

Cataract & Refractive Surgery **TODAY**

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The Progressive Laser Vision Surgeon



Cutting-edge laser and diagnostic technologies are taking treatment customization to a whole new level.

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Current Legal Issues in Laser Vision Correction

Discussion and documentation are refractive surgery's key words.

BY STEPHEN F. BRINT, MD

Two main concerns trouble refractive surgeons today. The first is whether there is a relationship between pupillary size and postoperative night vision problems such as glare and halos. The second is the possibility of corneal ectasia following LASIK, including how to identify patients who could potentially be ectatic and whether they should undergo LASIK or even a surface procedure or completely forego surgery.

DO PUPILLARY SIZE AND VISUAL SYMPTOMS CORRELATE?

In my practice, no matter which laser I use, I always document that I have measured the size of the patient's pupil. In today's medicolegal environment, this step is immensely important, whether it is performed with a Colvard pupillometer (OASIS Medical, Inc., Glendora, CA) or a more sophisticated Procyon infrared pupillometer (Keeler Instruments Inc., Broomall, PA). I personally believe that with the current Wavefront Optimized (WaveLight, Inc., Sterling, VA) and wavefront-guided ablation technologies, pupillary size is a nonissue. Both modalities minimize the induction of spherical aberration. Moreover, Schallhorn et al¹ conducted a study in young naval pilots that concluded that night vision problems are unrelated to the pupil's size.

Refractive surgeons used to debate the optimal ablation zone and treatment pattern—optimized versus customized versus conventional ablations and 6.5- versus 7.0-mm treatment zones. The current consensus favors a 6.5-mm treatment zone with either Wavefront Optimized or wavefront-guided technology (to minimize induced spherical aberrations). Holladay et al² used the Stiles-Crawford effect to explain that even if the effective treatment zone is less than 6.5mm, patients with large pupils do not experience night vision problems as long as the ablation references the wavefront and the zone is at least 6.5mm. The WaveLight ALLEGRETTO WAVE excimer laser (WaveLight, Inc.) features both wavefront-guided and Wavefront Optimized technologies and also delivers a 6.5-mm treatment zone to further prevent unwanted visual symptoms.

THE SPECTERS OF ECTASIA AND KERATOCONUS

The difficulty with keratoconus and ectasia is knowing whether a cornea, even one that appears normal on corneal topography, will progress to forme fruste keratoconus or frank keratoconus regardless of whether or not it undergoes refractive surgery. A 20-year-old cornea may have absolutely perfect topography and still develop keratoconus later in life without undergoing a laser procedure. Certainly, anything on corneal topography that suggests corneal asymmetry or asymmetric steepening is a red flag for the surgeon, and he must document it in the patient's chart and discuss the finding with the patient accordingly.

CONTACT LENSES AND ECTASIA Preoperative Guidelines Have Changed

Because the incidence of ectasia and keratoconus seems greater among contact lens wearers, refractive surgeons have developed guidelines for surgery in this population. The wearers of both soft and rigid gas-permeable contacts must cease wearing their lenses for a period of time prior to undergoing refractive surgery in order to allow their corneas to normalize. The standard waiting time used to be a few days for soft daily wear lenses, 1 week for regular soft contact lenses, and 1 month for rigid gas-permeable lenses.

Soft Contact Lenses

The current recommendation is at least 1 week of abstinence from soft contact lenses. If the topography is still abnormal, the surgeon must take subsequent topographies at 2 weeks, 1 month, etc. If a soft contact lens wearer has a completely normal corneal topography at 1 week, I consider him a fine LASIK candidate. If the topography at 1 week shows any asymmetry and inferior steepening, then I have him wait at least 1 month to allow his cornea to stabilize. If at 1 month there is still no change in the patient's corneal topography, or if it is a minimal change in a younger patient who meets all of the other parameters for surgery, then I will proceed with a surface ablation, but not LASIK.

Rigid Gas-Permeable Lenses

We now recommend that patients discontinue wearing their rigid gas-permeable lenses for 1 month per every decade they have worn them. For example, a patient who has worn these lenses for 20 years would need to leave them out for 2 months before the surgeon first checked his corneal topography. Then, if the topography shows any asymmetry or signs of steepening, the patient should abstain from wearing the lenses for another month. For patients who are still in their 20s, I generally advise against any surgical treatment because their corneal response will be too unpredictable. I do not expect patients in their late 30s or older (whose corneas have stabilized) to develop keratoconus, and I will generally proceed with surgery. However, I document that I explained to the patient that no surgeon can predict with 100% certainty that someone will not develop keratoconus, and then I opt for a surface procedure as opposed to LASIK. I will perform LASIK if these patients' corneas stabilize reliably.

It is most important to document all discussions with the patient in his chart. We must make sure that he understands that we cannot predict the process of the cornea despite our best knowledge at the present time and that he could develop keratoconus. Internationally, some patients with very mild keratoconus who were treated with surface ablation have fared well. Essentially, it is a matter of discussion and documentation.

ARE NEW CORNEAL ANALYZERS CHANGING THE FIELD?

Some wonder whether new devices for analyzing the cornea more accurately predict the development of ectasia

and keratoconus. The Pentacam (Oculus, Inc., Lynnwood, WA) is one such device; it analyzes both the anterior and posterior surfaces of the cornea. WaveLight AG (Erlangen, Germany) has partnered with Oculus Optigeräte GmbH (Dutenhofen, Germany) to incorporate the Pentacam's technology into the ALLEGRETTO WAVE system overseas and create the ALLEGRO Oculyzer, a topography-guided analyzer and diagnostics system. The Oculyzer features a Scheimpflug camera that takes five measurements of the anterior segment as well as detailed maps of the central cornea.

Certainly, such devices make more corneal data available to us surgeons and may allow us to better advise patients of their potential risk for various conditions. However, I do not think that a single device can definitively determine an eye's risk for developing corneal ectasia and keratoconus. Although the information provided by this technology will assist us in diagnosing keratectasia, it will not rule the disease in or out and must not replace informed consent. Again, the refractive surgeon's best protection when making determinations about keratoconus and ectasia are discussion and documentation. ■

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Strategies to Combat Corneal Ectasia

Careful screening and further study will help minimize the incidence of this disease.

BY R. DOYLE STULTING, MD, PhD

Ectasia is progressive steepening and thinning of the cornea that occurs after excimer laser corneal refractive surgery. Theo Seiler, MD, PhD, reported the first case in 1998,¹ and there are now approximately 160 cases in the published literature. My colleagues and I at Emory Eye Center in Atlanta have seen 66 eyes with ectasia so far. We found that forme fruste keratoconus, a low preoperative corneal thickness, low residual stromal bed thickness, and high myopia are risk factors for ectasia.² At first, it seemed that we could identify all at-risk eyes with preoperative screening. Then, refractive surgeons began to report ectasia in eyes that did not have any of these risk factors.

