

OCULAR SURGERY NEWS®



The voice of 65,000 ophthalmologists worldwide™

Vol. 20, No. 15 • August 1, 2002

Wavefront gains supporters, skeptics

Most patients undergoing conventional LASIK today can expect to achieve postop vision of 20/20 or better. According to ophthalmic laser expert **Irving J. Arons**, wavefront-guided ablation appears to offer even more — once certain problems are solved.

Problems to be overcome include

proper registration of eye trackers to ensure that a patient's custom ablation matches the wavefront diagnosis, in addition to biomechanical issues such as wound healing.

While many in the profession are positive about the promise of wavefront, some clinicians express doubt that these problems can be properly addressed.

"Wavefront is excellent at diagnosing spherical aberrations," said **Noel Alpines**,

MD, of Cheltenham, Australia. But he noted that some early hype may have practitioners expecting more from the technology than it can deliver.

The Spotlight on Refractive Surgery addresses wavefront technology from several angles. Read about the concerns of Dr. Alpines and others

Spotlight on
Refractive Surgery

Some foresee limitations in wavefront technology

Manufacturers are still declaring that wavefront and custom ablation are the future of refractive surgery. However, their need and effectiveness are becoming more hotly debated.

by **Michael J. Walsh**
Staff Writer

In the past 2 years, excimer laser and ophthalmic diagnostic manufacturers have touted wavefront diagnosis as the coming technology for a golden age of refractive surgery. But will the technology really be all that it has been promoted to be? Some researchers and clinicians are expressing doubt.

Some have posited that the higher-order aberrations identified by wavefront diagnosis are too small for today's lasers to address. In addition, some say, the healing power of the human body may undo any corrections to higher-order aberrations that are created by custom ablations. And if a noticeable change can be made, some ask, can it work for everyone, and can wavefront alone make it happen?

OCULAR SURGERY NEWS raised these issues and others with several clinicians with broad experience in refractive surgery. While all said they recognize a future for wavefront diagnosis, they do not see it as the universal answer.

Not the Holy Grail

Two years ago, OCULAR SURGERY NEWS interviewed **Noel Alpines**, MD, regarding the advantages of wavefront diagnosis vs. topography (August 1, 2002, page 1). At that time, when wavefront was new to the ophthalmic industry, he predicted that it was not going to have the impact on refractive surgery that many manufacturers were forecasting. Two years later some of his assertions have been borne out, and he has found that a number of other surgeons share his views.

"Everything I said 2 years ago is really coming to be," Dr. Alpines said. "It's now much more accepted that wavefront is not performing as well as people anticipated. Wavefront is not the Holy Grail. It's a sophisticated spectacle test that will become an indispensable diagnostic tool."

He acknowledged that, as a marketing tool, wavefront technology is attractive to patients. But he called it a tool with teeth.

"It will come back to bite you later when your patients return and tell you they did not get the results or supervision they were expecting. And it's tough to improve on unsatisfied expectations," he said.

Dr. Alpines suggests using a common-sense approach, not promising patients too much, whether in wavefront-guided or conventional surgeries, and then attempting to over-deliver.

"You're just creating headaches for yourself. I'd rather have people not have the surgery than to create unrealistic expectations. These unrealistic expectations become self-limiting because you have to take the time to deal with a lot of dissatisfied old business instead of working on your new business," he said.

However, with that said, Dr. Alpines acknowledged that wavefront will have a place in refractive surgery and that it has many positive factors.

"Wavefront is excellent at diagnosing spherical aberrations, especially where induced closer to the peripheral cornea. Wavefront can help you avoid or adjust those spherical aberrations, and you can reduce night vision symptoms, halos, second-order aberrations and defocus," he said.

Astigmatism is the issue

The technology has its shortcomings, he believes, in addressing astigmatism.

"You do not want to treat just for the refractive correction, but also for the corneal contours, in which case wavefront falls down in much the same way a spectacle value treatment would. You'll leave too much astigmatism on the cornea, and in addition you'll add an element of irregularity rather than reduce it," Dr. Alpines said.

