From Mind to Market

How an industry's need for change inspired the future of aberrometry.

BY TOM PADRICK, PhD, WITH DANIEL S. DURRIE, MD

The current method for performing cataract surgery can be traced back to 1949, when initial attempts to replace a diseased lens with an artificial one proved successful. Since then, inventive minds have improved surgical techniques, instrumentation, and lens materials and designs. Although these advances changed the industry for the better, they brought with them a need for further improvement: specifically, a need for better ways to calculate and predict the lens power necessary to achieve a desired surgical outcome.

In 1967, Svyatoslav Fydorov, MD, and his colleagues published the first formula for determining an IOL's power based on axial length and keratometry measurements.[1] Subsequent formulas offered greater accuracy. All, however, are based on nonrefractive anatomic parameters such as axial length, corneal curvature, and anterior chamber depth and are expected to generate a purely optical variable. Furthermore, preoperative calculations fail to account for surgically induced changes, and eyes that previously underwent refractive surgery often generate further challenges. Ultimately, no single method is universally accurate, particularly at the extremes of axial length or after refractive surgery.

In the past 10 years, an innovative new method for obtaining refractive measurements intraoperatively has made its way to market. The origins of this method lie in the Talbot-Moiré wavefront sensor, first applied in ophthalmology by Anthony Van Heugten of Sarasota, Florida. Talbot-Moiré measures the eye by using a light source to send a narrow, collimated beam through the pupil, where it reflects off the retina and subsequently passes through a series of relay lenses. Mr. Van Heugten's system employs a charge-coupled device camera to record a fringe pattern generated as the beam passes through two crossed grids set apart at a Talbot distance and rotated with respect to one another to create a Moiré effect. These patterns are then digitized and analyzed using algorithms that recognize and identify changes from an emmetropic eye. The result is a clear snapshot of the eye's refractive power, measured at many different points across the patient's pupil simultaneously.

Mr. Van Heugten's diagnostic breakthrough happened to coincide with the arrival of premium IOLs.

Figure 1. The ORA System.

Daniel S. Durrie, MD, the Director of Durrie Vision in Overland Park, Kansas, encouraged Mr. Van Heugten to make the Talbot-Moiré sensor small enough to attach to an operating microscope. Dr. Durrie reasoned that, although traditional diagnostic methods were sufficient for traditional cataract surgery, an improvement was required to complement the rapidly advancing field of refractive lens exchange. Accordingly, Mr. Van Heugten adapted his device to fit a microscope, and in 2004 Dr. Durrie tested the device on several patients during cataract surgery.

DISCUSSION LEADS TO DEVELOPMENT

If Dr. Durrie had been mentioned in Malcolm Gladwell's *The Tipping Point,* chances are he would have been labeled a "connector." After all, it was Dr. Durrie's interactions with colleagues that clued him in to the profession's desire for intraoperative measurements. With this in mind, Dr. Durrie introduced Mr. Van Heugten to venture capitalist Bill Link of Versant Ventures in Menlo Park, California. With money from Versant, WaveTec Vision was officially formed in May 2005.

During the next 4 years, scientists and engineers worked closely with a medical advisory team to develop and test a series of product prototypes. These were assembled at the company's headquarters and distributed to medical advisors throughout the United States and Mexico. The advisors' experiences using the product provided WaveTec's developers with a way to fine-tune it to better accommodate the profession. During the developmental period, communication between users and developers is crucial, a concept the WaveTec team understood and embraced.

In June 2008, WaveTec's first commercial product was used by Kerry Assil, MD. The ORange Intraoperative Wavefront Aberrometer was officially introduced at the 2009 annual meeting of the American Society of Cataract and Refractive Surgeons (ASCRS) in San Francisco.

The aberrometer was able to take phakic and pseudophakic measurements and address the correction of astigmatism with limbal relaxing incisions and toric IOLs. As effective as the device was, the WaveTec team realized it could be better. In the summer of 2009, changes were made that enabled the unit to acquire aphakic measurements, and algorithms were developed for the determination of effective lens position and IOL power calculation.

It has been said that, in the professional world, complacency is death. The company continued to refine its technology and, in 2011, released its re-engineered device—the ORA System (Figure 1). While the Talbot-Moiré technology stayed the same, 70% of the device's hardware and software components had been changed or adjusted. The laser light system was replaced with superluminescent light-emitting diode technology, the optics were improved, and the calibration routine was enhanced to increase precision in cylindrical measurements.

Having made improvements to intraoperative refractive measurements, WaveTec sought to facilitate the rapid, effective collection of data. When a surgeon uses the ORA System, measurements and images are uploaded directly to a cloud storage database. These metrics contribute to ongoing research toward improving the company's IOL power calculation algorithms and optimizing coefficients for improved outcomes. To date, WaveTec's intraoperative devices have been used in more than 55,000 cataract surgery cases; in excess of 25,000 of these cases have postoperative data entered into the ORA System AnalyzOR. More than 4,000 cases using the system have been presented at major medical meetings, a number that would have been significantly more difficult to achieve if not for the cloud technology pooling (data on file with WaveTec Vision).

THE FUTURE

Versant Ventures' initial backing provided WaveTec with not only the start-up capital the company needed but the credibility as well. WaveTec raised several rounds of funding to develop all prototypes and arrive at market; having a strong venture capital firm involved made that task easier. Although the device is designed to provide intraoperative information never before available to surgeons, performance does not guarantee funding. A successful business model is also essential, which is why WaveTec offers users a monthly unlimited-access subscription fee that includes but is not limited to all software upgrades, personalized lens constants, and clinical outcomes analysis to accompany its flagship device.

Those at the company continue to listen to their customers' needs and strive to add features and applications they feel will optimize patients' outcomes. The company's small size allows it to be nimble, facilitating the implementation of new ideas and enhancements.

When a technological breakthrough is successful, it paves the way for future innovations. The driving success behind WaveTec's aberrometer should open up an entire field of intraoperative measurements. Already, scientists and clinicians are considering adopting more diagnostic technologies, such as optical coherence tomography and aberrometry, to provide operating surgeons with real-time information. Although it can be hard to predict the future of diagnostic technology, it is entirely possible to learn from past successes and to implement winning strategies for the next era of development. ■

TAKE-HOME MESSAGE

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- Performance does not guarantee funding. A successful business model is also essential.
- Although it can be hard to predict the future of diagnostic technology, it is entirely possible to learn from past successes and to implement winning strategies for the next era of development.

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1. Fydorov SN, Kolinko AI, Kolinko AI. Estimation of optical power of the intraocular lens. [in Russian]. *Vestn Oftamol*. 1967; 80(4):27-31.