Patients who developed ectasia without identifiable risk factors tended to be younger than those with identifiable risk factors.³ We think some of these eyes had a propensity for ectasia, and some of them might have developed keratoconus if they had not undergone LASIK. In other eyes, flaps might have been thicker than anticipated, leading to residual stromal thicknesses that were less than predicted.

Identifying eyes that could develop ectasia after LASIK is important because ectasia is a rare, but devastating complication (Figure 1) of a procedure that provides independence from glasses and contact lenses for more than 1 million patients each year in the US.

HOW WE IDENTIFY SUSPECT CORNEAS

To identify eyes that may develop ectasia, refractive surgeons screen for recognized risk factors. Corneal curvature is measured by Placido, scanning slit-beam, or Scheimpflug imaging. My colleagues and I screen for thin residual stromal beds by measuring the initial corneal thickness and then calculating the depth of tissue that will, theoretically, be removed by the flap and the ablation. To be certain that the flap thickness is not significantly greater than predicted, we routinely measure the thickness of the stromal bed after flap

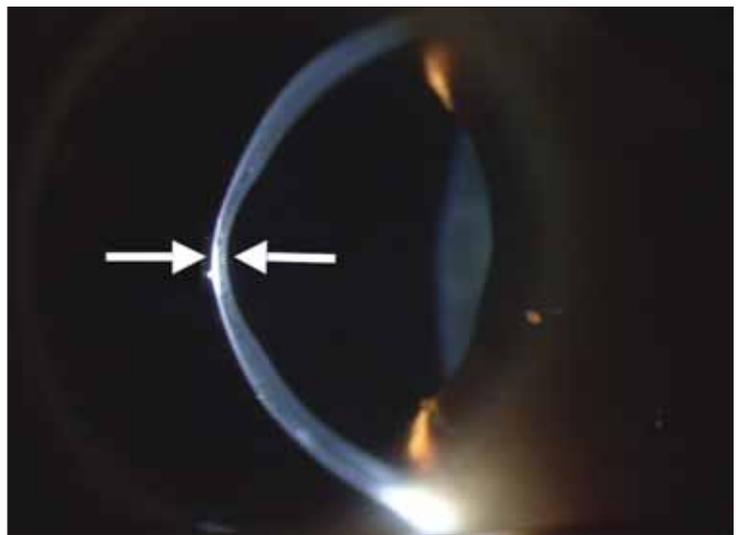


Figure 1. Central corneal thinning (arrows) in an eye that developed ectasia after LASIK.

preparation and before laser ablation.

There are other “soft” findings that suggest the possibility of developing ectasia after LASIK. These include unstable refractions, especially if there is increasing myopia or astigmatism. Also, people who cannot achieve 20/20 BSCVA may have irregular corneal curvatures that are associated with ectasia. Other soft risk factors include habitual eye rubbing and a family history of keratoconus. These factors should be considered for borderline eyes in which the surgeon is unsure whether to proceed with LASIK or not.

Most markers for ectasia are not absolute, but vary continuously—and there is no definitive line between values that predict that ectasia will occur and those that guarantee LASIK can be performed safely. I avoid LASIK in patients with forme fruste keratoconus, initial corneal thicknesses of less than about 480 μ m, and a residual stromal bed of less than about 250 μ m. I carefully evaluate patients with an unstable refraction, a BSCVA of less than 20/20, young age, a history of habitual eye rubbing, and a family history of kera-

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Optical Imaging of the Cornea

Developments in diagnostic imaging.

BY ALAN N. CARLSON, MD

Over the past 2 decades, advances in both hardware and software technologies have helped make computerized corneal topography readily available and reliable, to the point that corneal topography has largely replaced standard keratometry for analyzing the curvature of the anterior corneal surface. There are, however, limitations and even errors generated when using curvature information that relies exclusively upon Placido disc reflection, and these problems become more common and increasingly significant as we demand more information with greater precision under increasingly complex surgical circumstances.

LIMITATIONS OF PLACIDO DISC TECHNOLOGY

To begin, Placido disc-based topography units do not have the ability to measure the central 1.8 to 2.0mm of cornea, and this information is currently extrapolated from the smallest reflected ring. Most surgeons would agree that this information from the central cornea is most important, since this is the crucial pathway for light through the pupil. This is the most important light, from the standpoint of both the anterior and posterior segments, since photoreceptor alignment weighs this central light more importantly, thus accounting for the Stiles-Crawford effect.

Increasingly important is surgeons' ability to precisely measure the posterior cornea as opposed to their merely relying on the assumed relationship that exists between the anterior and posterior surfaces (as occurs when using keratometry- or curvature-based topography). This relationship does not hold constant when a corneal injury or surgery, particularly refractive surgery, alters the anterior corneal curvature only, and the surgeon must then calculate or estimate the posterior contribution to true corneal power using preoperative data or by refraction over a contact lens with known parameters. As a result, our estimation of overall or true corneal power includes potential error in eyes that undergo a change in the curvature of the anterior surface without a corresponding

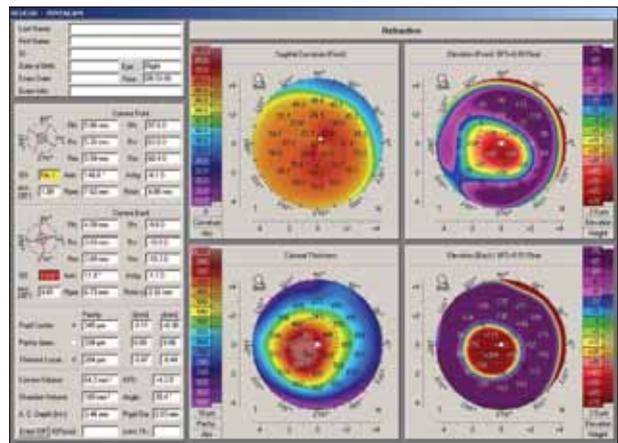


Figure 1. Severe ectasia following LASIK for high myopia in a patient referred for INTACS corneal ring segments (Addition Technology Inc., Des Plaines, IL).

change in the posterior surface, as with cases of corneal refractive surgery. This is considered the predominant source of error when trying to calculate IOL power in patients who have undergone previous corneal refractive surgery.

