

# A Vision for a New Era in Combined Glaucoma and Cataract Treatment



A Q&A with Elliot Friedman CEO, Elios Vision, Inc. and Murray Johnstone MD Clinical Professor, University of Washington

## TO ELLIOT

**Tell readers about Elios Vision and its background.**

Elios Vision was founded in partnership with MLase, a world leader in excimer laser technology. We shared a goal to create a glaucoma procedure that was safe and effective and optimised for use during routine cataract surgery. Elios Vision was formed to drive the global clinical and regulatory strategy for the novel excimer laser platform and procedure with a dedicated team.

**What specific value are you hoping to bring to physicians and their patients?**

Despite a decade of MIGS innovation, we are still seeking to improve surgical options to treat glaucoma at the time of cataract surgery, which affords such a perfect opportunity to access tissues implicated in glaucoma.

However, we estimate that only 15% of glaucoma patients worldwide receive a glaucoma treatment at the time of cataract surgery. Whilst access and reimbursement certainly have a role to play—especially outside of the US—we know predictable IOP and medication lowering is a must. And we have also learned that surgeons do not want to compromise cataract surgery safety and visual outcomes with glaucoma procedures that are overly complex or cause trauma. In addition, glaucoma implants during cataract surgery can be unappealing for many surgeons.

With around 6 million glaucoma and ocular hypertension patients being treated for cataract each year worldwide, we believe the ELIOS™ procedure is well placed to address these unmet needs because it is “implant free”, avoids thermal and mechanical trauma, and has a low level of intra- and postoperative complications. We’ve also observed a learning curve that can make the ELIOS procedure widely adoptable.

**So what is the ELIOS procedure, and how does it work?**

We know that bypassing the TM is a proven way to lower IOP. But as Murray will explain, it’s important to consider the physiology of the TM in order to restore or augment outflow predictably and with an enduring effect.

The ELIOS procedure bypasses the TM using precision laser ablation, creating ten 210-micron microchannels. This maximises the potential flow into the collector channels.

**The ELIOS procedure has demonstrated strong safety and efficacy in OUS studies. Can you describe this data and how you think it differentiates your approach?**

We have data on over 600 eyes from 14 studies which we find encouraging on several levels. Firstly, it appears the clinical effect is still present in more than 50% of patients assessed eight years after their procedure. Another observation is the extremely low incidence of severe complications thanks, at least in part, to the atraumatic mechanism of action of the excimer laser.

The University of Zurich just published eight-year follow-up results of ELIOS combined with cataract surgery, showing a >20% reduction in mean IOP at eight years post-operation [Figure 1]. Another study in Spain showed more than 80% of patients were “medication free” at 12 months following the ELIOS procedure [Figure 2].

