FEMTOSECOND LASER, IMAGE-GUIDED, HIGH-PRECISION TRABECULOTOMY

A NOVEL, NONINVASIVE PROCEDURE FOR PATIENTS WITH PRIMARY OPEN-ANGLE GLAUCOMA

INTRODUCTION

Glaucoma is a leading cause of irreversible blindness, affecting approximately 76 million people worldwide—a number expected to rise to 112 million by 2040.[1,2] Despite advancements in medical and surgical interventions, there remains an unmet need for a safe, effective, and truly noninvasive treatment for patients ineligible for cataract surgery or those who are either dissatisfied with or uncontrolled on topical therapy.[3]

The only proven strategy to slow glaucoma progression is lowering intraocular pressure (IOP), which helps preserve optic nerve function by reducing stress on retinal ganglion cells.[4,5] Current options include medications, laser therapy, and surgical procedures, each with varying risk-benefit profiles. While medications effectively lower IOP, they require lifelong adherence. Traditional surgery provides significant IOP reduction but carries a higher risk of complications. Minimally invasive glaucoma surgery (MIGS) has emerged as a safer alternative, yet these procedures are still invasive and often restricted to patients undergoing cataract surgery.[10,11] Consequently, a large underserved population remains—patients who would benefit from a novel noninvasive procedure that effectively reduces IOP without requiring an incision.

Femtosecond laser technology has been widely adopted in ophthalmology since the early 2000s due to its unparalleled precision, safety, and non-thermal tissue interaction. Originally developed for refractive and cataract surgery, this technology is now being leveraged for glaucoma treatment.

The ViaLuxe™ Laser System (ViaLase Inc.) is an image-guided femtosecond laser designed to noninvasively create a precise aperture in the trabecular meshwork, facilitating aqueous humor outflow. This novel procedure, femtosecond laser, image-guided, high-precision trabeculotomy (FLIGHT), offers a groundbreaking approach to addressing this unmet need.

FLIGHT PROCEDURE

The FLIGHT procedure noninvasively creates an aperture in the trabecular meshwork, allowing direct aqueous humor outflow from the anterior chamber to Schlemm's canal. This process, illustrated in Figure 1, enables a controlled and precise bypass of outflow resistance, preserving adjacent tissue integrity.

