iTrack™

THE VERSATILITY OF STANDALONE CANALOPLASTY

Just as MIGS has evolved into a suitable option for standalone glaucoma management, the iTrack canaloplasty microcatheter (Nova Eye Medical) has the potential to lower IOP, reduce medication usage, and is broadly applicable for mild, moderate, and severe disease.

WITH IQBAL IKE K. AHMED, MD, FRCSC; AHMAD A. AREF, MD, MBA; DAVID LUBECK, MD; JAMES T. MURPHY, MD, AND MANJOOL SHAH, MD

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INTRODUCTION

With a growing focus on working with, rather than against, the conventional outflow pathway in the treatment of mild-to-moderate glaucoma, more physicians are looking for tissue-sparing, implant-free procedures as a first-line surgical approach. Nova Eye Medical, in tandem with *Cataract & Refractive Surgery Today* and *Glaucoma Today*, recently recorded a video series of respected panelists discussing the role of canaloplasty in glaucoma. This monograph features excerpts of that discussion. Read about how these panelists (Iqbal Ike K. Ahmed, MD, FRCSC; Manjool Shah, MD; James T. Murphy, MD; Ahmad A. Aref, MD, MBA, and David Lubeck, MD) describe their clinical approach to canaloplasty and how they use the iTrack canaloplasty device (Nova Eye Medical) within their practices. Scan the QR code on this page to watch the full discussion.

SUCCESS WITH PSEUDOPHAKIC PATIENTS: PERFORMING ITRACK AS A STANDALONE PROCEDURE

Iqbal Ike K. Ahmed, MD, FRCSC: We are seeing glaucoma practitioners increase the range of application for canaloplasty and employ different techniques with it. Let's begin by talking about the role of canaloplasty as a standalone procedure in pseudophakic patients.

Most MIGS procedures are done in combination with cataract surgery, which is how most of the MIGS procedures available in the United States were approved by the FDA. Now we have data from clinical trials on a few of the MIGS devices in a standalone setting, and they point to a huge opportunity for patients to benefit. Potential candidates perhaps have had cataract surgery, have undergone some form of MIGS in the past and need something more than medications, or perhaps they are not tolerating medications very well. Standalone MIGS can be an important way to achieve an efficacy endpoint in these patients.

Dr. Lubeck, there is a bit more pressure on us as surgeons to deliver a great result when we are performing standalone canaloplasty versus combining it with cataract surgery. What has been your experience with your standalone patient population?

David Lubeck, MD: My primary indication for standalone canaloplasty has been eyes with severe ocular surface disease that can no longer tolerate medications, in which selective laser trabeculoplasty (SLT) has been ineffective, and filtering surgery is not ideal. Really, my entire series of standalones have been for the reduction of medications. I have been able to either reduce or eliminate medications in more than 80% of my standalone canaloplasty patients, to the point that the ocular surface

diseases resolved. From the point of view of a cornea/anterior segment practitioner, that's where standalone surgery fits in most perfectly.

Ahmad A. Aref, MD, MBA: That point is so important, because we are so used to doing standalone bleb procedures to achieve a profound drop in IOP. As you said, the indication here in the MIGS space is not necessarily that; it is really to address patients' quality of life. Canaloplasty can address IOP fluctuation, medication load, etc., and that realization takes a bit of a change in our mindset when approaching these patients.

The safety margin of MIGS is incredible, and we all agree that it's a big jump from treating glaucoma patients with medical therapy and SLT all the way to a bleb-forming procedure such as trabeculectomy and/or glaucoma drainage devices. Phacoemulsification combined with MIGS has become popular for that reason. There is no reason why pseudophakic patients cannot enjoy the advantages of MIGS surgery, too. I consider standalone surgery for those patients who may have moderate glaucoma and need a few more points of IOP reduction, or who need to reduce their medications for ocular surface disease. Canaloplasty is one of a handful of surgical options in the United States that we can perform as a standalone procedure for these patients, without any of the logistical barriers presented by some of the other MIGS procedures currently.

Dr. Ahmed: What is the clinical role of iTrack as a standalone procedure? There's a bit of reluctance, perhaps, among some clinicians to perform iTrack by itself. Give us your pearls.

James T. Murphy, MD: I have a huge group of patients in my practice who underwent cataract surgery 10 or 15 years ago, before combined MIGS procedures were widely available. Now, some of these individuals have undergone SLTs; many are using eyedrops, which compromises their ocular surface, and the iTrack procedure is great for this type of patient, because it gets so much bang for the buck in terms of lowering IOP. iTrack is an excellent option for pseudophakic patients.

