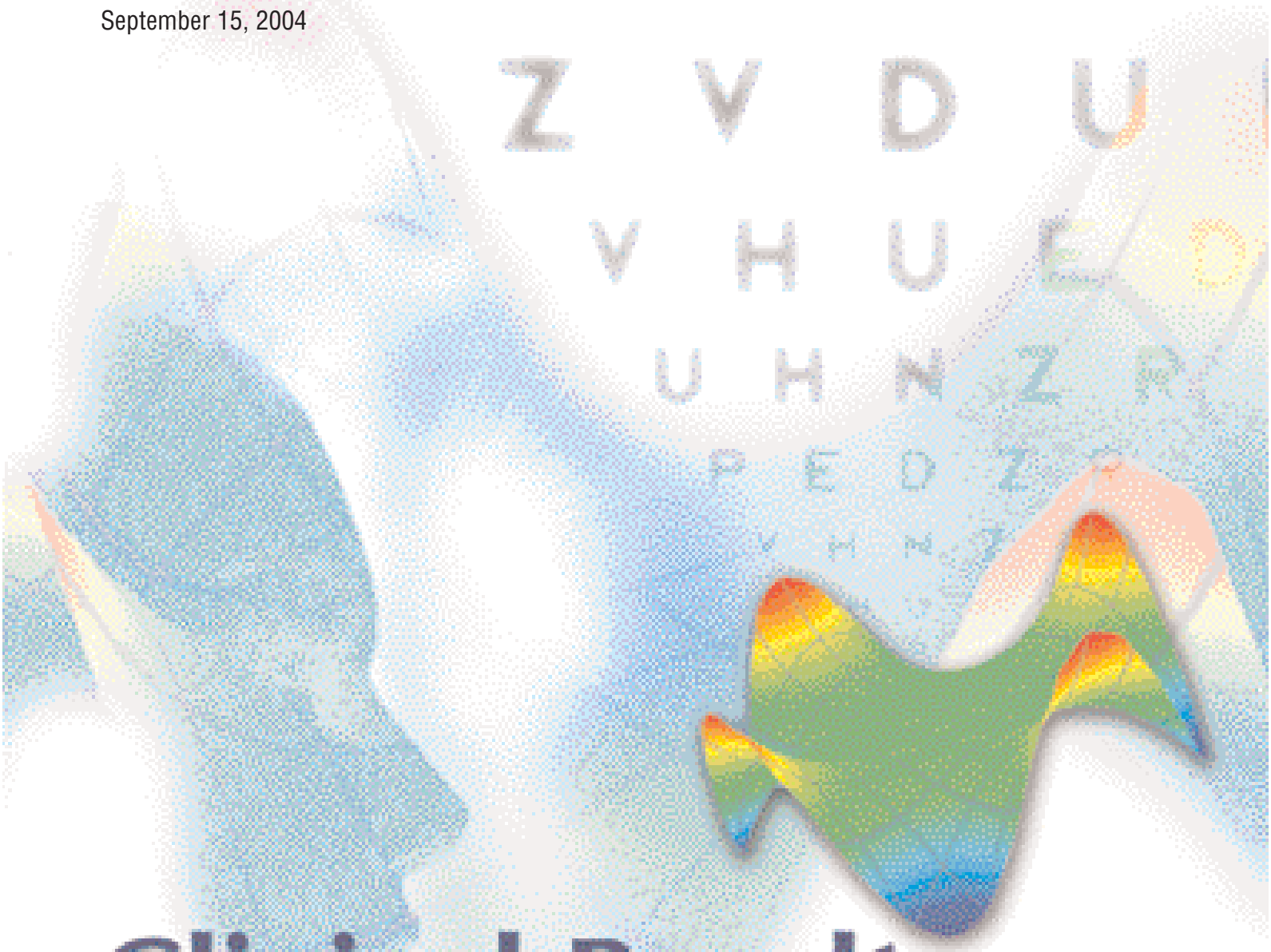
OCULAR SURGERY NEWS®
September 15, 2004



Clinical Results with Customized Ablation Technology

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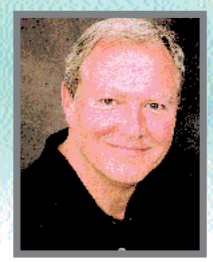

