BALANCING CORNEAL HEALTH AND PRESSURE CONTROL WITH MIGS PROCEDURES

Performing *ab interno* canaloplasty with iTrack lowers IOP while preserving the cornea.

BY KAMRAN M. RIAZ, MD

Protecting the corneal endothelium is a priority for every patient undergoing eye surgery, but especially for those who have corneal disease or who have previously received a corneal transplant. Performing surgery for glaucoma in a patient with a compromised cornea requires a delicate balance: there is a need to safely and effectively reduce the IOP without impacting the health of the cornea. In these types of patients, *ab interno* canaloplasty with iTrack (Nova Eye Medical) is an ideal option, as it has been shown to preserve the corneal endothelium. In a 5-year prospective multicenter study evaluating endothelial cell density (ECD) in eyes undergoing *ab interno* canaloplasty with iTrack with cataract surgery, interim 12-month results demonstrated a change in both groups: mean change in ECD of 4.8% (SD ±6.5%), with the majority of endothelial cell loss occurring primarily in the initial 6 months postoperatively (D.M. Lubeck, MD, and R.J. Noecker, MD, unpublished data, 2020; accepted for presentation at ASCRS 2021). This compares to historical rates 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] Based on my experience and our institutional data, *ab interno* canaloplasty with iTrack offers three benefits in patients with glaucoma and corneal disease: effective IOP lowering, potential to reduce or eliminate eye drop use, and minimal risk to the corneal endothelium.

GLAUCOMA AND CORNEAL DISEASE

Corneal disease and glaucoma are interrelated. Each may precede, coincide with, or follow the other. Corneal transplant surgery, in particular, may be directly or indirectly related to the development of glaucoma.[3]

Patients undergoing corneal transplant surgery (ie, penetrating keratoplasty [PK] and Descemet stripping automated and Descemet membrane endothelial keratoplasty [DSAEK and DMEK, respectively]) may require long-term topical steroids, which further increase the risk of elevated IOP and secondary glaucoma. Furthermore, inflammation resulting from corneal surgery can give rise to secondary open-angle glaucoma or even inflammatory mixed-mechanism angle closure glaucoma. Conversely, some glaucoma treatments can damage the cornea. Chronic use of topical hypotensive agents, particularly those with preservatives like benzalkonium chloride (BAK), can

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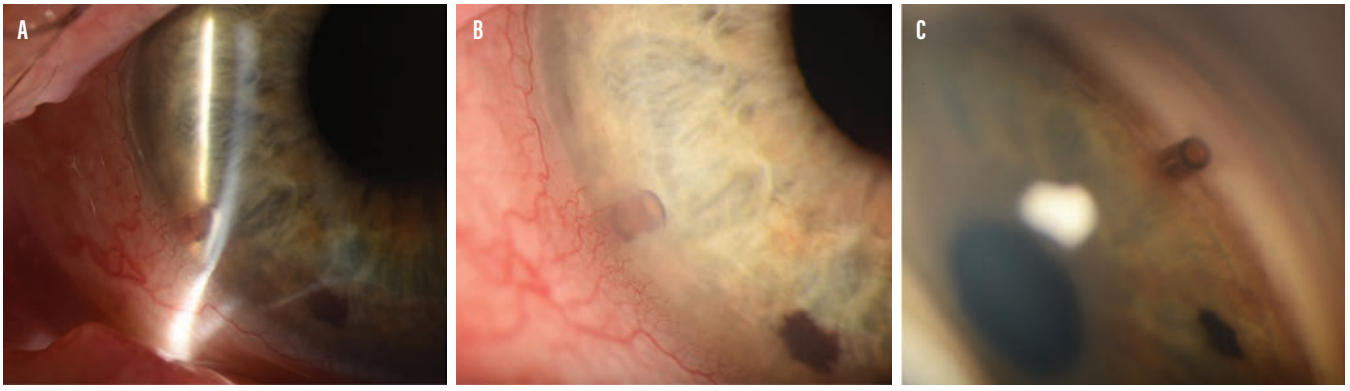

Figure 1. Clinical images (A, B, and C) from a patient who experienced corneal touch following implantation of a CyPASS device. Clinical findings included decreased endothelial cell count, increased central corneal thickness (640 µm), and decrease in VA to 20/40.

damage the corneal epithelium, leading to decreased visual acuity and epithelial erosions. In rare cases, infection may occur, which may require more invasive interventions. Additionally, topical hypotensive medications, particularly those with preservatives, may cause undesirable corneal toxicity in patients with corneal transplants.