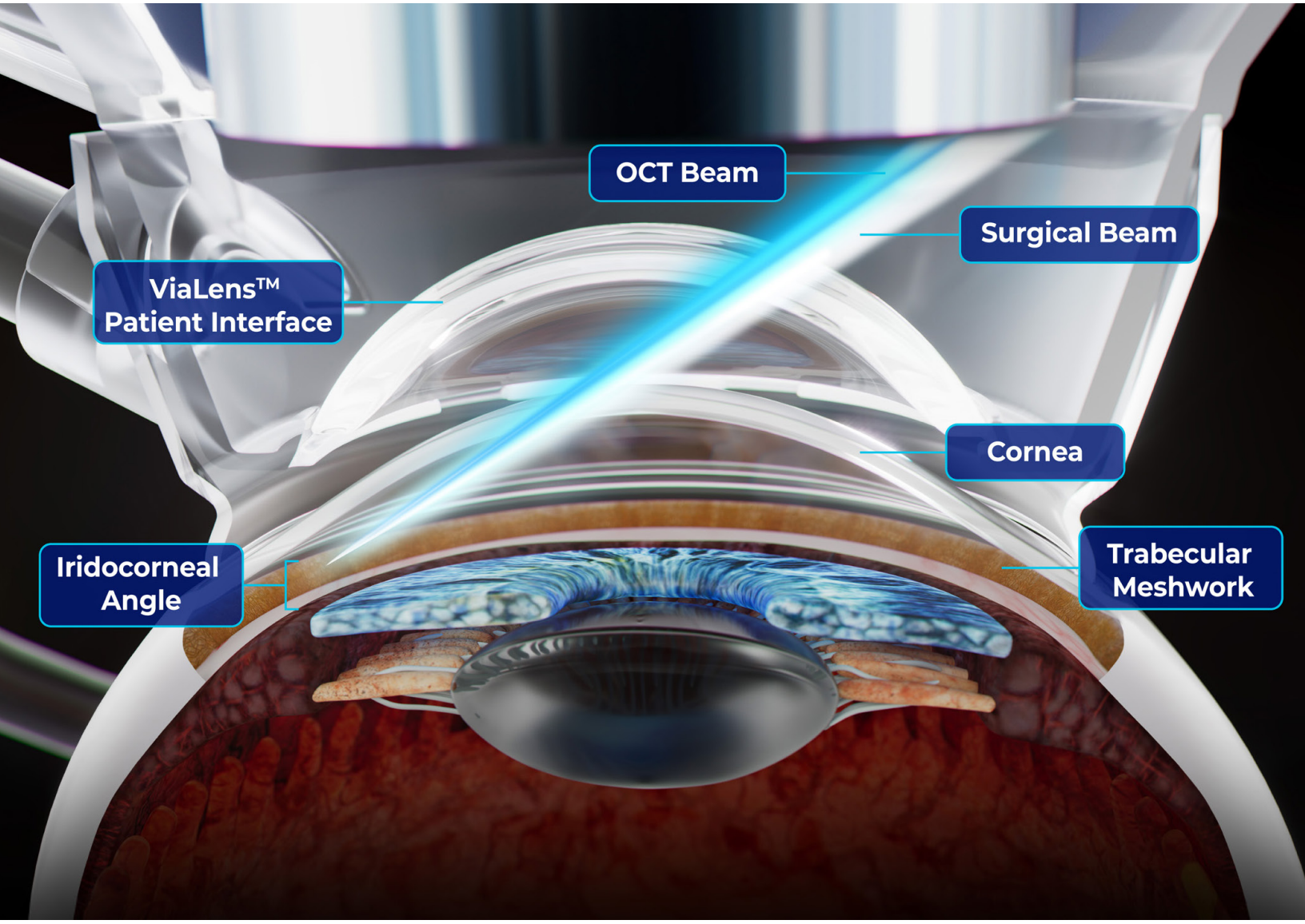


FIGURE 1

Schematic view of dual femtosecond laser and OCT beams addressing the trabecular meshwork via photodisruption.

ADVANCED IMAGING FOR PRECISION TREATMENT

Accurate visualization of the iridocorneal angle is essential for successful angle-based interventions. The ViaLuxe™ Laser System integrates a proprietary dual imaging system, combining high-definition gonioscopic imaging (ViaVue™) with micron-accurate optical coherence tomography (OCT). This combination enhances anatomical visualization and ensures precise placement of the laser treatment. During the procedure, a 500-micron-wide by 200-micron-high aperture is created through the trabecular meshwork, targeting a 5-degree sector of the angle. Because no incisions are required, the FLIGHT procedure minimizes the risks typically associated with intraocular surgery.