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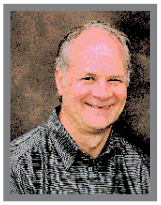

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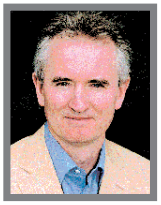

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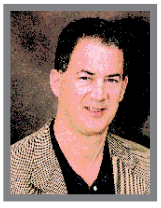

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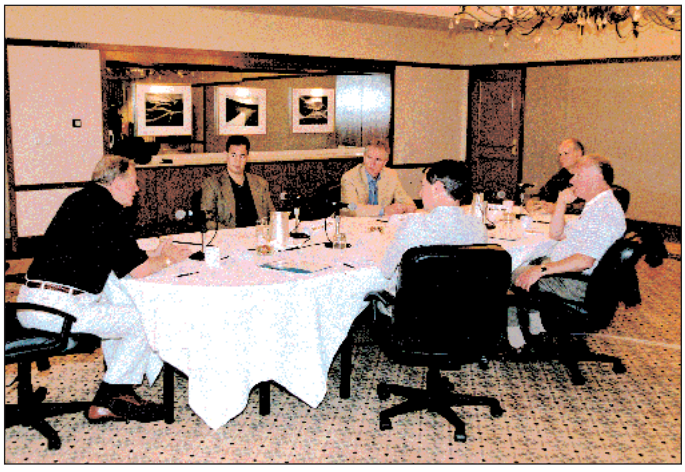
Introduction

Customized wavefront ablation technology has allowed for more precise surgical outcomes in LASIK procedures and several clinical trials have shown the technology to be superior for correcting higher-order aberrations.

The purpose of this discussion was to compare wavefront systems with each other and conventional LASIK systems in terms of treating aberrations and reducing induced aberrations during the surgical procedure. Additionally, the faculty compared the different features that are available on the approved customized wavefront platforms and how these differences translate to capability for precision in surgical outcomes. I would like to thank OCULAR SURGERY NEWS for organizing this roundtable symposium and Alcon for its support.

Richard L. Lindstrom, MD
Chief Medical Editor
OCULAR SURGERY NEWS



Clinical Results with Customized Ablation Technology

Centration with wavefront

Stephen F. Brint, MD: When Alcon (Fort Worth, Texas) first acquired the LADARVision from Autonomous in 2001, this system was the only laser for wavefront ablations that had the capability for registration. Currently, many more laser manufacturers are realizing the importance of registration and, as a result, are making attempts to incorporate registration into their platforms.

Dr. Steinert, you have used the LADARVision system for several years and have also used other wavefront systems. First, can you explain the importance of registration and, second, can you compare this feature on the systems that you have used?

> The wavefront must be measured accurately and registered to the same area of the cornea at which it was originally measured at the time of surgery.
>
> — Eric D. Donnenfeld, MD

Roger F. Steinert, MD: Registration has come to symbolize the concept that wavefront optical measurement is taken on a system different than that on which the laser treatment is performed. Thus, the wavefront measurement data must be transferred to the patient who is lying under the laser in a different location, which is registration.

The LADARVision system has always had a version of registration, so when wavefront technology became available, it was an easy match for this system. Additionally, the LADARVision system has always considered astigmatism and the true horizontal axis, so applying limbus alignment for a patient in a supine position is a natural transition, allowing surgeons to match the wavefront information to the patient to treat the correct area.

Our early studies with the basic LADARVision system without the wavefront component showed that at least one-quarter of patients treated had potential for misalignment from basic astigmatism, which is a lower-order aberration. When wavefront technology became available, I found that the higher-order aberration errors were magnified considerably. A small misalignment in terms of axis can have a major impact on undercorrection and, in some cases, can actually cause new higher-order aberrations due to misalignment of the pattern of treatment to the actual wavefront error on the eye.

