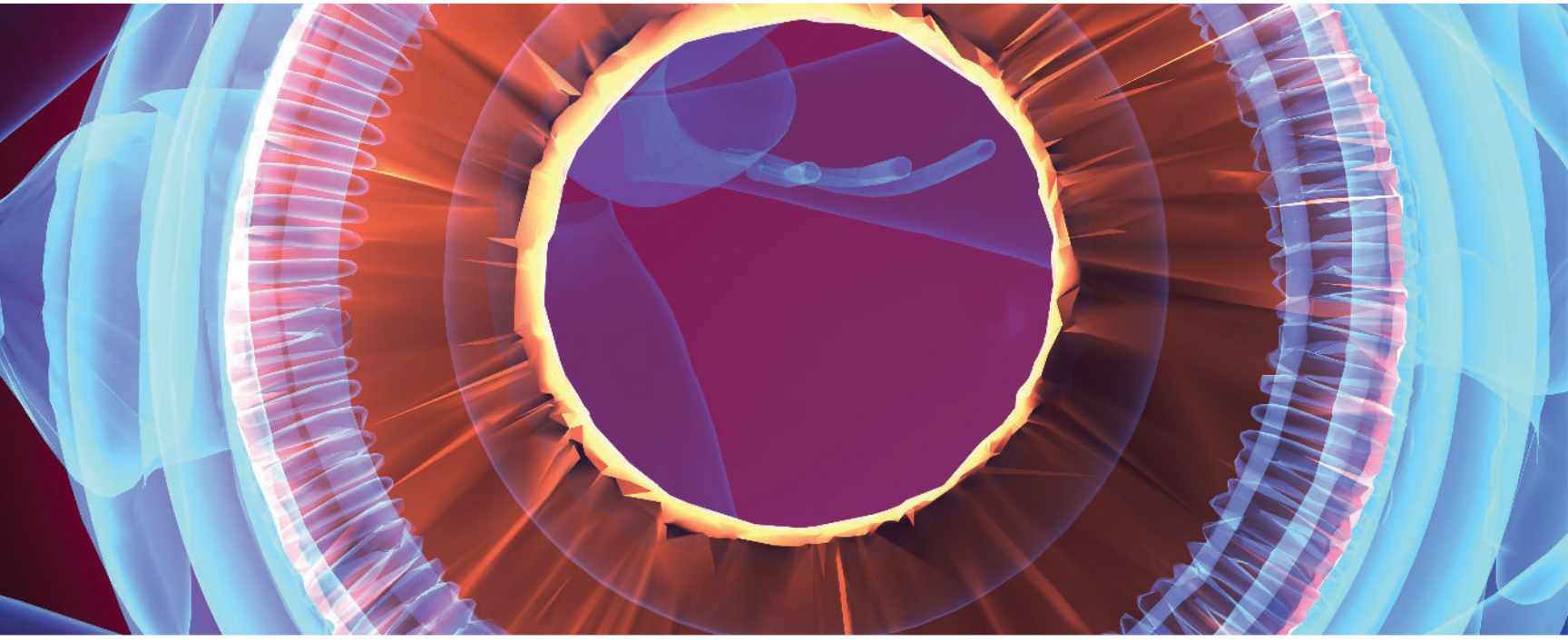

RETHINKING OUTFLOW

A new glaucoma management tool measures what eye care providers strive to improve.

BY LESLIE O'DELL, OD, FAAO, AND FRANCIS Y. FALCK JR, MS, PHD, MD

Glaucoma is a progressive optic neuropathy that can result in permanent vision loss. For years, treatment has focused on controlling IOP to delay ganglion cell death. IOP is determined by the rate of ciliary body *aqueous humor production* and the rate of *aqueous humor outflow* from the eye via the trabecular meshwork (TM).

The rate of aqueous humor production is not constant. It follows the body's circadian rhythm; it is highest in the morning and then fluctuates throughout the day. This variation of ciliary body aqueous humor production is the reason we see daily variation in IOP, and it reinforces the need to perform serial tonometry before initiating treatment.

In contrast, the rate of aqueous humor outflow through the TM is constant.[1] Published studies have shown that glaucoma is an outflow disease. These studies have also shown that eyes with advanced glaucoma have the worst outflow.[2]

TONOMETRY AND TONOGRAPHY

Predicting IOP is pretty straightforward. When aqueous humor production increases, IOP increases. When aqueous humor production decreases, IOP decreases. If an eye has impaired outflow due to disease, then an increase in aqueous humor production will result in a greater rise in IOP. Tonography can be used to predict which eyes will have the greatest rise in IOP.

A single IOP reading with current tonometry devices provides only a brief snapshot in time. How can we know with certainty whether our outflow therapy is effective if we are measuring a patient's IOP only in the office or clinic? The answer is that we cannot, because we are measuring IOP rather than outflow, and the underlying natural variation in IOP can give the false impression that therapy has worked or has been ineffective, when in fact the patient's true highest IOP measurement has never been observed.[2]

Tonography, which allows us to measure the rate of aqueous humor outflow through the TM, can provide

additional valuable clinical management information.[2]

If impaired outflow is the primary cause of glaucoma, then why have we not been routinely measuring it using tonography? Until recently, the method to measure aqueous humor outflow was cumbersome and difficult. Tonography was a mechanical indentation process during which a 10 g weight was placed on the eye with the patient supine. Measurement took 4 minutes with no blinking, and the procedure was technician-dependent, potentially leading to increased measurement variation.