However, he believes wavefront can be a help in conjunction with other tests.

"If you examine the cornea using vector planning, you can adjust the treatment to take into account what really needs to be treated, a combination of astigmatism and refractive error. You can move the maximum ablation closer to the principal meridia, and you'll get a greater reduction of astigmatism from less 'off-axis' effect," he said.

Dr. Alpines said he thinks wavefront analysis in conjunction with vector planning will result in less astigmatism and second-order aberration. With less corneal astigmatism, patients will have less second- and third-order aberration, he said.

"This is likely to provide greater contrast sensitivity and improved quality of vision," he said.

In 1998 Dr. Alpines developed a combination of diagnostic tools into the ASSORT program, which helps the surgeon to decide what astigmatism types need to be corrected and what can remain as is to get the best possible outcome.

Early in the development of refractive surgery, he said, most surgeons relied on manifest refraction for surgical planning. Then came topography, and many surgeons advocated that technology and for a time abandoned manifest refraction. With the introduction of wavefront, he expects that many surgeons will move to that technology as the tool of choice. However, Dr. Alpines said the best answer is to use a combination of all three.

In a comparison of ASSORT with wavefront vs. wavefront alone, Dr. Alpines said one would expect to be able to get results that benefit the cornea, but with no additional negative effects on second-order aberrations.

"Wavefront tries to correct for every aberration in the eye on the corneal surface," he said. "If you do that, you'll get a cornea that is 'cobblestoned' to fix all the errors in the eye behind it. By using a technique to find out where all the

errors are, you get a much better outcome with less disturbance to the corneal surface."

Patient interaction

Dr. Alpines said use of wavefront technology also limits a patient's interaction with the planning of his or her surgery.

"All the major companies have decided to rely on the Shack-Hartmann version of wavefront with their own modifications. However, these machines are really just a very sophisticated autorefractor. That in itself may not be a bad thing. But by using an autorefractor to draw a conclusion, the surgeon excludes the patient's cortical perception of astigmatism, as is the case with manifest refraction. That has an impact on the treatment. Not involving the patient's conscious input

in the surgery risks having a less satisfied patient," he said.

"While some machines include an option to allow the patient to get an idea of what they'll be seeing after surgery, it's not really an accurate representation and not at a level where the human brain can appreciate it," he continued.

Another potential problem is the fineness of the ablations dictated by wavefront diagnosis.

Wavefront technology

"We're talking about microns of change, maybe 10 μm ," Dr. Alpíns said. "That small amount of change is easily influenced in the measurement process, especially by drying of the eye. Studies have shown that wavefront refractions change as the tear film changes. The machine is that sensitive. Therefore it's hard to get an idea of the changes required, depending on the state of the tear film when measured and how the tear film changes before surgery."

The LASIK flap may also present a problem. "No matter how finely tuned a microkeratome is, it's still a gross change to the cornea as opposed to the changes required with wavefront-guided treatments," Dr. Alpíns said.

"I think wavefront is a great idea, but its ability to deliver on its promise is limited," said Michael Goggin, MD, of Adelaide University. Technical problems including the individuality of patients, the type of treatment and how the eye is mapped may restrict the effectiveness of wavefront-guided treatment, he said.

"This term 'super-vision' has appeared, but I believe most well-done excimer ablations deliver that now without wavefront," Dr. Goggin said. "My patients are receiving great results with my Nidek."

He said two recent papers suggest that wavefront-guided ablation, although it induces fewer aberrations than a standard ablation, actually induces aberrations rather than reducing them. However, he said, the Snellen visual acuity results are about the same. Low-contrast, low-illumination acuity is likely to be a better measure of wavefront outcome, he said.

"I think there will be a use for wavefront, but I don't think it will be for general use. Not all machines will work as well on all patients. And wavefront may not be useful for gross errors such as keratoconus. A lot of people have a belief that this is an answer to a maiden's prayer, but it's not," Dr. Goggin said.