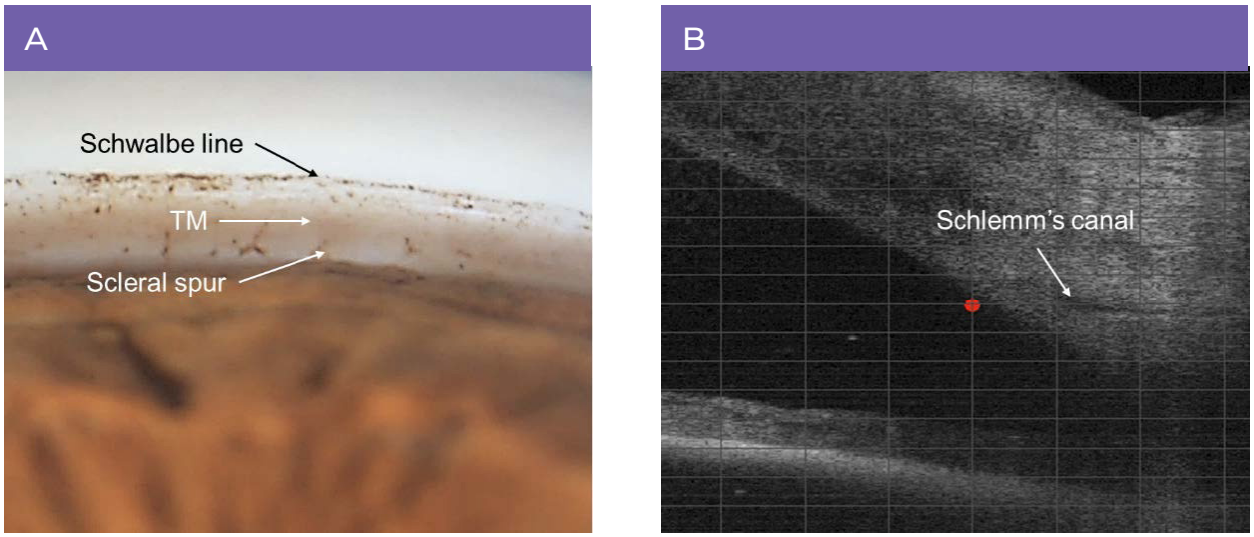


FIGURE 2

A. High-definition gonioscopic imaging (ViaVue™) provides en face visualization of the trabecular meshwork (TM) and surrounding angle anatomy.

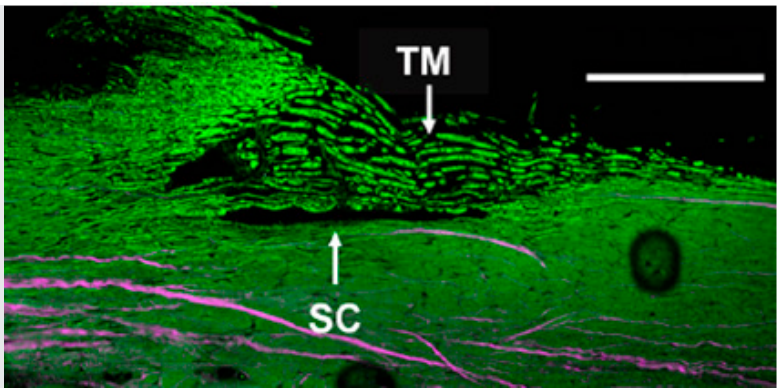
B. Cross-sectional optical coherence tomography (OCT) imaging offers micron-accurate depth assessment of angle structures.

Displayed in real time, these proprietary imaging modalities give the surgeon unparalleled visualization of the iridocorneal angle to guide precise treatment.

PRECLINICAL AND CLINICAL EVIDENCE

Preclinical studies assessed the femtosecond laser's ability to create precise apertures in human corneoscleral shells and whole human eyes. Results confirmed clean, well-defined apertures without collateral damage to surrounding tissue.[13,14] | figure 3.

BEFORE FLIGHT



AFTER FLIGHT

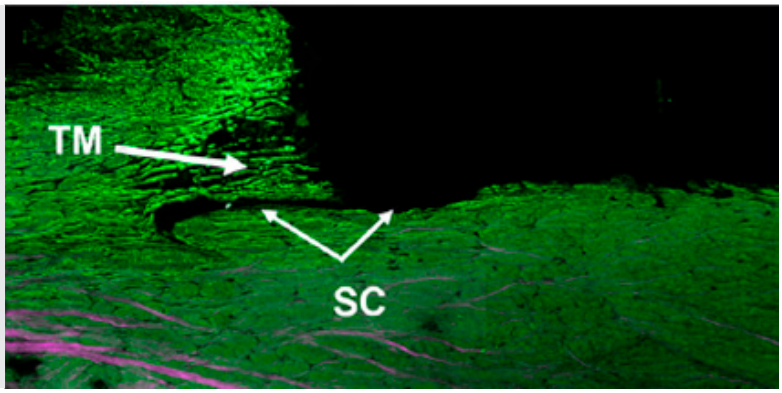


FIGURE 3

Two-photon autofluorescence (Green)/SHG (Magenta) showing the intact trabecular meshwork region before and after the FLIGHT aperture demonstrating no collateral damage to adjacent tissue (20× magnification). TM=trabecular meshwork; SC=Schlemm's canal. From Mikula et al. 2022.[14]

FIRST-IN-HUMAN STUDY: 24-MONTH OUTCOMES

A clinical study evaluated the safety and efficacy of FLIGHT in 18 eyes of 12 patients with open-angle glaucoma (Shaffer grade ≥3) and baseline medicated IOP of 22.3 ± 5.5 mmHg.[15] The results demonstrated a significant reduction in IOP, reinforcing the procedure's clinical potential.

At 24 months post-procedure, IOP was reduced to 14.5 ± 2.6 mmHg, a statistically significant 34.6% decrease (p=0.00005). Additionally, 82.3% of eyes achieved ≥20% IOP reduction, demonstrating robust and sustained efficacy.