I am not aware of any system other than the LADARVision that currently has an effective means of registering the information captured on the wavefront device to the patients' eyes when under the laser. With other systems, centering on the pupil may result in shifts of alignment because the pupil does not expand concentrically, even with natural dilation on different illumination.

Several companies have recognized that this is an issue and are now trying to find a means of anatomical landmark registration such as with iris recognition software.

Marc A. Mullie, MD: The Zyoptix (Bausch & Lomb, Rochester, N.Y.) system's iris recognition software uses a type of limbal retical similar to CustomCornea's (Alcon). However, it appears that because centration is not computer-driven, the surgeon is required to manually set the light onto the apparent center of the pupil, which can result in a 200-µm to 300-µm error.

Eric D. Donnenfeld, MD: The biggest difference between conventional and customized ablation is that the concept of centration has shifted from the center of the pupil to the center of the wavefront map. Therefore, the wavefront must be measured accurately and registered to the same area of the cornea at which it was originally measured at the time of surgery.

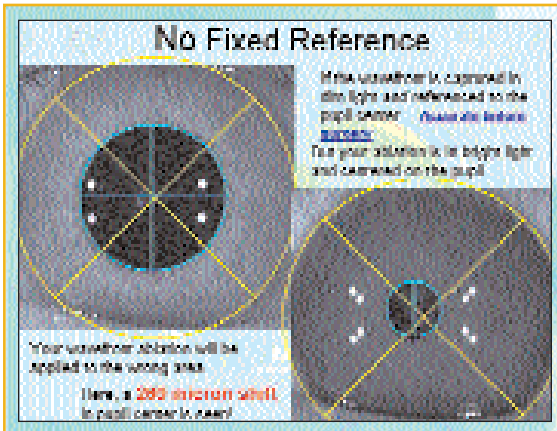


Figure 1. No fixed reference results in a decentered ablation due to difference in lighting conditions between when the wavefront was taken and the ablation was performed.
Figures 1 and 2 courtesy of Eric D. Donnenfeld, MD.

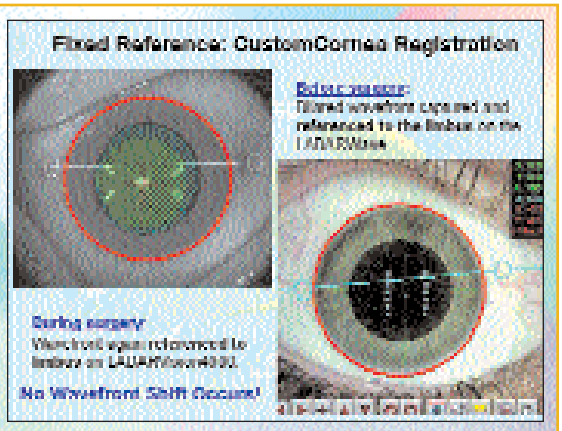


Figure 2. The fixed reference with CustomCornea registration does not cause any wavefront shift because the registration is fixed on the limbus for both the wavefront measurement and the ablation, not the pupil.

To say that a pupil-tracking system can accomplish this is ludicrous — because the pupil is a moving target, it will continually move with illumination level. Thus, with pupil tracking, the surgeon may apply wavefronts to areas of the cornea that do not correspond to the areas of the cornea that were measured (Figure 1) and, in doing so, induce significant aberrations. The LADARVision is the only system available that allows the surgeon to directly apply wavefront to the areas from which they were taken.

Brint: It seems fairly straightforward that when tracking the pupil relative to the limbus, a fast video-tracking system should, theoretically, be sufficient. However, it seems that even though the movement of the eye may be tracked, the movement of the pupil within the eye is a different matter and results in an inferior landmark.

Donnenfeld: It is important for surgeons to understand that the pupil cannot be classified as a landmark because it moves. Rather, the limbus is a landmark. In our study, we found that there was a mean 177-µm movement in pupil positions between dim and bright illumination; 10% of patients measured in our study had a 300-µm movement. **[AU: Please provide reference.]** If the intent is to treat a patient for spherical aberration with measurements that are off by 300 µm, the surgeon will actually be treating coma and will induce significant aberrations.