In addition, Dr. Goggin said he believes the wavefront systems now in development and use are still not accurate enough to get rid of all aberrations.

"As fine as each lenslet is, they're still slightly aberrated. They're actually not fine enough to deliver on the promise of aberration-free vision. Also, the light most wavefront systems use is infrared. But infrared light penetrates the retina at different depths from person to person. If you don't allow for that individual change you'll get an inaccurate representation of spherical errors," Dr. Goggin said.

Another potential problem with the technology, Dr. Goggin said, is that to be really effective the wavefront-guided ablation must be done to suit specific physiological conditions.

"What suits an eye for near vision in low light may not suit for distance in sunlight," he said.

Dr. Goggin also wondered about the long-term benefit of making minuscule changes to the corneal surface.

"Aberrations increase with age," he said. "What we do today may lose its effect in 10 years. And there is some evidence that suggests our brains actually see very well in the presence of significant aberrations."

As for the question of the flap erasing higher-order corrections, Dr. Goggin quoted a recent lecturer who said, "It's hard to appreciate a parquet floor through a shag rug." This issue raises the separate question of whether surface ablation will be better than LASIK for use with wavefront-guided ablation.

Looking to the future, Dr. Goggin wondered whether there will be problems matching IOLs to customized corneas in patients who develop cataracts after wavefront-guided ablations.

In his own practice, he said he and his patients have been happy with results achieved without wavefront. He said his patients regularly achieve 6/6 and in about 60% of cases 6/4. He suggested surgeons need to focus more on their own techniques than any diagnostic tool.

"If you're careful about how you do your conventional treatment you'll get better results," he said.

Recent studies

During the 2002 Association for Research in Vision and Ophthalmology (ARVO) meeting, two paper sessions were devoted to discussing the potential of wavefront technology in refractive surgery.

A notable difference from similar sessions at previous meeting sessions was the restrained tone of many of the speakers presenting their study data on wavefront.

Marguerite McDonald, MD, said that while patients can be ablated perfectly, some will simply never be happy.

"Some patients have 20/20 vision but 20/400 minds," Dr. McDonald said. She suggested that surgeons need to evaluate their patients closely to see who will make good candidates, not just physically but psychologically as well.

Both Raymond A. Applegate, OD, and Steven E. Wilson, MD, warned during separate presentations that while wavefront diagnosis can find minuscule aberrations in the eye, the body's healing process may wipe out corresponding changes produced with a laser. The minute changes needed to fix wavefront aberrations is the biggest hurdle for most customized ablations, the presenters said.

Also at ARVO, Michael K. Smolek, PhD, presented a study showing that extremely irregular corneas may not be candidates for customized corneal ablations because they are inadequately described by Zernike polynomials. Zernike polynomials are the algorithms that allow refractions to be extrapolated and turned into a useful rendering of a corneal surface. (See the accompanying article for a primer on how wavefront diagnosis works.)

Dr. Smolek said surgical laser algorithms that use Zernike terms only up to the fourth order will be inaccurate for treatment of complex corneas, such as those that have previously undergone refractive surgery.

Dr. Smolek and Stephen D. Klyce, PhD, analyzed a variety of eyes

including those with normal sphere and astigmatism; LASIK, PRK, and RK postoperative maps; mild, moderate, and severe keratoconus eyes; and eyes with pellucid marginal degeneration (PMD), contact-lens-induced corneal warpage and corneal transplants.

Their study showed that the greater the irregularity of the cornea or the lower the order of Zernike terms used for fitting, the higher the RMS error. The normal spherical cornea group achieved the lowest RMS error and did not require terms above the fourth order to describe their shapes. Astigmatic and keratoconus suspect corneas used terms up to the fifth order. LASIK, PRK, RK, mild and moderate keratoconus, PMD and contact-lens-warped eyes were grouped similarly, and needed at least eight orders to describe. Keratoplasty and advanced keratoconus had RMS errors 8 to 16 times that of normal corneas and never met the threshold.

