Intraoperative Aberrometry Enters the World Stage

With growing interest among US surgeons in its technology, WaveTec expands to European centers.

AN INTERVIEW WITH TOM FRINZI, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF WAVETEC

WaveTec Vision introduced its ORange intraoperative wavefront aberrometer in 2009 at the annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS). The microscope-mounted device for the first time offered surgeons the opportunity to measure a patient’s refraction during surgery, with the aim of improving postoperative refractive results. ORange has since been succeeded by the Optiwave Refractive Analysis (ORA) System, featuring a precise light source and optics, the assurance of a live display of the eye, a convenient system-aligned, on-demand reticle, and optimized algorithms to guide refractive decisions for cataract patients.

CRST Europe spoke to WaveTec’s President and Chief Executive Officer, Tom Frinzi, to learn about the germination of this novel technology, its current state, and what the future might hold.

CRST Europe: Please talk about how the technology for intraoperative aberrometry came to ophthalmology.

Tom Frinzi: An article appeared in CRST Europe recently that gives a brief history of how the company came to be (“From Mind to Market,” by Tom Padrick, PhD, with Daniel S. Durrie, MD; February 2013; pgs 22-24). That article gives the best introduction to our technology and how it was brought to ophthalmology. In a nutshell, Anthony Van Heugten of Sarasota, Florida, conceived the idea of using Talbot-Moiré interferometry to measure the eye’s refractive power. Ophthalmologists are familiar with the concept of wavefront sensing with Hartmann-Shack aberrometry. Our technology uses a similar principle, but we found that Talbot-Moiré provides a much broader dynamic range than Hartmann-Shack and is better suited to measure the eye throughout the range of dioptric power involved in IOL power calculation.

The original intended use for this technology, when the product was being incubated, was as a pediatric vision-screening tool. That would have been a useful therapeutic application; however, from a commercial point of view, it would not have had much of a market. In the early 2000s, with the help of Daniel S. Durrie, MD, the developers started thinking about how this technology could be applied to cataract surgery. That was when they caught the attention of Versant Ventures. The investigators received their first institutional funding from that venture capital firm in 2005, and the company was founded and moved forward.

With the idea of using the interferometry technology in cataract surgery, the engineers, along with Dr. Durrie, began to work on streamlining the device, making it adaptable to an operating microscope.

This is a good example of how innovation can inspire new and often unexpected market opportunities. Here is this diagnostic technology that can improve the accuracy of postoperative outcomes of cataract surgery, and it appears at a time when improved accuracy is required to complement the rapid growth of the premium IOL market.

CRST Europe: An interesting point made in that earlier article is that all current IOL power calculation formulas rely on anatomic inputs, such as axial length and keratometry, but are expected to generate an optical output—an IOL lens power. This technology measures the optical power of the eye, rather than anatomic structures.

Mr. Frinzi: Exactly, and I think the core of our approach is the value of that apheratic refraction. Once the cataract is removed and the pristine optical system remains, measuring the power properties of the eye at that point gives a more accurate depiction than trying to estimate it preoperatively in the presence of a cloudy medium, the natural crystalline lens.
All the current formulas attempt to predict effective lens position (ELP). We think we have a good understanding of that. Additionally, the pseudophakic measurement is particularly important from the point of view of astigmatism. Regardless of where that lens sits in the anteroposterior direction, the axis and magnitude of cylinder are not going to change.

So the combination of the two measurements, aphakic and pseudophakic, helps surgeons to achieve accurate results. The aphakic refraction helps to get the power of the IOL right, and the pseudophakic measurement, whether the surgeon is using arcuate incisions or a toric implant to correct astigmatism, helps to determine the magnitude and axis of cylinder.

Ming Wang, MD, PhD, of Nashville, Tennessee, has demonstrated good correlation between the spherical equivalent measured intraoperatively and postoperative outcomes at 1 and 3 months.1 This is a dynamic process, and we continue to monitor and study it. We are constantly updating our algorithms. One of the beauties of our technology is that we work through a cloud-based system. When surgeons use the ORA System, all of their data and images are uploaded to cloud-based data storage. As our users submit more postoperative data, we have the opportunity to refine our formulaic backbone, so to speak.