In addition, ocular elasticity was a confounding factor. In myopic eyes with thin sclera, outflow was overestimated, and in hyperopic eyes with thick sclera it was underestimated. Outflow was calculated based on the change in baseline IOP minus final IOP. A fixed ocular elasticity value was used in this calculation. Because of these issues, tonography was relegated to being used as a research tool; however, some clinical practices saw the benefit and need for tonography and incorporated the measurement into routine use.[3]

CHANGING FOCUS

New treatments such as minimally invasive glaucoma surgery (MIGS) procedures and novel prostaglandin medications focusing on the outflow pathway have directed increased attention on this pathway. If glaucoma is an outflow-based disease, as explained above, then using tonometry alone to confirm a diagnosis, perform risk assessment, and measure therapeutic response can lead to the wrong conclusion. Thus, it's time to rethink glaucoma and focus on outflow. By measuring outflow one can determine risk, confirm response to therapy or lack thereof, and know when it is time to proceed to a different therapy.

A New Tool

The Falck Medical Multifunctional Device (FMAT1; Falck Medical) is a new FDA-cleared technology using artificial intelligence that performs serial tonometry, ophthalmodynamometry, ocular perfusion pressure, and tonography measurements all in one unit (Figure 1).[4]

The FMAT1 mounts on a slit-lamp microscope and uses single-use disposable prisms that block transmission of infectious disease. All testing is done with the patient upright. Typical measurement takes less than 10 seconds and is user-independent with the use of topical proparacaine or tetracaine.

AT A GLANCE

- The gold standard treatment for patients with glaucoma has been aimed at improving outflow through the use of drugs, laser, or surgery. Therefore, it makes sense to assess outcomes by measuring outflow.
- Tonography measures the rate of aqueous humor outflow through the trabecular meshwork and can provide additional valuable clinical management information.
- The Falck Medical Multifunctional Device (FMAT1) performs serial tonometry, ophthalmodynamometry, ocular perfusion pressure, and tonography.

Figure 1. The FMAT1 device can be used to measure IOP, ocular pulse amplitude, tonography, and ophthalmodynamometry.

The ocular of the slit-lamp microscope is used to place the optical prism in contact with the patient's cornea. The optical prism has a circle and crosshairs to assist with alignment. After placing the prism in contact with the central cornea, the user activates the automated measurement process by touching the display screen, and data capture happens in milliseconds.

The collected data are statistically analyzed for precision and accuracy. Acceptable data are averaged and displayed. The percent variation is also displayed to provide the user with feedback regarding the repeatability, accuracy, and precision of the data. If data are out of range, the device prompts the user to repeat the measurement (Figure 2). Results are displayed graphically and numerically and can be transmitted via Bluetooth and saved electronically. Data saved in a file can be analyzed using Microsoft Excel. This method of data storage, unique to the FMAT1 technology, allows quantitative trend analysis. The captured and stored electronic data can also be used as documentation for verification and reimbursement purposes.

The FMAT1 overcomes all the difficulties of the mechanical indentation tonography method

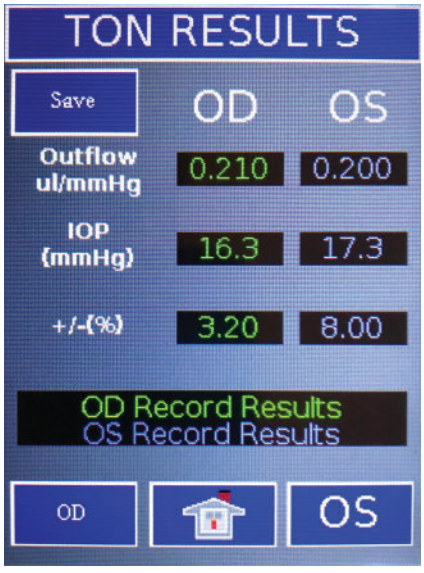

Figure 2. Data show that outflow is 0.21 uL/mm Hg OD and 0.20 uL/mm Hg OS. The average IOP is 16.3 mm Hg OD and 17.3 mm Hg OS. The data repeatability is less than 10%: 3.2% OD and 8.0% OS.

described above. The FMAT1 uses a sophisticated computer-driven optical system to measure aqueous humor outflow without the need for assumed values of ocular elasticity.

In FMAT1 clinical studies for FDA clearance, all eyes with glaucoma had outflow values less than 0.18 uL/mm Hg. In these studies, the severity of glaucoma was correlated with outflow. As one would expect, eyes with advanced untreated glaucoma had outflow values less than 0.10 uL/mm Hg.[4]

RETHINKING OUTFLOW

The gold standard of treatment for patients with glaucoma has been aimed at improving outflow through the use of topical prostaglandin analogues, laser trabeculoplasty, and/or MIGS or more invasive surgeries. With the FMAT1, we now have an FDA-cleared device to add to our diagnostic toolkit that allows us to measure what we are trying to improve. This technology is useful for assessing glaucoma risk, verifying the effectiveness of outflow medical therapy, deciding when to change outflow therapy, and determining the effectiveness of outflow surgery. It will also help us to manage our patients using a target outflow value. ■

1. Aqueous humor dynamics. In: Kaufman PL, Alm A, eds. *Adler's Physiology of the Eye*. 10th ed. Mosby:2002:248-249.
2. McDermott JA. Tonometry and tonography. In: Epstein D, et al. *Chandler and Grant's Glaucoma*. 3rd ed. 2002:45-48.
3. Methods for measuring facility of outflow. In: Hoskins HD, Kass, M, eds. *Becker-Shaffer's Diagnosis and Therapy of the Glaucomas*. 6th ed. Mosby:1989:53-55.
4. United States Food and Drug Administration 510k Clearance 151491. falckmedical.com.

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