SCHEIMPFLUG IMAGING

One of the most significant advances in our evaluation of eyes subject to the limitations and error by curvature-based topography is the development of corneal tomography, first with the Orbscan (Bausch & Lomb, Rochester, NY) and more recently with the Pentacam (Oculus, Inc., Lynnwood, WA), which utilizes Scheimpflug tomographic imaging. Corneal tomography involves optical sectioning with a three-dimensional mathematical reconstruction that includes both the anterior and posterior corneal surfaces. This technology is capable of producing extremely accurate and reproducible elevation-based data and mapping of the anterior and posterior surfaces measuring microns of elevation or depression against a best-fit sphere. Relative to previous curvature-based methods, this imaging technology greatly improves our ability to

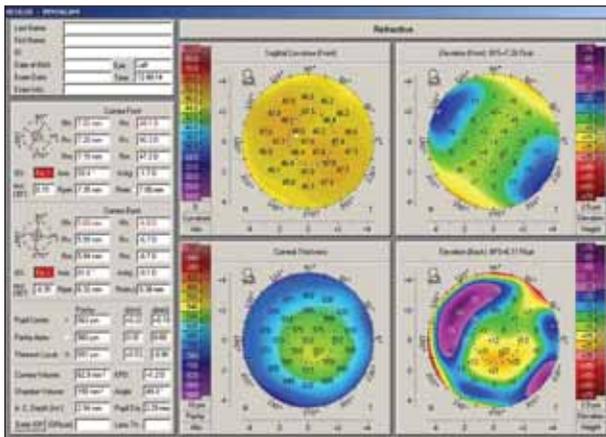


Figure 2. A patient with a positive family history for keratoconus presented for LASIK surgery showing early keratoconus. Refractive surgery and eye rubbing were discouraged.

evaluate patients with early forms of keratoconus or surgically induced ectasia. The Pentacam has defined a new standard with respect to our ability to accurately, reliably, and reproducibly evaluate elevation data using Scheimpflug imagery of the anterior segment.

SCREENING APPLICATIONS

One of the most important and practical applications of the Pentacam includes screening for patients who may be poor candidates for LASIK surgery, particularly those at risk for developing ectasia (Figures 1-3). Forme fruste keratoconus is essentially a retrospective diagnosis made in patients who develop keratoconus after corneal surgery. Yet, we are asked to consider this diagnosis prospectively without the benefit of hindsight. So, we are left with needing more sensitive methods of preoperatively identifying individuals with corneal problems such as early keratoconus as well as those whose corneal findings may represent contact lens-induced irregular astigmatism or even chronic eye rubbing. Ideally, our diagnostic threshold should be set to screen out poor candidates while offering surgery to those patients who have an acceptable long-term risk-to-benefit ratio.

PERSONAL EXPERIENCE

The Pentacam has provided a remarkable benefit to our practice in both its utility and practicality during the screening of routine patients presenting for refractive surgery. This benefit applies equally to the patients with complex eyes who present for evaluations as well as to keratoconus or surgical ectasia. The Pentacam operates using a noncontact method of measuring a patient's cornea. In less than 2 seconds, the system obtains 50 images in an accurate, powerful, and repro-

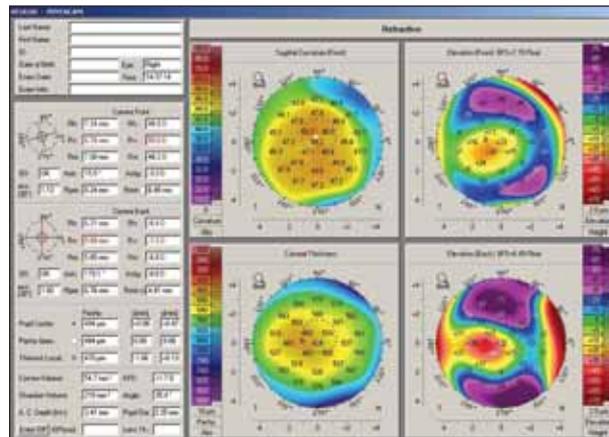


Figure 3. The Pentacam's four-map display shows moderate keratoconus. Note the thinning and elevation of the anterior and posterior surfaces against a best-fit sphere.

ducible manner, and then it presents these data in a variety of versatile, user-friendly, and customizable options. The Pentacam has become a regular part of our LASIK screening process, in which we utilize elevation mapping against a best-fit sphere of both the anterior and posterior surfaces along with optical pachymetry measurements that compare favorably to ultrasonic measurements. This diagnostic approach has allowed us to detect and avoid or postpone operating on certain ocular conditions that were not detected by curvature-based topography. Such information has also allowed us to proceed with greater confidence in some patients who merely have astigmatism rather than keratoconus or ectasia. We have also followed contact lens-induced corneal warpage with greater confidence with regard to stabilization and whether or not surgery is recommended.

ENHANCING WAVEFRONT DIAGNOSTICS

Wavefront analysis and wavefront-guided LASIK have limitations, particularly in cases in which wavefront analysis calculates a corneal treatment in an eye that has lenticular or noncorneal aberrations. This lack of information or confusion becomes more of an issue in patients who have early or progressing cataracts. It is of particular concern in patients who might experience an induced corneal aberration that mathematically offsets the measured aberration that was in the lens and creates a visual problem that might worsen after subsequent cataract surgery. Such a limitation is one of the factors supporting newer modes of customized treatments, including topography-guided LASIK, for which the early data are striking. Adaptation of the Pentacam technology in this manner is expected to provide a

remarkable advance, particularly in the treatment of complex eyes and previous surgical complications, by using the necessary data from the posterior and anterior corneal surfaces to generate improved customized ablation patterns.

FUTURE MODALITIES

The future of anterior segment imaging is bright with the promise of improved resolution on the Pentacam, currently available as the Pentacam HR. I also anticipate an improved and synergistic utilization of multiple technologies; for example, combined higher-resolution Scheimpflug imaging and high-resolution optical coherence tomography can help us evaluate more complex eyes. Beneficiaries would include patients who present for evaluation after previous surgery without clinical records, those followed for potential problems such as ectasia, and those needing their residual beds' thickness measured without having their existing flaps

lifted. Such technology, along with other advances, will likely allow us to optimize bioptic treatment parameters better than we do now. For example, our most common manner of evaluating patients currently is to identify their best single procedure. In some ranges, they are considered better LASIK patients, and at a higher range, they become phakic IOL or clear lens extraction candidates. In the future, we will likely have more creative and effective methods of calculating ideal endpoint parameters as we try to optimize each treatable part of the optical system. ■

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Clinical Outcomes With the ALLEGRETTO WAVE

BY MICHAEL MANN, MD, FACS

Since acquiring the ALLEGRETTO WAVE excimer laser (WaveLight, Inc., Sterling, VA) almost 3 years ago, the refractive outcomes among the physicians in our practice have improved dramatically and continue to do so. To track our refractive results, my colleagues and I use Refractive Surgery Consultant (Refractive Consulting Group, Inc., Scottsdale, AZ), a program designed by Guy Kezirian, MD, and Jack Holladay, MD. According to the program, our results with the ALLEGRETTO WAVE are better than they have been with any other laser (we previously used the VISX Star S3 and Star S4 excimer lasers with customized treatment profiles [Advanced Medical Optics, Inc., Santa Ana, CA]).