Traditional incisional glaucoma surgeries, such as trabeculectomy and tube shunt procedures, may induce postoperative corneal endothelial damage.[4] A significant number of these patients develop secondary corneal decompensation (such as bullous keratopathy) and may require DSAEK/DMEK, which, in turn, necessitates use of topical steroids. Thus, a vicious cycle of corneal damage and undesirable increase in IOP may result.

Just as MIGS procedures have attracted attention among glaucoma specialists, cornea specialists are intrigued by MIGS procedures to effectively lower IOP, especially in patients with corneal disease. Our enthusiasm is accompanied by caution as well, as MIGS procedures may similarly cause corneal damage, though to a lesser degree. Notably, the recent withdrawal of CyPASS from market (Alcon; August 2018) due to reported corneal endothelial damage raises concerns about an implant/device in the anterior chamber (Figure 1).

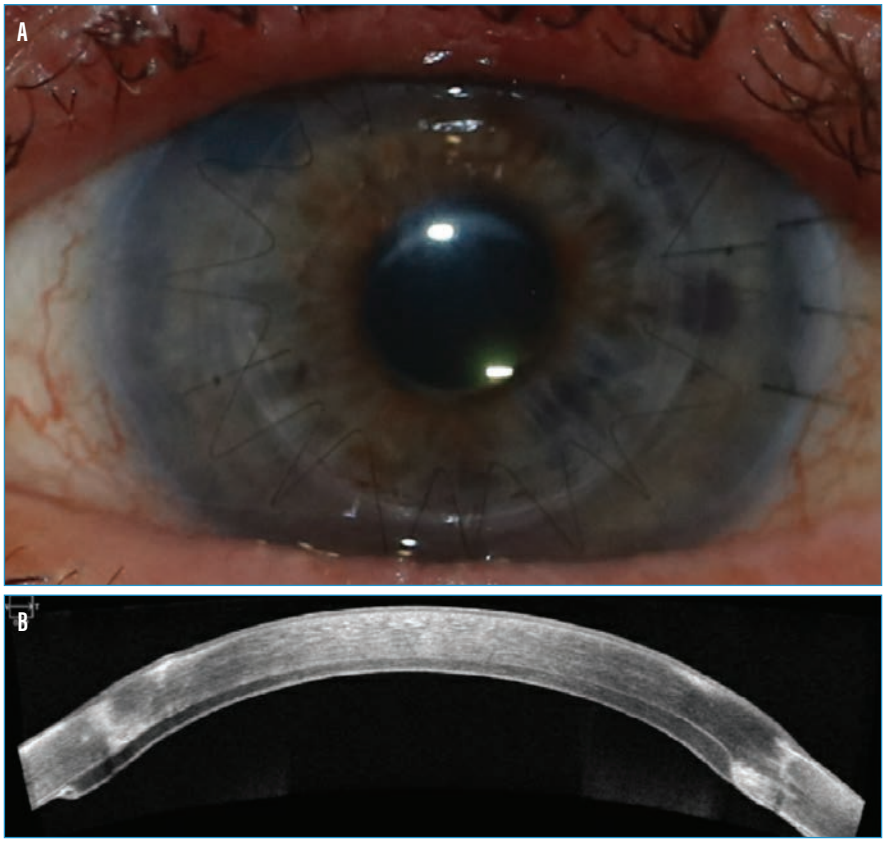

Figure 2. Slit lamp photo (A) and anterior-segment optical coherence tomography (B) of a patient with previous PK and DSAEK with concomitant glaucoma. Despite using latanoprost daily, the pressure was routinely above 20 mm Hg and progressive field loss was evident. An *ab interno* canaloplasty with iTrack was performed in October 2020. Subsequently, IOP measured between 7 and 15 mm Hg during six visits since the surgery. The patient is continuing to use fluorometholone once daily to prevent graft rejection, but latanoprost has been stopped.

HOW GLAUCOMA SURGERIES CAN CAUSE CORNEAL DAMAGE

If you keep filling a cup with water, eventually the water will overflow the 360° rim. If you create a spout in the rim and keep filling the cup with water, the overflow will be directed through the spout. This simple analogy describes the difference between natural aqueous outflow and outflow through

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a trabeculectomy or tube shunt: The aqueous humor drains, thus lowering the IOP, but the resulting directional flow may cause mechanical damage to the adjacent corneal endothelium. This altered flow may be one reason why corneal decompensation occurs after traditional incisional glaucoma surgeries.

