beginning on day seven.

“There are some reports of hyphema occurring, but it’s early and self-resolving. There are multiple reasons that it could have occurred in the first place, among them the surgical approach we take. There’s a back flow of blood from the dissection that reaches back in the eye when the pressure is low, for instance. You need to cauterize the offending vessel and prevent low pressure in the first 24 hours post-op. In my experience with the GMS, hyphema has been very, very rare. For me, it’s a non-issue,” Dr. Ahmed said.

Further, he said the method he prefers to implant the GMS involves putting it through the scleral shelf so the base is in the suprachoroidal space.

Slitlamp and gonioscopy findings were reported on days two and seven post-op, Dr. Ahmed said. In both groups, the most frequently reported findings were anterior chamber cells, conjunctival, anterior chamber flare, and iritis, all of which had resolved by the one-month follow-up. The majority of adverse events (75%) were considered mild, and the incidence was the same between the device groups, Dr. Ahmed said.

A learning curve

The surgical learning curve coupled with potential inadequacies in surgeon training likely played significant roles in the adverse events, he said.

“Implanting the GMS involves a different technique than glaucoma surgeons are used to,” Dr. Ahmed said. “We need to re-assess the anatomy we’re working in, and we need to be comfortable working in the suprachoroidal space.”

The Ahmed valve dissection takes place outside the eye, where the device is placed on the eye and sutured to the sclera, about 10 mm back from the limbus, he explained. The GMS is positioned within the scleral anterior chamber, in the suprachoroidal space.

“The target space where the fluid is meant to drain is different between the two devices,” he said. As a result, when the GMS receives U.S. regulatory approval, Dr. Ahmed expects the surgical indication to be different from the Ahmed valve as well.

"I think this device may be used much earlier in the management of a patient with glaucoma because of its safety profile, quicker recovery time, and because the surgery itself is less invasive than the Ahmed," he said.

Surgeons considering the GMS will need to ensure the device is placed posteriorly in the anterior chamber, which will play an even larger role in patients with higher myopia.

"You don't want it to be close to the cornea," Dr. Ahmed said. "In the 'normal' eye, the scleral spur—where you want to enter—is typically about 1 mm posterior from the visible limbus. In a high myope, it'll be a couple of millimeters back. As surgeons, we need to be aware of that because if we plan on making the entrance only 1 mm back, we'll enter too anteriorly."

Shlomo Melamed, M.D., who practices at the Goldschleger Eye Institute, Tel Aviv, Israel, described his technique for implantation as first creating a fornix-based conjunctival flap. Then he dissects the sclera about 2 mm posteriorly to the limbus, which allows him to expose the ciliary body. He then dissects forward into the anterior chamber, inserting the head of the GMS device into the anterior chamber and the tail into the suprachoroidal space. Two scleral sutures are typically used to close the incision.

"This is an entirely new idea in glaucoma surgery," Dr. Ahmed said. "This is a technologically-driven device that allows the adequate titration of aqueous into the suprachoroidal space. Here, we have a situation where we're enhancing the physiologic outflow."

"It's a cleaner approach into the anterior chamber," Dr. Melamed said during the AAO annual meeting. "We can avoid the cyclodialysis that's often associated with a higher IOP. The scleral shelf is easier to reach, so we're doing more of a 'guarded cyclodialysis' that's associated with a lower early post-op IOP."

SOLX is the glaucoma division of OccuLogix (Toronto), which bought the company in September 2006.

Editors' note: Drs. Ahmed and Melamed are consultants to SOLX.