OUTCOMES

Our patients' gain in lines of BSCVA for myopia and hyperopia are 48%. Their UCVA's are 97% 20/25 or better for myopia, and 94% 20/25 for hyperopia at 3 months. These results continue to improve as we tighten our nomograms. Our volume has grown 68% over 2005, primarily due to word-of-mouth referrals from happy patients.

ENHANCEMENT RATE

Using the Wavefront Optimized approach, our enhancement rate has dropped from between 8% and 10% with the Star S4 laser to less than 1% with the ALLEGRETTO WAVE optimized platform. Needless to say, such a low

enhancement rate speaks volumes about patient and physician satisfaction.

PERFORMANCE

We are also very pleased with the ALLEGRETTO WAVE's performance; it is a workhorse that requires very little maintenance. We have never lost a surgical day because of this laser. Also, the laser is doctor-friendly. It has a slit beam that allows us to examine the interface and the flap, and this cuts the amount of surgical time and thus has improved our efficiency.

PREDICTIONS

Over the next 5 years, I see the ALLEGRETTO WAVE being offered to more and more patients. The candidate criteria will tighten, and better outcomes will be the result. Furthermore, I feel that the average age of patients treated with this laser will decrease as younger people continue to accept and are able to afford this surgery. Safety is a big reason why patients do or do not undergo refractive surgery, and I feel that the ALLEGRETTO WAVE helps address this concern. It is a great new technology.

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When and How to Use Topography-Guided Technology

Making the most of the ALLEGRETTO WAVE's newly enhanced system

BY MATTHIAS MAUS, MD, AND STEPHAN KRÖBER

Corneal irregularities have a huge impact on both visual acuity and quality of vision. Visual symptoms can frequently be traced back to aberrations caused by irregularities due to corneal scars, keratoplastic surgery, or IOL insertion. An abnormal corneal shape caused by previous photorefractive treatments with small optical zones is often responsible for poor night vision. Decentered ablations can lead to a loss of BCVA and coma-like visual effects. Acuity can further be compromised by localized areas of central steepness (central islands) often associated with legacy laser platforms.

Due to the very nature of these disorders, even aspheric Wavefront Optimized (WaveLight, Inc., Sterling, VA) treatments come up short: their ablation pattern is uniform and does not cater to the respective localized changes in curvature. To become treatable, corneal irregularities call for a precise rendering of corneal topography, an evaluation of the available data and the subsequent immaculate correction of the cornea with the excimer laser.

REPRODUCING CORNEAL TOPOGRAPHIES: TOPOLYZER AND OCULYZER

The Topolyzer

WaveLight, Inc., offers two solutions for acquiring corneal topography data. Its Placido-ring-based topographer (the ALLEGRO Topolyzer) captures topographic data by projecting 20 concentric rings onto the cornea and computing the corneal curvature based on the reflection. Elevation data are then derived from the corneal curvature. The Topolyzer features an interactive elevation map with user-selectable reference bodies and the option to utilize a best-fit sphere.

The Topolyzer ushers in a realm of diagnostic and treatment options previously unheard of. Courtesy of its highly accurate rendering of the corneal surface, even subtle irregularities that can nevertheless be very bothersome for the patient become evident. The Topolyzer boasts a high

resolution of 22,000 data points. It comes with a module for keratokonus detection that strengthens screening safety. Optionally, the Topolyzer features a pupillometer that allows for testing pupillary reactions with or without glare and yielding min/max and mean pupil diameter values for defined testing conditions.

Measurements with the Topolyzer are automatically released once the eye is properly aligned. The measurement itself is very quick, lasting only a fraction of a second, and thus avoids lengthy periods in which the tear film might evaporate. A compromised tear layer can introduce artifacts into the topography. Between measurements, the patient is asked to blink in order to maintain a stable tear layer.

The Topolyzer is a tried-and-true technology that has been used extensively abroad. It is routinely employed when enlarging small optical zones, recentering decentered ablations, and for more complex irregularities. Its introduction in the US is forthcoming.

One drawback of the Topolyzer's results that all Placido-based corneal imaging devices share is that the central position of its camera necessitates the interpolation of central data, thus introducing a source of error. Enter the Oculyzer.

The Oculyzer

WaveLight, Inc., is the first company to integrate the acclaimed Oculus Pentacam (Oculus Inc, Lynnwood, WA) into its refractive line-up. In the ALLEGRETTO family, the unit is called the *ALLEGRO Oculyzer*. Using a rotating Scheimpflug camera, the device takes up to 50 photographs of the anterior segment. Each single image yields 500 true corneal elevation points, resulting in an impressive total of 25,000 points.

The Oculyzer's true virtue for problematic cases is its high central resolution. Because the device's camera rotates around the cornea's center, the distance between intersecting rays decreases approaching the corneal center and

thereby translates into a denser spacing of the data points. Consequently, central disorders of the cornea are best treated with the Oculyzer-based approach.

With the Oculyzer, elevation in comparison to a best-fit sphere is measured directly and not derived from curvature. Data of even higher fidelity are the result. The system can display sagittal and tangential curvatures, various power maps, anterior chamber depth, and the all-important pachymetry. The Oculyzer's comprehensive imaging capability includes a complete rendering of the anterior segment.

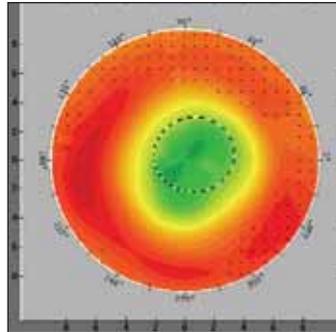


Figure 1. The small optical zone after PRK.

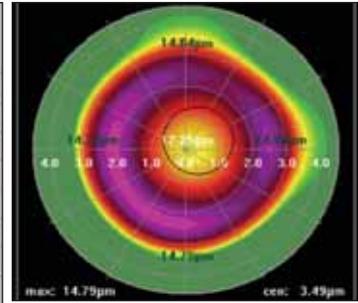


Figure 2. The enlargement of the patient's optical zone resembled a hyperopic treatment.