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> – David Lubeck, MD

Dr. Ahmed: We have all described the patient who is older, has had cataract surgery, and has ocular surface disease and other issues; iTrack certainly is an option in that population. In those individuals, I tend to focus more on mild-to-moderate glaucoma. I find they have a higher success rate with treatment than patients with severe glaucoma.

THE VERSATILITY OF CANALOPLASTY IN CLINICAL PRACTICE

Dr. Lubeck: As a cornea and anterior segment specialist, I was drawn to canaloplasty because it has such broad indications, as it is an atraumatic procedure compared to tearing and stripping surgeries. Canaloplasty is effective in a range of glaucoma severity, from mild to severe.[1] It can address pseudoexfoliative, pigmentary, post-trab, post-tube, and mixed-mechanism glaucoma. It was the ideal procedure to bring into my practice to avoid having to do filtering surgeries (in some cases).

Dr. Ahmed: I agree. There are many ways we can apply canaloplasty, and we have a widening group of patients who can benefit from it, whether in combination or standalone surgeries. That speaks to the versatility of canaloplasty, and each surgeon has his or her preferred technique for using it. Dr. Shah, what are your thoughts? There's a lot of talk about sparing patients' tissue for potential future procedures.

Manjool Shah, MD: Yes, its ability to spare tissue is one of the hallmarks of canaloplasty. We are preserving as much of the structure, the scaffold, as we possibly can while having a meaningful impact on the system. As glaucoma treatments continue to grow and evolve, it is important to preserve that tissue. In the future, we may use it for scaffolding devices, sustained-release implants—things we haven't even conceived of. We surgeons should absolutely try to preserve as much tissue as possible.

Also, I find that from a versatility standpoint, the juvenile-onset open-angle glaucoma patients and secondary open-angle glaucoma patients are great candidates for canaloplasty. Even in eyes with open-angle glaucoma in which we are doing cataract surgery, canaloplasty is a nice addition, because it does not interfere with the primary goal of that surgery. Canaloplasty has a synergistic effect with these procedures, and we can have a

profound quality-of-life impact on these patients, getting them off drops and stabilizing their postoperative course.

Dr. Ahmed: One way in which canaloplasty is very versatile is the variations within the procedure: how much viscoelastic we inject, and where, among other considerations.

Dr. Lubeck: Most interestingly, as we are doing the viscodilation, we can see waves of pigment or debris coming from the trabecular meshwork (TM) into the anterior chamber. The effect is a clearing and probably a microfracturing of the TM, creating more passage within it. Schlemm canal, outflow channels, distal collector system—all of these are impacted simultaneously by viscodilation.

Dr. Aref: I completely agree with that point. We may not be performing an explicit goniotomy, but it's almost like microperforations within Schlemm canal that we achieve with the viscodilation.

NONTRADITIONAL DEFINITIONS OF SUCCESS USING ITRACK

Dr. Murphy: Typically, glaucoma specialists measure success by these criteria: (1) no progression of the disease, with patients maintaining their vision; and (2) IOP as low as possible, because statistically, the lower the better. In conversing with patients, however, my definition of success and their definition of success don't always align. Has anyone had a case in which the patient's expectations might have changed how you approach management or define success?

Dr. Shah: I can share an example: a patient who has an IOP of 13 mm Hg—stable—on four classes of medications. You do a procedure on this patient, and his postoperative pressure is 15 mm Hg on one class of medication. Even though the patient's IOP is higher after your intervention, I would argue it was still a pretty huge success from the standpoint of the patient's quality of life. Although the outcome would not be considered a success by any conventional criteria, what matters is the patient's experience. This is the niche where canal procedures like canaloplasty can benefit patients. They may not reduce the IOP further, but they can get us closer to that floor where we are able to keep an individual's IOP stabilized with fewer medications.

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>
>  – Manjool Shah, MD

Dr. Ahmed: We are always comparing our clinical experiences with the findings from clinical trials and their study designs. I still see a lot of practitioners around the world comparing iTrack canaloplasty to trabeculectomy. I hope it is now clear that those procedures entail different patient populations, different needs, and different metrics. Is there a comparative procedure to canaloplasty with iTrack?

Dr. Aref: The iTrack procedure is interesting. It is such a benign procedure in that it leaves the TM and collector channel system intact; it basically rejuvenates them. Because it is performed through an incision, however, there is a tendency to compare iTrack to incisional interventions. The best comparator to iTrack might be laser trabeculoplasty. That procedure's effects on the TM are probably very similar to those of canaloplasty, although not to the same degree.

Dr. Ahmed: Dr. Lubeck and I have had conversations about the data from the Laser in Glaucoma and Ocular Hypertension (LiGHT) study[2] and other mixed studies.[3] Wright et al found a measurable reduction in visual field progression and the need for further surgery. How should we set expectations with our patients about canaloplasty?