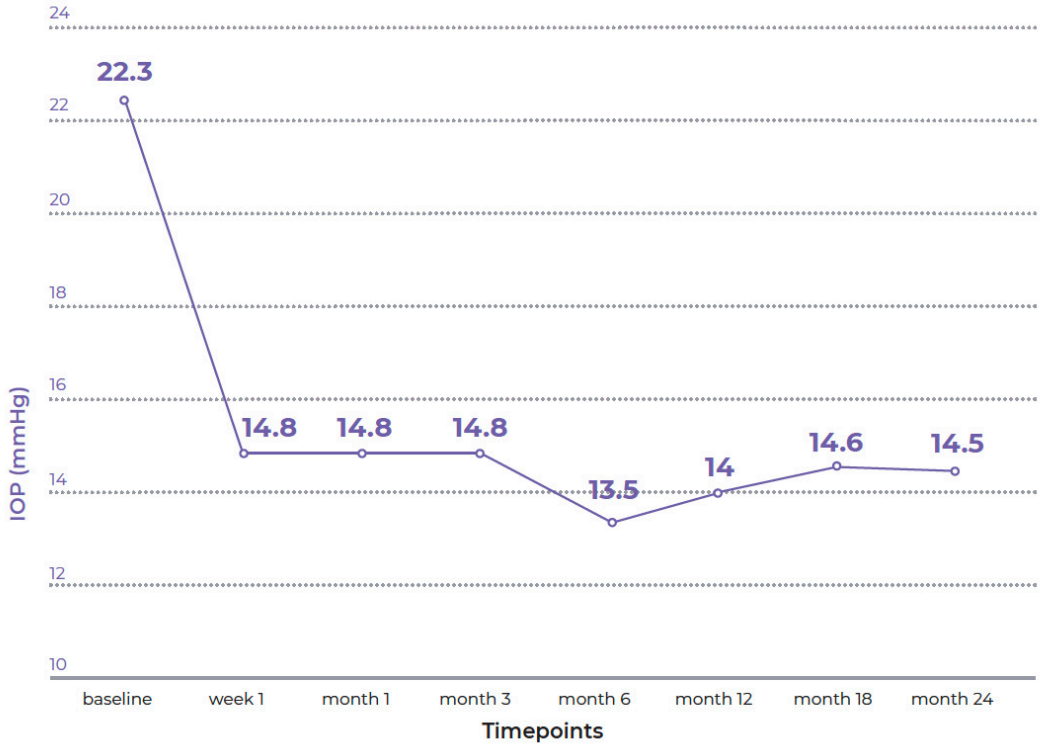


FIGURE 4

Intraocular pressure (IOP) over the course of 24 months after treatment. Intraocular pressure at baseline was 22.3 ± 5.5 mmHg and reduced to 14.5 ± 2.6 mmHg at 24 months (a reduction of 34.6%).