Commonalities

Both the Oculyzer and the Topolyzer capture information about the spatial relationship between topography and the pupil. This information is automatically transferred to the laser, making manual centering of the treatment superfluous. This feature is especially useful when treating hyperopia: angle kappa is automatically taken care of.

WaveLight's topography-guided treatments use the same algorithm that drives its wavefront-guided procedures: topographic data are automatically converted to wavefront equivalents (ie, Zernike polynomials) for treatment.

THE TREATMENT APPROACH

Any sensible refractive treatment must fit the patient's needs. When someone presents with visual disturbances such as halos, starbursts, or glare, the underlying cause must be identified. Optical aberrations can be rooted anywhere in the optical pathway of the eye. The cornea, crystalline lens, and vitreous all contribute their respective aberrations.

For corneal surgeons, correcting these errors can only take place in the corneal plane in order to counterbalance the given aberrations found throughout the eye. Luckily, the most profound aberrations are primarily corneal in nature. This, of course, is not surprising, since the cornea is the most powerful refracting surface of the eye.

It is a good idea to begin with a wavefront measurement for any patient who reports visual symptoms. If the measurements are successful and reproducible, a wavefront-guided treatment is a good choice, since it deals with both corneal aberrations (spherical aberrations, coma, trefoil, tetrafoil) as well as with those found elsewhere in the optical pathway. In some cases, however, obtaining a valid wavefront measurement is impossible: for example, with a steep cornea after a hyperopic treatment or more pronounced corneal irregularities. In such an eye, a topography-guided procedure is the way to go.

If the wavefront of an eye is measurable but poorly reproducible, it can at least give a hint of what kinds of aberrations prevail. If they are mainly corneal, then we may confi-

dently proceed with the preoperative topographic regimen.

Quality measurements and subsequent comprehensive validation are the foundation of a sound refractive treatment. Of the measurements taken (usually 15 to 20), the surgeon chooses the eight topographies most suitable for the treatment. Criteria for selection include reproducibility of keratometric values and axes (taking into account the axis of manifest refraction), topography, and centering. The selected data are then exported to the laser's software. The final selection and tweaking occurs directly at the ALLEGRETTO's ablation profile planner.

TOPOGRAPHY-GUIDED TREATMENT: ENLARGING A SMALL OPTICAL ZONE

With good measurements in place, the next step is turning them into the ideal treatment profile. What follows is an interesting case study that showcases how to approach a difficult scenario.

In 2006, a 45-year-old white male presented with major night vision problems after undergoing PRK for myopia (-8.00D) in 1997. Topography revealed a small optical zone. The goal of the treatment was to enlarge the optical zone and thus eliminate the patient's night vision problems.

Once the preoperative workup was done, the measurements were loaded into the ALLEGRETTO WAVE's planning software. The ablation pattern for enlarging the patient's small optical zone resembled a hyperopic treatment (Figure 2), which would induce myopia. Therefore, it was necessary to compensate for the myopic shift. This was where the topography neutralizing technique (TNT) came into play.

The goal of the TNT is to create a homogeneous central ablation (ie, a 3-mm radius around the pupil) to produce a more predictable refractive outcome.

A given TNT ablation pattern consists of three components. The first is the smoothing pattern designed by the ALLEGRETTO laser's software based on the captured topographies. Second is the added sphere and cylinder to neutralize the topographical refractive effect, and third is the manifest refraction (Figure 3). The ALLEGRETTO WAVE's

visualization of the ablation pattern helps the surgeon plan appropriately.

In spite of these efforts, a second treatment might become necessary to correct the residual refractive error of a given case due to its complexity. In this case, the postoperative topography was convincing. Remaining irregularities on the first postoperative day were due to swelling caused by the bandage contact lens that the patient wore overnight (Figure 4).

CONCLUSION

Knowing how to make the most of the topographical technology available in the WaveLight ALLEGRETTO platform goes a long way toward increasing treatment success and patient satisfaction. A quality workflow is pivotal for sound treatments. Topographical data must be reproducible and valid in order to optimize the customized treatment pattern. Finally, accounting for the induction of unwanted refractive change necessitates appropriate planning.

Used correctly, topography-guided treatments are a worthwhile asset in the refractive armory. They also come with an added bonus: the pleasant reward of seeing those people with diminished visual quality smile again. ■

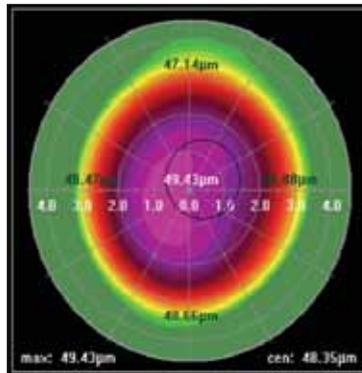


Figure 3. The final three-in-one pattern: smoothing + neutralization + refraction.

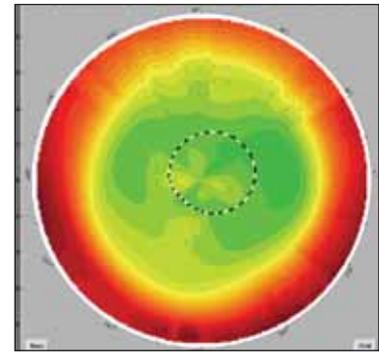


Figure 4. Slight swelling on the first postoperative day was caused by the bandage contact lens he wore overnight.

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(Stulting from page 4)

toconus, and I am especially wary of eyes with more than one of these factors.

RESEARCH FOCUS

My colleagues and I are developing a Web-based ectasia registry that will be available to refractive surgeons worldwide for reporting cases of ectasia. We hope this database will promote communication among refractive surgeons, help us to identify new risk factors, and facilitate the design of clinical trials to evaluate the results of LASIK in borderline cases. The registry, which is supported by the ASCRS, Clinical Research Consultants (Cincinnati, OH), and Document Solutions Group (Malvern, PA), should be operational this month.

Brad Randleman, MD, Mike Lynn, MD, and I are also working on a scoring system that evaluates multiple factors to calculate the overall risk of developing ectasia for each individual eye. We hope this will improve our ability to predict the occurrence of ectasia.

PUBLIC EDUCATION ALSO IMPORTANT

Thanks to recent large jury judgments, ectasia has become an important medicolegal issue. I think it is important for refractive surgeons to use the best prope-

active screening techniques available to avoid the disorder. In addition, we must educate potential patients and the legal profession that the occurrence of ectasia per se does not mean that malpractice has occurred. Keratoconus develops in many people who do not undergo refractive surgery, and some of these will coincidentally undergo LASIK before keratoconus becomes clinically apparent. One day, we hope to have more sophisticated screening techniques to identify these eyes.

