PRESERVING THE CORNEAL ENDOTHELIUM WITH iTRACK

A look at interim 12-month data on ECD and discussion of the principles that make *ab interno* canaloplasty both effective and atraumatic.

I. PAUL SINGH, MD; DAVID M. LUBECK, MD; ROBERT J. NOECKER, MD

I. Paul Singh, MD: A topic that's drawn attention in MIGS is the loss or damage of endothelial cells, which can cause blurred vision, pain, and edema.

Drs. Lubeck and Noecker, you recently presented the interim results of a prospective multicenter study in which you assessed the stability of endothelial cell density (ECD) in patients who underwent *ab interno* canaloplasty with the iTrack canaloplasty microcatheter (Nova Eye Medical) in conjunction with cataract surgery compared to a control group of patients undergoing cataract surgery alone, correct?

David M. Lubeck, MD: Yes, we're pooling our data over a 5-year period. Specular microscopy was used to measure ECD prior to treatment, and we're taking additional measurements at 6-month intervals post-treatment.

Dr. Singh: What did the data tell you about how adding iTrack to cataract surgery affects ECD?

Robert J. Noecker, MD: The rate of ECD loss with iTrack was similar to cataract surgery alone in the 12-month data, which is what we've accumulated to date. The mean change in ECD was 4.8% (SD +/-6.5%), with the majority of endothelial cell loss occurring primarily in the initial 6 months postoperatively. This compares to ECD of -10% and -12.3% in the control groups of the FDA pivotal trials for the Hydrus Microstent (Ivantis) and iStent (Glaukos), respectively.[1,2]

Dr. Noecker: ECD loss is high with traditional filtration procedures—studies estimate between 8.0% and 18.6%[3-6] at 2 years for tube shunt surgery and between 9.5% and 28.0% at 1 year[7-10] for trabeculectomy. That's one reason we're moving away from those procedures. The second reason is that the safety of MIGS allows us to intervene earlier, so we reach the point less often where more invasive surgery is needed.

iTrack is quite benign by contrast. We're not leaving the device behind. CyPass Micro-Stent (Alcon) was a relatively large device, and it was associated with high ECD loss.[11] It's likely that after the procedure, the device could cause trauma in some patients over time. With iTrack, all of the activity happens in the target tissue, the canal of Schlemm, so it's very atraumatic to structures within the anterior segment space. We're staying well away from the corneal endothelium. We do not remove or ablate tissue. Those characteristics ensure endothelial cells remain intact.

Dr. Lubeck: In regard to the process, we insert the iTrack microcatheter through the trabecular meshwork (TM) and advance it through Schlemm canal. This achieves the first mechanism of action—the mechanical removal and/or severing of any adhesions that might be present in Schlemm canal. This creates 360° outflow improvement in Schlemm canal, not just in one local area, which saves us from determining which part of the canal to treat.

In the second mechanism of action, the iTrack microcatheter is withdrawn, and viscoelastic is injected via a process of pressurized viscodilation, causing expansive reopening of Schlemm canal and the collector channels, as well as dilation of distal outflow passages. With the iTrack microcatheter, we can control how much viscoelastic we push into Schlemm canal, creating two- or three-times distension to improve outflow.

Dr. Singh: Is this approach with pressurized viscodilation related to the viscocanalostomy of the past?

Dr. Noecker: Viscocanolostomy has been around since Robert Stegmann, MD, started doing it with an *ab externo* approach.[12] We've moved away from doing *ab externo* viscocanolostomy because the procedure is time-consuming and requires a skilled dissection.

With the current-day *ab interno* canaloplasty, viscodilation occurs along the entire 360° of Schlemm canal, compared to only 180° with the former viscocanalosotomy procedure. It offers an elegant procedure that is both efficient and atraumatic. It's not uncommon to get pressures down into the mid-teens. The iTrack is the only device indicated for canaloplasty, with a clearance from the FDA 510(k) for viscodilation of Schlemm canal.