DURABILITY AND SAFETY PROFILE

1 DAY | 18 MONTHS | 24 MONTHS

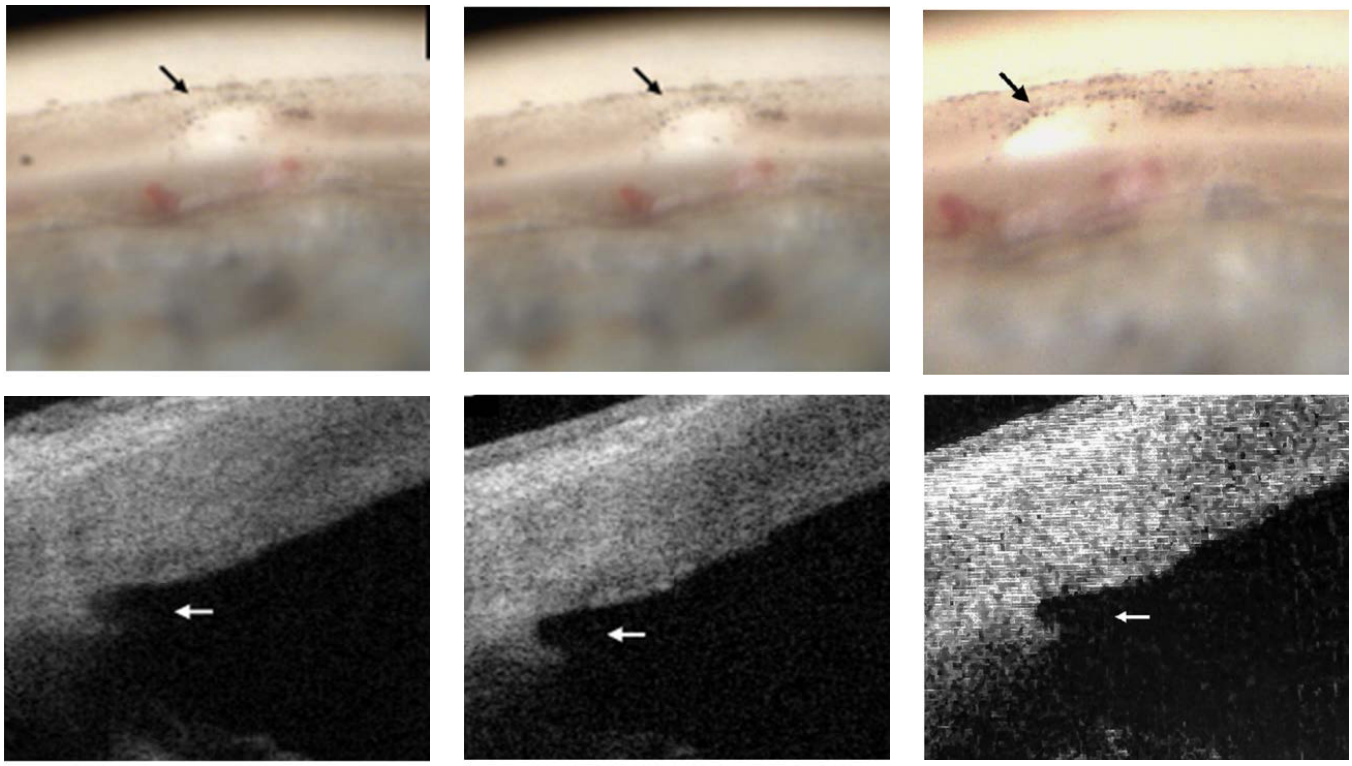


FIGURE 5

Postoperative gonioscopic (top) and OCT (bottom) imaging confirmed that the created apertures remained patent up to 24 months, with no signs of closure or scarring.

FAVORABLE SAFETY PROFILE

Safety analysis revealed no serious device-related adverse events, with only minor, self-resolving blood reflux observed in 11 eyes immediately after surgery. Importantly, no patients reported significant postoperative pain or vision disturbances.

DISCUSSION

FLIGHT represents several major advantages compared to currently available trabecular bypass procedures. Unlike MIGS procedures, which requires intraocular implantation or tissue manipulation, FLIGHT is completely incision-free, which may reduce the risks associated with intraocular surgery while maintaining effectiveness. One prospective analysis found that as many as 45% of iStent inject microstents—one of the most commonly performed MIGS procedures—were misplaced in the eye.[16] The FLIGHT procedure leverages advanced imaging to ensure accurate treatment placement and enables the surgeon to overcome traditional visualization challenges.

ELT, like FLIGHT, creates apertures in the trabecular meshwork but requires a corneal incision and direct contact with the trabecular tissue. Unlike ELT, FLIGHT eliminates these invasive steps, reducing procedural complexity and potential complications.

SLT is a widely used first-line laser therapy for glaucoma but relies on a Q-switched Nd:YAG laser, which induces cellular turnover rather than directly bypassing outflow resistance. The FLIGHT procedure, in contrast, creates a physical conduit for aqueous outflow, potentially leading to more durable IOP control.

Further, conventional SLT requires the user to manually manipulate the position of the treatment; a misplaced pulse can (and does) happen if the patient moves. In contrast, the curvature of the ViaLens™ patient interface, designed to secure and stabilize the eye, gives the surgeon complete control of the patient's eye, head, and body movement.

CONCLUSION

The FLIGHT procedure represents a breakthrough in noninvasive glaucoma treatment, leveraging femtosecond laser technology to create a precise, durable aqueous humor outflow pathway. With an initial safety and efficacy profile comparable to or exceeding existing interventions, FLIGHT has the potential to redefine the treatment paradigm for patients seeking a non-surgical, long-lasting solution for glaucoma management. Ongoing multicenter, randomized controlled trials will further establish its role in clinical practice.

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