Patients must recognize that we will not be able to identify all eyes that will develop ectasia after LASIK, no matter how hard we try. Further efforts to identify additional risk factors and develop new screening procedures should increase our odds of being able to predict the occurrence of ectasia after LASIK. ■

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The Effectiveness of Laser Vision Procedures in Correcting Hyperopia

Early results of a comparison study between the ALLEGRETTO WAVE and the LADARVision 4000.

BY DANIEL S. DURRIE, MD

I have been conducting an ongoing study to answer the question of whether hyperopes are unable to achieve the same quality of vision as myopes with laser vision correction. FDA and individual studies on all the excimer lasers have shown that hyperopic results are consistently less than those reached for myopes. With myopic corrections, most refractive surgeons generally achieve 20/20 UCVA in 90% and 20/40 in 100% of their patients by 3 months. Hyperopic treatments average 20/20 UCVA in 60% of patients and 20/40 in 90% by 3 months. Moreover, many clinicians have stated in the literature that refracted hyperopes simply do not see as well as myopes and that surgeons should not expect as much from a hyperopic correction. Regardless of the validity of these statements, I feel we need to continue improving the results of hyperopic laser correction as much as possible.

MOTIVATION BEHIND THE STUDY

Those who have compared multiple laser platforms tend to list the LADARVision 4000 (Alcon Laboratories, Inc., Fort Worth, TX) as one of the top excimer lasers for hyperopic treatments. I have been using the LADARVision platform to treat hyperopia since it first received this approval in 2002. My results with this platform have been very good, and I personally underwent a hyperopic CustomCornea procedure on my right eye with an excellent result.

I began using the ALLEGRETTO WAVE excimer laser (WaveLight, Inc., Sterling, VA) in 2005 in clinical studies conducted at my practice. I was impressed by its performance and wanted to evaluate where this laser could fit in my clinical practice, so I decided to test its hyperopic ablations. The ALLEGRETTO WAVE has a slightly larger optical zone at 6.5mm versus 6mm for the Alcon laser. After hearing international colleagues report achieving better surgical results with larger optical zones on other

laser systems, I was intrigued to test the different zones of the ALLEGRETTO and the LADARVision.

Many clinicians wonder whether Wavefront Optimization, which seems to have a benefit for myopia, also improves hyperopia. The engineers at WaveLight, Inc., told me that when they developed the ALLEGRETTO's Wavefront Optimized algorithm for myopia, they also made some changes to its hyperopic algorithm to try to optimize the laser's blend zones in order to achieve the best treatment profile possible. This knowledge also prompted me to study this laser's capabilities.

PARAMETERS

I conducted a randomized study of 100 eyes of 50 patients. I treated 50 eyes with the LADARVision 4000 and 50 with the ALLEGRETTO WAVE. I used a 6-mm optical zone with the LADARVision 4000, according to its FDA approval, and a 6.5-mm optical zone with the ALLEGRETTO WAVE. The treatment with the LADARVision 4000 was conventional phoropter-driven, not wavefront-guided, and the ALLEGRETTO WAVE's treatment was Wavefront Optimized in its transition profiles.

I created all the LASIK flaps in the study with the IntraLase FS laser (IntraLase Corp., Irvine, CA), because I think it produces very consistent flaps, something especially important for hyperopes. The plano flap must drape completely over the area that is ablated for an optimal correction.

RESULTS

The data I discuss herein are preliminary; I have only included the dominant eyes that were targeted for plano with both lasers (26 eyes in each group). The 1-day postoperative visits revealed a significant difference between the two groups' uncorrected distance vision, with 65% of the

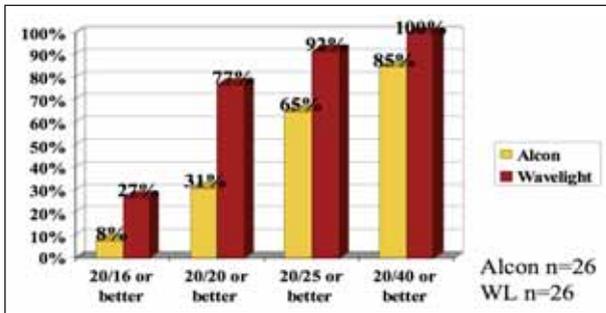


Figure 1. UCVA at 1 week postoperatively.

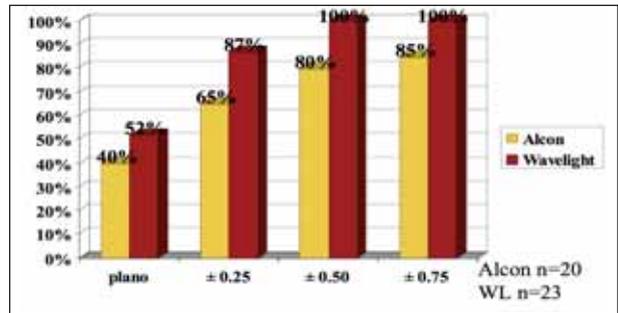


Figure 3. Predictability at 3 months postoperatively.

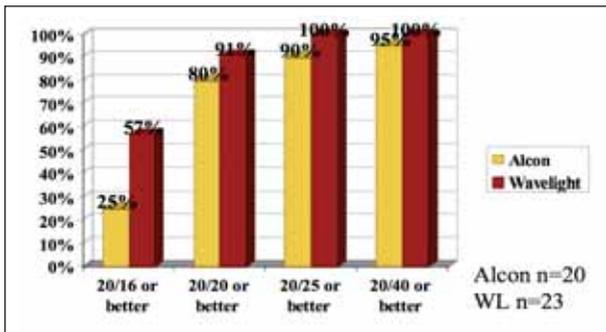


Figure 2. UCVA at 3 months postoperatively.

		Pre-Op	1 week	1 month	3 months
MRSE	Alcon	+1.72	-0.41	-0.21	-0.05
	Wavelight	+1.52	-0.29	-0.13	-0.10
Cylinder	Alcon	-0.55	-0.34	-0.50	-0.35
	Wavelight	-0.40	-0.08	-0.13	-0.12

Figure 4. Stability through 3 months postoperatively.