Dr. Smolek said corneal shape has a major effect on refraction, particularly in abnormal corneas. He said a normal cornea that has undergone LASIK surgery requires approximately three times more Zernike terms to accurately represent its new shape.

In a study of 52 eyes undergoing routine LASIK, Dan Z. Reinstein, MD, and colleagues found that biomechanical and epithelial effects need to be accounted for to achieve desired curvature changes in the cornea.

His LASIK cases, with corrections ranging from -1 D to -10.25 D, were analyzed using Orbscan topography (Bausch & Lomb) and three-dimensional very-high-frequency digital ultrasound scanning (Artemis, Ultralink LLC) of 1- μm precision both preoperatively and at least 3 months postop.

The curvature of the surface of Bowman's layer was calculated from the anterior best-fit sphere and the epithelial thickness profile. Change in the curvature of the back surface of the cornea was treated as a bioelastic or "bowing" factor. Curvature change of the anterior corneal surface was dissociated into epithelial and "bowing" components.

He found that postoperative refractive error was highly correlated with borderline significance to residual stromal thickness (RST) for cases with RST below 290 μm . Fifteen percent of the flattening produced by ablation was lost to "bowing" of the cornea. Five percent of flattening produced by ablation was lost to epithelial profile changes.

Dr. Reinstein concluded that these epithelial and biomechanical effects were significant in magnitude to adversely affect the accuracy of custom ablation.

"We are still not operating on the cornea in a way that is individually predictive; we do not alter surgery based on an individual's corneal anatomy. The same wavefront measurement will result in the same surgery in two individual eyes; however, no two eyes are alike. True individualization of corneal refractive surgery may require us to go the whole hog: to characterize and be able to predict epithelial and biomechanical responses for a particular individual," he said.

No super-vision

"The hype is gone and we are back to earth," said Frank Goes, MD, of Antwerp, Belgium. "But the technique is fascinating, and we are at the start of an improvement in diagnosis, scientific work, treatment, evaluation and patient selection."

Dr. Goes said companies will probably cease marketing the idea of super-vision, "although some patients may gain in acuity after wavefront-guided LASIK."

The important applications for custom ablation, he said, will be as a primary treatment "in selected patients with important higher-order aberrations."

"By using an autorefractor to draw a conclusion, the surgeon excludes the patient's cortical perception of astigmatism. That has an impact on the treatment."

— Noel A. Alpíns, MD

tions, and as a touchup in patients with subjective complaints."

Steven C. Schallhorn, MD, said corneal topography will still be an important part of refractive diagnosis for the near future for several reasons.

"Corneal topography displays the shape of the surface that is being operated upon with PRK or LASIK, unlike wavefront which measures the entire optics of the eye, including the posterior cornea and lens. The community understands corneal topography and is familiar with the displays, such as indices for keratoconus," he said.

Dr. Schallhorn said that claims of super-vision are still premature.

"It's too early to tell how much improvement custom ablations will have over traditional. Preliminary studies suggest that there may be fewer quality-of-vision complaints. If true, this alone would be extraordinarily beneficial and would lead to custom ablations being considered standard of care. But it certainly won't be a 'holy grail' for everyone," he said. "Another important role for custom ablation may be to improve the vision of those patients with suboptimal outcome from previous surgery, such as decentered ablations or patients with significant night-vision complaints."

Dr. Alpíns agreed that the technology has a place.

"I realize wavefront is a technology that's here to stay. It's a wonderful diagnostic tool, but it needs something additional to refine its capabilities. It's not the last step in the perfection process," he said.

DSN

For Your Information:

Noel A. Alpíns, MD, FACS, can be reached at NewVision Clinics, 7 Chesterville Road, Cheltenham Vic. 3192, Australia; (61) 3-9584-6122; fax: (61) 3-9585-0995; e-mail: alpíns@newvisionclinics.com.au. Dr. Alpíns has a direct financial interest in the ASSORT program. Frank