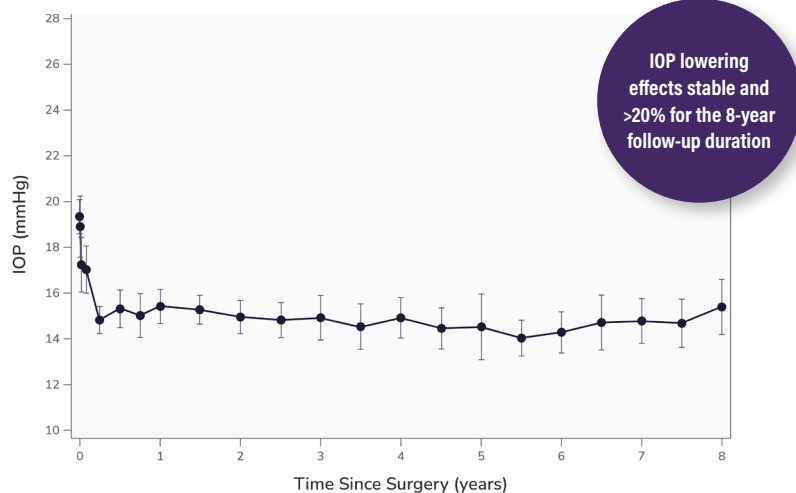


Figure 1: Sustained IOP lowering effect observed unto eight years<sup>1</sup>

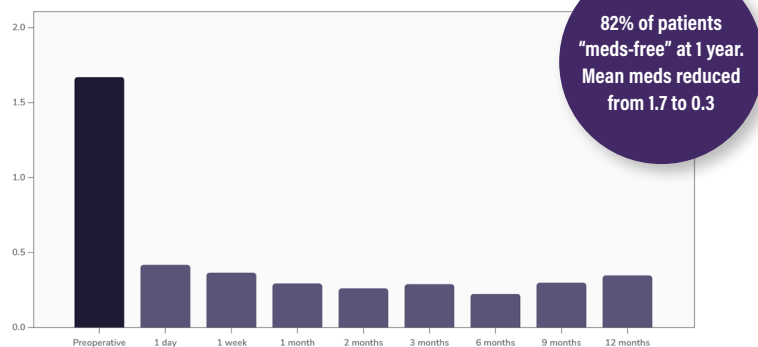


Figure 2: Significant reduction in medications observed at one year<sup>2</sup>

**Can you tell us about your regulatory, reimbursement, and commercial plans?**

The ELIOS technology is CE marked, and we have started a focused commercial rollout in Europe to generate data, establish our per-procedure fee model, expand our reimbursement coverage, and grow our key opinion leader base.

In the United States, our combination cataract ELIOS pivotal trial is well underway, and we expect to launch in 2024. We have just filed an IDE for standalone treatment and been granted our own unique reimbursement code for the ELIOS procedure.

In China and Canada, we have commenced data generation activities to support regulatory filings in the near term.

## TO MURRAY

**Murray, for those not familiar with your work, could you summarise your research area of expertise and share the main appeal of the ELIOS procedure?**

My research focuses on aqueous outflow regulation and what goes wrong in glaucoma.

The research points to aqueous outflow regulation by a mechanical mechanism like the lymphatic and venous pumps present throughout the vascular system [Figure 3].

Studies show that SC is a collapsible chamber with inlet and outlet valves.

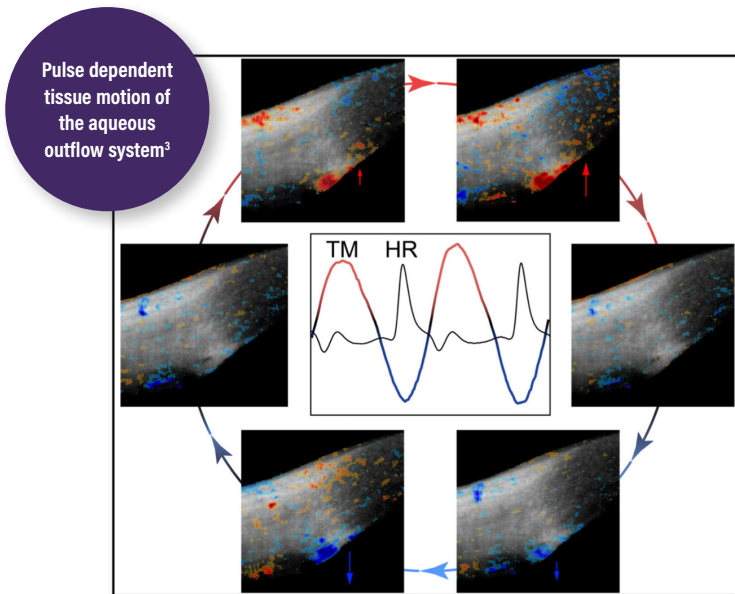


Figure 3

The pumping mechanism fails in glaucoma.

Ideally, we want to restore the normal pump function without causing damage.

The appeal of the ELIOS procedure is that it creates small openings in the outflow system by vaporizing tissue [Figure 4]. The procedure does not tear away or burn trabecular tissue, and does not require introducing and leaving foreign objects in the canal.

#### What are the main structural and functional changes that have been observed in the TM and SC in patients with glaucoma (versus non-glaucomatous eyes)?

As glaucoma progresses, there is a loss of normal trabecular tissue elastance. Because of the increased stiffness, the TM tissues can't distend and recoil properly in response to pressure changes [Figure 5]. Loss of elastance causes the TM to lose its ability to resist pressure, and it expands outward, occluding SC and collector channels.

#### Is there an optimal "time" in the disease course to enhance/restore Schlemm's canal physiology? Is there a point beyond which the opportunity is lost?

Pulsatile flow and TM motion stop as glaucoma progresses.

The pulsatile flow and TM motion loss are associated with the TM distending into SC, closing the lumen, and preventing flow.

Early intervention is likely to be valuable in preventing chronic apposition and eventual adhesion between SC walls.

Early treatment is a likely key to preventing this cascade of negative events.

The caveat is that the benefits of earlier intervention need to outweigh the risks.