ALLEGRETTO WAVE patients seeing 20/20 compared with 19% of the LADARVision eyes. At 1 week, both groups had continued to improve, but still twice as many eyes saw 20/20 with the ALLEGRETTO WAVE (Figure 1). The LADARVision eyes took longer to reach their maximum distance UCVA. Although they were continuing to improve at 1 month, their acuities were still not as good as the ALLEGRETTO eyes. At 3 months, 91% of the ALLEGRETTO group saw 20/20, and 80% of the LADARVision group had reached that mark (Figure 2). However, 57% of the ALLEGRETTO eyes saw 20/16 versus 25% of the LADARVision eyes.

Next to uncorrected vision, the most important comparison between two laser platforms is predictability. The predictability on the spherical correction between the LADARVision and the ALLEGRETTO WAVE groups was essentially the same: -0.05 and -0.10 MRSE, respectively (Figure 3). Also, there was no statistically significant difference between the overall correction of sphere between the groups. Patients' cylinder was better corrected by the ALLEGRETTO WAVE (Figure 4), perhaps in response to the better distance UCVA achieved with that laser.

DISCUSSION

I attribute the ALLEGRETTO WAVE's better visual results to its larger optical zone. Although the laser's performance could be due to its Wavefront Optimized ablation versus the LADARVision's conventional treatment, making that determination is nearly impossible, and I suspect that the

larger optical zone is the more important factor.

Based on this study's initial findings, I now use my ALLEGRETTO WAVE laser to treat primary hyperopes with low corrections, and I reserve the LADARVision 6000 laser (my current, upgraded platform) for complicated eyes, retreatments, and those that need a wavefront-guided hyperopic correction. I still have a lot of confidence in the LADARVision 6000. In fact, I requested it be used on my dominant eye for customized hyperopic correction, along with the Intralase FS laser, because I had a lot of coma, and I knew that I needed a wavefront-guided treatment. I believe both lasers offer value. For healthy hyperopic corneas that do not need a wavefront-guided correction, I am very comfortable using the ALLEGRETTO WAVE laser.

CAVEAT

These preliminary data from my study do not include the data on wavefront, topography, and contrast sensitivity between the two lasers. This will be presented after the study is completed and may provide additional information. Nevertheless, my preliminary findings indicate that laser vision correction using modern lasers and femtosecond laser technology for cutting flaps can achieve similarly high visual acuity results for hyperopes as for myopes in well-selected patients. However, I do not consider any excimer laser capable of successfully treating hyperopia of greater than 3.00D, and I therefore limit my hyperopic treatments

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Better Patient Flow With the ALLEGRETTO WAVE

How this laser lets TLC centers treat more patients per day.

BY AARON ELDER

The TLC Laser Eye Center in La Jolla, California, was the first TLC location to use the WaveLight ALLEGRETTO WAVE excimer laser (WaveLight, Inc., Sterling, VA). The clinic received the laser in mid-2005, about 1 year before other TLCs. When the physicians there responded favorably to using the system, we started rolling it into the other centers. My center in Ontario, California, received its unit approximately 15 months ago.

We wanted to give each of our surgeons the opportunity to make up his own mind about the technology, so while we integrated the ALLEGRETTO WAVE, many surgeons also continued to use our previous system, the aberrometer-driven LADARVision 4000 with CustomCornea (Alcon Laboratories, Inc., Fort Worth, TX). Nevertheless, we quickly learned that the outcomes from the ALLEGRETTO were as good as, if not better than, those our surgeons obtained with the LADARVision 4000. Furthermore, the ALLEGRETTO WAVE significantly reduced the time that patients spent in our office on their day of surgery.

MULTIPLE REASONS TO SWITCH

Our staff found that the entire LASIK procedure was faster with the ALLEGRETTO WAVE compared with the LADARVision 4000. We no longer had to lay the patient down on the bed, take a picture of his eye, dilate him, perform the aberrometry, and export the readings to the laser before conducting the ablation. Even the ALLEGRETTO WAVE's ablation time is faster—a 200-Hz repetition rate and a 250-Hz eye tracking system—compared with the LADARVision's 60Hz. Furthermore, none of our patients complained about postoperative glare and halos, thanks to the ALLEGRETTO's prolate ablation pattern.

Simply put, we decided to switch the majority of our LASIK procedures to the ALLEGRETTO WAVE because we could not foresee any issues that that laser would present compared with a fully customized, wavefront-guided laser. Our surgeons now use the ALLEGRETTO laser for 90% of their surgeries. The only procedures for which we still use the LADARVision 4000 are enhancements and the treatment of severely irregular corneas that require aberrometry

and fully wavefront-guided, aberrometry-driven LASIK. These cases are rare, however.

ROUTINE PATIENT FLOW

Our basic patient workup flows smoothly. When a patient walks in the front door, we collect his paperwork, review his consent forms, and locate his chart. After this check-in, we bring him back to the clinic, where we reconfirm his prescription and targeted refraction. If these measurements check out and the patient has no questions for the optometrist, he proceeds to the preoperative workup room, where the technician explains what the patient should expect from the procedure and reviews the postoperative instructions. We then dress him for surgery and move him to the IntraLase FS laser (IntraLase Corp., Irvine, CA), which we use in conjunction with 99% of our LASIK procedures. Once the laser cuts the corneal flap, we move the patient to the ALLEGRETTO WAVE and perform the laser ablation. Finally, we take the patient to the postoperative area, where we give him a shield for his eye or eyes before he goes home.

One huge benefit to patient flow is the ALLEGRETTO's built-in slit lamp. With other laser systems, the surgeon must move the patient from the bed to the slit lamp to check the corneal flap before continuing with the procedure. Once the ALLEGRETTO WAVE stops firing, the surgeon swings the slit lamp out over the patient and checks his cornea without moving him from the bed.

With the ALLEGRETTO WAVE, we can comfortably treat four patients per hour, barring any complications or issues, without them feeling rushed. With the LADARVision 4000, four patients an hour was tough—we were more comfortable treating 3 to 3.2 per hour. The ability to care for more patients in a day with the Allegretto obviously benefits our bottom line.

OUTCOMES

Although we have heard theories about potential problems with cyclorotation affecting the centration of the

(Continued on page 15)

Enhancements With the ALLEGRETTO WAVE

This laser minimizes enhancement rates and optimizes previous treatments.

BY ROY S. RUBINFELD, MD

Over the last decade, I have used nine different excimer laser systems, and I consider the ALLEGRETTO WAVE (WaveLight, Inc., Sterling, VA) the best so far. Specifically, the laser's reliability and advanced technology provide excellent enhancements and primary treatments.