CRST Europe: Your own experience in ophthalmology reaches back to the 1980s, with the early foldable IOL companies Iolab and Chiron Vision, followed by experiences at other companies including Bausch + Lomb, before your current position as President and CEO at WaveTec. How does your perspective from several decades in the industry help you to guide a modern start-up company like WaveTec?

Mr. Frinzi: Twenty-eight of my 32 years in the medical device business have been in ophthalmology. I joined WaveTec in August 2010, after the company was incubated.

I believe that my time in ophthalmology, in both corporate environments and start-ups, has made me a better leader. I have been blessed to have good mentors and gain a lot of knowledge—and, I hope, wisdom—through all of those experiences. What my mentors taught me is pretty simple: If you treat people the way you want to be treated, if you don’t knowingly disappoint one another, and if you can get an organization to really believe and have hope for reward, then good things will happen. My leadership style is centered on performance, accountability, high expectations, and compassion. At WaveTec, we have followed the principles of high performance management, and that has helped us to develop a successful organization. When an organization is focused on what is important to that organization, productivity begins to soar. We have been pleased with what we have accomplished to date.

CRST Europe: What about the future of the company and the technology: Where do you see it going?

Mr. Frinzi: Our focus is to continue to refine this technology. Could we get to a day when preoperative biometry is not even required—when our technology is so accurate and so consistent that the surgeon can do all of his or her measuring right on the table and draw conclusions there? That is our ultimate goal, and we think the technology is capable of that.

The clinical need is born out of 35 years of biometry experience. Despite all the evolution and advances in cataract surgery, before the introduction of intraoperative aberrometry, to be accurate within ±0.50 D of the refractive target in cataract surgery happened only about 60% of the time. That need to improve refractive outcomes for cataract patients has fostered the evolution of our technology.

Our technology continues to evolve as we make enhancements that get us closer to our goal. The most recent enhancement to the ORA System, VerifEye, was launched at this year’s ASCRS. VerifEye is our monitoring hardware upgrade that continuously provides refractive information, resulting in more refined measurements. With VerifEye, even more patients achieve their targeted refractive outcome.

What we are doing is vital to other current developments in cataract surgery. Everything we read about in terms of advances in IOL technology, advances with femtosecond laser-assisted cataract surgery, all could benefit from a device like ours that provides useful information on the table to allow surgeons to optimize and not compromise their refractive outcomes. Part of our success to date has been that we have remained focused on that task.

CRST Europe: You mentioned the femtosecond laser. There are proliferating technologies surrounding cataract surgery, with the phaco machine, the femtosecond laser in an adjoining room, and now your device mounted on the microscope. Do you see the costs of adding all these technologies as a barrier?

Mr. Frinzi: I really do not. As long as these technologies are improving outcomes in patient care, there is going to be a place for them, whether they are being paid for by the government or the private sector. In the United States, the Medicare administration now allows...
beneficiaries to pay out of pocket for technologies that they believe will improve their visual outcomes. As new technologies come into the marketplace, Medicare, or the government health insurance programs in other countries, cannot pay for all of them. But as long as the beneficiary has the ability to pay out of pocket for an improved outcome, and the technology is improving outcomes and providing overall better patient care, I believe that technology will find its place in the market.

Better medicine and better business go hand in hand. This trend can also be economically beneficial for the physician because it can translate into revenue streams from technologies that are not covered by insurance. Physicians are under great pressure in this country with continued Medicare cutbacks, and I am sure the same is true in other countries.

**CRST Europe: What are your plans for the European market?**

Mr. Frinzi: In 2012, one of our goals was to establish several centers of excellence in Europe. We established four centers last year, and we want to grow upon that base in 2013. Our efforts outside the United States have been targeted and focused to date. Our goal was to demonstrate that this technology has global appeal, whether in Belgium or Boston, and we are beginning to see that kind of global interest.

Our plan is to grow in Europe through third-party distribution. We are focusing on key markets, and we expect some significant growth, having proven that the device has global appeal.

---