Dr. Singh: Viscodilation with iTrack is achieved using a high molecular weight hyaluronic acid (HA)-based ophthalmic viscosurgical device. What affect does HA have on surgerical outcomes?

Dr. Lubeck: There are HA receptors in the TM and in the endothelium

of the Schlemm canal outflow system. HA binds with CD44, the main receptor, which causes an increase in matrix metalloproteinases, facilitating the clearing of extracellular matrix from the TM and outflow system and increasing outflow.[13]

In the glaucomatous eye, there is decreased HA and unbound CD44, which is cytotoxic to the TM and outflow endothelium. A decreased expression of matrix metalloproteinases leads to an accumulation of extracellular matrix, thickening of trabecular beams, and increased resistance to outflow.

It makes sense that by injecting high molecular weight HA-based viscoelastic via a process of pressurized viscodilation, we're not only dilating the canal hydraulically, but also biochemically.

Dr. Singh: We don't know where the resistance to outflow is located preoperatively (i.e. TM, the canal, the distal channels, or a combination of all three). What is the value of not having to worry about which part of the outflow system is pathologic?

Dr. Noecker: We know that flow in Schlemm canal is not continuous circumferentially; it's sectoral. In some patients, perhaps one quadrant is underperforming. By targeting the entire 360° of the TM, we know that we've addressed the problem area by default.

Dr. Singh: Dr. Lubeck, how are you incorporating iTrack into your MIGS armamentarium?

Dr. Lubeck: I began using iTrack about 4 years ago to fill some needs that iStent didn't meet. I use it as a standalone procedure for patients with mild, moderate, or severe disease who are not adequately controlled on multiple medications, patients who have already undergone cataract surgery, and those for whom other glaucoma surgeries aren't ideal.

Dr. Noecker: For mild-to-moderate patients, we want to address the disease proactively. We lean toward a benign procedure like iTrack *ab interno* canaloplasty in those cases. It's nice that the iTrack is not tied to cataract surgery at the reimbursement level, so we can offer the procedure to young patients with no cataracts and older patients with previous cataract surgery. Importantly, iTrack also does not destroy any future options for glaucoma therapy, making it a viable option at any point in the disease spectrum. ■

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I. PAUL SINGH, MD

- President, The Eye Centers of Racine and Kenosha, Racine, Wisconsin; Surgical Instructor, The Chicago Medical School
- ipsingh@amazingeye.com
- Financial disclosures: Consultant/Speaker (Aerie Pharmaceuticals, Alcon, Allergan/AbbVie, Bausch + Lomb, Glaukos, Iantech, New World Medical, Nova Eye Medical, Omeros, Sight Sciences, Shire, ZEISS)

DAVID M. LUBECK, MD

- Assistant Clinical Professor of Ophthalmology, UIC Eye Center, Chicago; Director of Advanced Anterior Segment Surgery, Arbor Centers for Eye Care, Homewood, Illinois
- dmaclubes@earthlink.net
- Financial disclosures: Consultant/Speaker (Alcon, Glaukos, Nova Eye Medical)

ROBERT J. NOECKER, MD

- Ophthalmic Consultants of Connecticut, Fairfield, Connecticut; Assistant Clinical Professor of Ophthalmology, Yale University School of Medicine, New Haven, Connecticut; Clinical Professor of Surgery, Frank H. Netter MD School of Medicine, Quinnipiac University, North Haven, Connecticut
- noeckerrj@gmail.com
- Financial disclosures: Consultant (Aerie Pharmaceuticals, Alcon, Alimera, Beaver-Visitec, Diopsys, Ethis Communications, Glaukos, InnFocus, Inotek, Iridex, Nova Eye Medical, Novartis, Ocular Therapeutix, Omeros, PolyActiva, Santen, Shire, Solx, Sun Pharmaceuticals); Speaker (Alcon, Allergan, Beaver-Visitec, Diopsys, Imprimis, Iridex, Novartis, Quantel); Researcher (AqueSys, Glaukos, InnFocus); Ownership interest (ISP Surgical, Ocular Therapeutix, Tula Medical)