ENHANCEMENT PERFORMANCE

Having used the ALLEGRETTO WAVE since 2004, I have performed a significant number of retreatments with it. I have had excellent results enhancing eyes that underwent previous wavefront-guided as well as conventional LASIK procedures. The laser offers certain advantages over other enhancement modalities, because more patients receiving touch-ups these days have undergone either cataract surgery or some other intraocular procedure. Wavefront-guided enhancement is often difficult to perform on eyes implanted with the new IOLs, because the lenses' technologies make imaging the eye extremely difficult, and this would compromise the treatment plan. Wavefront Optimized treatments avoid this problem because they are based on corneal curvature and not wavefront maps.

I approach each enhancement by determining how well the patient sees with a spherocylindrical correction placed in front of his or her eye. If the patient sees well, I recommend a Wavefront Optimized retreatment. If he or she is experiencing strong halos, glare, starbursts, poor quality of vision, or reduced contrast sensitivity, then I endeavor to identify the reason for these symptoms before proceeding. For example, perhaps the patient underwent laser vision correction 6 years earlier and is now experiencing significant lenticular aging issues. Or, perhaps some major higher-order abnormality is interfering with the quality of vision. If the patient's BSCVA is not compromised, which is the case for the overwhelming majority of patients who require retreatment, then Wavefront Optimized enhancements are easy to perform, extremely accurate, and my first choice.

LOWEST ENHANCEMENT RATE

My enhancement rate with the ALLEGRETTO WAVE is

approximately 4% for a range of corrections from +5.00D to -12.00D with up to 6.00D of cylinder—the lowest of any laser I have used. Thus, enhancements are less of a factor in my practice now than ever before. My previous enhancement rate varied a great deal with the various systems I used.

Enhancements are difficult for both the surgeon and the patient because they impart a sense of failure, even if the initial surgery was largely successful. Therefore, anything that can reduce a surgeon's rate of retreatments is beneficial. The ALLEGRETTO WAVE's highly reliable treatments have significantly reduced my need to enhance, and practitioners worldwide have anecdotally reported the same experience. There is also consensus among ALLEGRETTO users that patients very rapidly reach excellent quality of vision post-operatively and have a much more immediate "wow" response compared with other laser systems. I attribute these advantages to the laser's preservation of the natural shape of the cornea—it delivers a more prolate ablation than many other laser systems. Other benefits of the ALLEGRETTO WAVE, in my opinion, include its small spot size, 200-Hz speed, short ablation time, few hydration issues, and incredible reliability. On that note, during the 2.5 years I have been using the system, it has never malfunctioned, a fact that demonstrates a degree of reliability that is unusual among excimer lasers. I am a certified trainer for several lasers, and I have never seen a system perform as solidly as the ALLEGRETTO WAVE. The laser's technical specifications and performance are remarkably consistent.

OPTIMIZING RESULTS

In addition to choosing the Wavefront Optimized technology for 99% of my refractive surgery patients, I take other measures to guarantee good results and minimize enhancements. I am fully involved in the entire surgical process. I delegate carefully to technicians and allow only two extremely skilled technicians to refract for me. After all, refractive surgeons live and die by refractions. I use the WaveLight nomogram exactly as prescribed and with great success. My staff will confirm that I am a stickler for follow-up and detail.

THE ALLEGRETTO PROVES ITSELF

Until I started using the ALLEGRETTO WAVE myself, I did not believe its results were as good as many colleagues had told me. I initially started using the ALLEGRETTO on patients who I could not treat with the VISX Star S4 laser with the CustomVue system (Advanced Medical Optics, Inc., Santa Ana, CA). Not only was it easy to use, but when I collected my data from the ALLEGRETTO WAVE, I realized they were better than the Star S4's. I then began using the ALLEGRETTO more and more, and now it is my first-choice workhorse laser. ■

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to this maximum. Although I attempted 4.00D corrections in both patient groups for the purpose of the study, I think steepening the cornea beyond 3.00D degrades quality of vision. We have all heard anecdotal reports of patients who received more than 3.00D of hyperopic correction. Their eyes appeared stable at the phoropter, but they later complained of night vision symptoms and were unhappy with their results. These patients' topographies resembled those of keratoconic eyes: overly steep, multifocal, and difficult to refract. Such treatments are more suitable for the excellent IOL procedures now available.

LOOKING AHEAD

Because this is not a contralateral eye study, I could not ask the patients which eye they preferred. However, I have commenced a contralateral eye study of myopic astigmatic treatments between the LADARVision 6000 (Alcon Laboratories, Inc.) and the ALLEGRETTO WAVE. The purpose is to help determine which laser performs better for which patients—a question that I and many other clinicians have. I am looking forward to the results, which should be ready in early 2007. ■

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treatment with the ALLEGRETTO WAVE, we have not experienced this and routinely achieve 20/20 to 20/15+ outcomes, especially on myopes. For hyperopes, the ALLEGRETTO performs well, but hyperopic treatments are more difficult with all laser platforms. The number of retreatments we perform is approximately 4% of patients, compared with 6% to 8% with the LADARVision 4000.

USABILITY

The ALLEGRETTO WAVE is somewhat more complicated to use than the LADARVision 4000, because the former runs on plus cylinder. The ALLEGRETTO automatically converts the minus cylinder data to plus cylinder before operating, which makes double-checking the data more difficult. Also, the ALLEGRETTO WAVE is not one large unit like the LADARVision 4000 or a VISX laser (Advanced Medical Optics, Inc., Santa Ana, CA); it is more compartmentalized and requires more attention to operate. The laser has been very reliable, however. Although customer service for the ALLEGRETTO WAVE is not yet on the same level as VISX's or Alcon's, this is due to WaveLight's smaller presence in the US market and is improving.

COST AND ADVERTISING

The overall cost of the ALLEGRETTO WAVE is about the same as the LADARVision 4000, although we are building ownership in the ALLEGRETTO, which offers even more financial advantages. We do not advertise as having a different laser procedure from other centers; instead, we promote that we have more than one laser platform to offer patients and will choose the best one for them. We do not identify these systems by name, because the names do not mean much to most patients.

CONCLUSION

Overall, our physicians and administrators have been very happy with WaveLight, Inc., and its ALLEGRETTO WAVE laser; we have not experienced many problems. In fact, we have just recently incorporated the mixed astigmatism upgrade, which we expect to further expand our patient base. Naturally, we were pleased to learn about the ALLEGRETTO WAVE's recent FDA approval for wavefront-guided treatments, which adds another dimension to its patient base. ■

Aaron Elder is Executive Director of TLC Laser Eye Centers in Ontario, California. He acknowledged no financial interest in the companies or products mentioned herein. Mr. Elder may be reached at (909) 605-1975; aaron.elder@tlcvision.com.



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