Dr. Lubeck: I consider canaloplasty an opportunity for which there are varying degrees of cost to the patient, to the system, and to our practices. If a patient is willing to listen to the discussion about glaucoma's disease progression over 10 years, then canaloplasty is easy to insert in a presentation of the most effective, lowest cost, and lowest risk treatments. For others, we can just lay it out for them: that they'll progress from drops, to laser, to bridging procedures like canaloplasty, to penetrating incisional surgeries.

Dr. Ahmed: I prefer to control IOP without medications whenever possible. That is the mantra of interventional glaucoma. Of course, we always have to consider safety and adherence. We are already seeing stronger data on IOP control with combination cataract surgery.

Dr. Shah: It's important to tell patients that in addition to their pre- and postoperative IOP numbers, there's a qualitative aspect to controlling IOP. The LiGHT trial touched on this, and we're seeing it in the EAGLE study.[4] When we compare built-in mechanisms to control disease process versus topically applied medications, we see disparate outcomes in terms of long-term IOP stability.

Dr. Ahmed: Dr. Murphy, how do you counsel your patients about what constitutes a successful glaucoma disease management strategy?

Dr. Murphy: Canaloplasty is one step in a multistep process to control glaucoma. Many ophthalmologists neglect to explain to patients that this is one surgery, and its efficacy often has a time limit, and that the patient is likely to require multiple, serial interventions throughout his or her lifetime. We have to look at glaucoma management as a continuum of care, and we have to think two, three, or four steps ahead—we're playing the long game. A successful strategy is one in which the glaucoma does not progress, and the treatment—whatever that consists of—does not compromise the patient's quality of life.

Let's consider a pseudophakic patient who is on four eye drops, each three times per day, for ocular surface disease. If I can reduce this load to maybe one eye drop, that patient's quality of life will improve greatly. Even if the patient must add a drop back within 1 to 3 years, that's still a big win, because he or she gained time without needing a tube or trabeculectomy.

CONCLUSION

Dr. Ahmed: It has been about 12 years since we tried to define MIGS in an effort to differentiate those procedures from typical incisional procedures. Canaloplasty is on a similar trajectory, and it is exciting to see it evolve. It has been great to be here with this group of nontraditional surgeons who continue to innovate with iTrack, and I look forward to seeing what opportunities this procedure will provide our patients. ■

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IQBAL IKE K. AHMED, MD, FRCSC
- Professor, Department of Ophthalmology and Visual Sciences, University of Utah, Salt Lake City
- Director, Alan S. Crandall Center for Glaucoma Innovation, John A. Moran Eye Center, University of Utah, Salt Lake City
- Director, Glaucoma & Advanced Anterior Segment Surgery (GAASS) Fellowship, and Research Director, Kensington Eye Institute, University of Toronto, Canada
- Division Head, Ophthalmology, Trillium Health Partners, Mississauga, Ontario, Canada
- Chief Innovation Officer, Prism Eye Institute
- Chief Medical Editor, *Glaucoma Today*
- ikeahmed@mac.com
- Financial disclosure: Consultant (Sight Sciences)

AHMAD A. AREF, MD, MBA
- Associate Professor of Ophthalmology, Medical Director and Vice Chair for Clinical Affairs, Glaucoma Fellowship Director, Illinois Eye & Ear Infirmary, University of Illinois at Chicago College of Medicine, Chicago
- aaref@uic.edu; Twitter @ahmadaref
- Financial disclosures: AbbVie/Allergan, Aerie Pharmaceuticals, Nova Eye Medical, New World Medical, Inc

DAVID LUBECK, MD
- Founder, Arbor Centers for Eye Care, Director of Cataract, Cornea, and Advanced Anterior Segment Surgery, Homewood, Illinois
- Assistant Clinical Professor of Ophthalmology, Illinois Eye & Ear Infirmary, University of Illinois at Chicago College of Medicine, Chicago
- dmaclubes@earthlink.net
- Financial disclosure: Consultant (Alcon, Nova Eye Medical, Glaukos, BVI)

JAMES T. MURPHY, MD
- Glaucoma specialist with Scarsdale Ophthalmology Associates of New York and ReFocus Eye Health of Connecticut
- jamestmurphyiiimd@gmail.com
- Financial disclosure: Clinical investigator for Nova Eye Medical

MANJOOL SHAH, MD
- Clinical Assistant Professor, Glaucoma, Cataract, and Anterior Segment Disease, Kellogg Eye Center, University of Michigan, Ann Arbor, Michigan
- manjool@med.umich.edu
- Financial disclosures: Consultant (AbbVie/Allergan, Glaukos, Ivantis, Katena, ONL Therapeutics)