MIGS stents like iStent and Hydrus Microstent also create preferential outflow in one area of the angle, so the same risks seen with traditional incisional glaucoma surgeries may potentially occur with MIGS procedures utilizing stents that similarly create a preferential or directional aqueous outflow. The damage may not be as significant as would occur after trabeculectomy or tube shunt, and it will not cause a significant problem in most eyes. However, in the patient with Fuchs dystrophy and mild-to-moderate primary open-angle glaucoma, directional outflow caused by a stent could be damaging.

Mechanical damage caused by the "river" of preferential outflow is not the only way glaucoma surgery can harm the cornea. The corneal endothelium needs to have the perfect environment to perform its function of keeping the cornea clear. Disruptions to that perfect environment such as postoperative inflammation can damage the corneal endothelium. Invasive glaucoma surgeries trigger an inflammatory response by causing upregulation of inflammatory proteins and cytokines.[5] MIGS procedures that are tissue-destructive, such as goniotomy, gonioscopy-assisted transluminal trabeculotomy (GATT), and Kahook Dual Blade (New World Medical), can cause significant inflammation after surgery as well. Therefore, the optimal procedure for patients with corneal disease or previous corneal surgery is one that effectively lowers the IOP without causing unwanted inflammation, corneal damage, and corneal decompensation.

SAFETY AND EFFECTIVENESS OF ABIC WITH iTRACK

Ab interno canaloplasty with iTrack combines a process of 360° microcatheterization and viscodilation to target all aspects of the conventional outflow pathway, including the trabecular meshwork, Schlemm canal, and the distal outflow system. With more than 100 µL of OVD delivered during a process of pressurized viscodilation, it can pop open herniations of the collector channel ostia and thus improve flow through to the episcleral venous system. It effectively improves physiologic outflow rather than opening up one or more isolated points of drainage that might create a potentially damaging preferential outflow pathway. Additionally, no device is left behind in the eye, so there is nothing to touch and mechanically damage the cornea during or after the procedure. For patients with corneal disease and even previous PK, we can safely perform *ab interno* canaloplasty with iTrack without damaging the endothelium. As well, the procedure preserves the possibility to perform other MIGS procedures in the future if needed because it is not a tissue-

HOW DOES iTRACK PROTECT THE CORNEA?

1. Improves Flow Throughout the Entire Conventional Outflow Pathway

Improves physiologic outflow rather than opening up one or more isolated points of drainage that might create a potentially damaging preferential outflow pathway.

2. Implant-free

No device is left behind in the eye—and thus there is nothing to touch and mechanically damage the cornea during or after the procedure.

3. Tissue-sparing

Preserves tissue and does not cause postoperative inflammation resulting in damage to the corneal endothelium.

destructive or an implant-based procedure.

At our institution, we have noted that a cohort of patients with corneal transplants who underwent *ab interno* canaloplasty with iTrack have achieved a very predictable reduction in pressure and maintained it over time (Figure 2). In 17 eyes after corneal surgery (8 PK, 6 Descemet stripping endothelial keratoplasty [DSEK], 2 PK + DSEK, 1 DMEK), IOP was reduced from a mean 26 mm Hg at baseline to 13 mm Hg (n = 14) and 16 mm Hg (n = 9) at 3 and 6 months, respectively. Mean number of medications was reduced from 3.6 to 2.6 and 2.5 at 3 and 6 months, respectively (unpublished data).

In addition to use in standalone procedures, *ab interno* canaloplasty with iTrack can also be combined with endothelial keratoplasty. To date, we have done this for four patients with successful reduction of IOP, reduction of topical hypotensives, and graft success. We are currently compiling 1-year data on these patients.

PROTECTING THE CORNEA WITH iTRACK

I expect that use of *ab interno* canaloplasty with iTrack will continue to grow as the idea of using procedural interventions early in glaucomatous progression becomes more popular. I would encourage my cornea and glaucoma colleagues to think about the interplay between the cornea and many of the current MIGS procedures. If we look through our own patient databases, we may see how many patients develop corneal issues after incisional glaucoma surgeries and stent-based and tissue destructive MIGS procedures.

Although there is a minimal learning curve associated with *ab interno* canaloplasty with iTrack, it is not a difficult procedure—if I can do this procedure, anyone can! The beneficial effects for patients are well worth the small effort it will take any surgeon to learn this procedure. See *How Does iTrack Protect the Cornea* for more information. ■

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