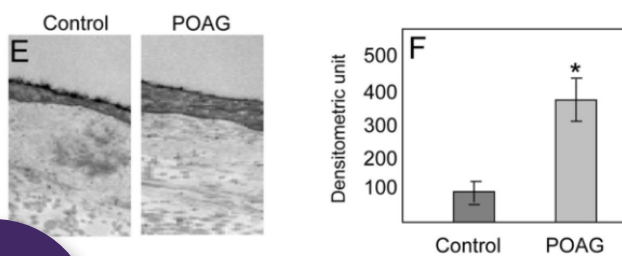


Figure 5: The representative BM changes in the intra-trabecular space in transmission electron micrographs (TEM) en-bloc staining with uranyl acetate (Alcian Blue 8GX).<sup>iii</sup> As indicated, control (55-year-old) and primary open-angle glaucoma (POAG; 55-year-old), both male cadaver donor eyes respectively. (F) Assessment of intratrabecular BM thickness from 50 locations each from individual TEM images from 6 control and POAG donors each (age 55-59, equal distribution of genders). Asterisk indicate significance ( $p < 0.05$ ) using two-tailed equal variance t-test.<sup>3</sup>

Thickening and loss of elasticity of the TM in glaucoma

#### Some MIGS procedures rely on physical removal of the TM by excision—Is the impact of these techniques on Schlemm's canal and the angle understood in the mid-/long-term?

SC is not a pipe but instead a delicate organ with compressible chamber containing valve-like inlet and outlet structures that can control aqueous flow.

Removal of the TM or instrumenting SC can damage structures in the distal outflow system that normally control aqueous outflow and IOP.

#### What has the industry learned (from MIGS?) about stenting the TM in the past 10 years, and how does ELIOS build on this?

Procedures that tear away the TM or instrument the lumen of SC can damage the physiologic regulatory structures.

Although they reduce IOP, they rely on non-physiologic mechanisms.

The ELIOS procedure creates a series of small openings into SC while leaving most of the pressure regulatory apparatus intact.

The idea that the procedure may minimise damage to the normal physiologic mechanism, combined with the fact that it is an adoptable technique, is attractive.

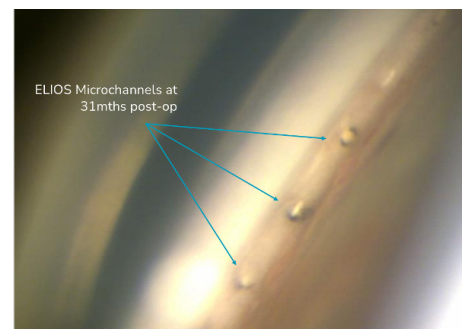


Figure 4

#### TO ELLIOT

#### So in closing, how do you think glaucoma treatment will be different five years from now based on the introduction of the ELIOS procedure?

We think combining glaucoma and cataract will be the standard of care in five years, and we certainly hope the professional community will embrace these benefits of the ELIOS technology and make it the procedure of choice for their patients.

#### Disclaimer:

Elios Vision GmbH is the EU distributor of the ELIOS Console manufactured by MLase AG located at 82110 Germering, industriestr 17, Germany and the FIDO laser applicator manufactured by WEINERT Fiber Optics GmbH, Mittlere- Motsch-Strasse 26, 96515 Sonneberg, Germany. The ELIOS Console and FIDO Laser Applicator are CE marked and licensed for use in adult patients with glaucoma. Product feedback should be sent to [productsurveillance@eliosvision.com](mailto:productsurveillance@eliosvision.com)

#### References:

- Figure 1 Riesen M, Funk J, Töteberg-Harms M. "Long-term treatment success and safety of combined phacoemulsification plus excimer laser trabeculostomy: an 8-year follow-up study". *Graefes Arch Clin Exp Ophthalmol*. 2022 Jan 16.
- Figure 2 Moreno-Valladares A, Puerto Amorós N, Mendez Llatas M, Pazos-López M, Ahmed IIK. "Combined excimer laser trabeculostomy and phacoemulsification: One year follow-up real world data of a laser-based MIGS". *Arch Soc Esp Ophthalmol (Engl Ed)*. 2021 Dec; 96(12): 631-639.
- Figure 3 & 5. Carreon T, van der Merwe E, Fellman RL, Johnstone M, Bhattacharya SK. "Aqueous outflow - A continuum from trabecular meshwork to episcleral veins". *Prog Retin Eye Res*. 2017 Mar; 57: 108-133.