Daniel S. Durrie, MD: I often use wavefront technology to provide custom upgrades for patients who have had previous surgery, sometimes to correct 1 µm or more of spherical aberration. The ablation pattern of the laser when it is set for higher-order aberrations is dramatic in that the hot and cold spots are in close proximity to one another, especially with coma. There are 5º to 7º of rotation, so a few microns of deviation can have a significant effect.

The CustomCornea system has a sophisticated registration system, which starts at the LADARWave (Alcon) (Figure 2). The LADARWave locates the center of the undilated pupil and the limbus. Then, two small ink dots are placed on the conjunctiva outside the limbus. The eye is then dilated to capture the largest amount of data and a wavefront measurement is taken. This measurement records the location of the pupil center, the ink marks and the wavefront. After these data are loaded into the LADARVision system, registration of the wavefront to the exact position on the patient's eye is simple and laser correction is delivered to the correct location.

I perform a large number of custom upgrades for patients who have had previous surgery. The LADARVision's registration system allows me to feel comfortable that I am delivering the appropriate correction to these eyes in complicated cases.

With the LADARVision system, two dots are marked on the eye to align the eye to the laser,

which is a slight adjustment from simply using limbal registration. This system of taking a dilated wavefront on the LADARWave, registering it to the limbus and the two small dots and visually realigning to the points in the operating room, is a vast step beyond what other platforms offer.

Steinert: Surgeons have labored over the idea that the ideal treatment is centered on the pupil. Based on the literature from the 1980s, surgeons were using the corneal light, or apical, reflex for centration, which was less reliable than the pupil center. However, prior to wavefront technology, ophthalmologists were, in theory, looking for the true visual axis as it intercepted with the cornea, which is an indeterminable point.

With the proper registration technology, such as is used by the LADARWave, this all becomes a non-issue. I predict that the impact will be even greater when hyperopic wavefront technology is available, because many patients with hyperopia have angle kappa deviations. My results treating hyperopia improve dramatically when I recognize these deviations. That said, there is also a significant number of patients with myopia and some degree of angle kappa deviation for whom centering on their pupil will bring poor results.

The pupil issue fades away with the use of wavefront technology, and the improved results that I have achieved corroborate this. The registration on the LADARWave ensures that all patients are well centered.

Brint: It will be interesting to see the results of the study comparing Bausch & Lomb's pupil tracking system compared to Alcon's registration system.

Mullie: In my opinion, three potentially significant sources of error exist with the Technolas 217 system (Bausch & Lomb). First, the wavefront measurements are taken on a dilated pupil and the treatment is performed on an undilated pupil, which may result in a large error in treatment. Second, the surgeon must manually set the machine to what he or she perceives to be the pupil center. Third, there is no registration with respect to a fixed reference such as the limbus on the present system.

Brint: Dr. Speaker, how do your results in dilated situations compare with those in non-dilated situations, relative to the systems that you have used?

Mark G. Speaker, MD: With CustomVue (Visx, Santa Clara, Calif.) technology, I must use mydriatic agents often because undilated pupils are not large enough to capture an adequate wavefront. Dilating the pupil even a modest amount can dramatically change the wavefront that is captured. I have looked at the difference in a patient for whom I captured the wavefront from the pupil at both 5.5 mm and dilated to 6.5 mm. The wavefront that I received from the dilated pupil was truer, both numerically and qualitatively. Being able to capture a wavefront through a dilated pupil is a significant advantage.

> The pupil issue fades away with the use of wavefront technology, and the improved results that I have achieved corroborate this.
>
> — Roger F. Steinert, MD

Mullie: With the LADARVision system, the cornea stays clear during the treatment in comparison to Technolas 217. We are performing a contralateral eye study using LADARVision and Technolas 217, and have seen a tremendous difference.[1] With the Technolas 217, a 2 -mm beam hammers away at the cornea and, as a result, the cornea tends to become gray during long treatments and patients lose the fixation light. With LADARVision, the cornea is perfectly clear throughout the procedure.

In the study, after the patients had been treated with LADARVision for one eye and Technolas 217 for the other, we asked patients with which eye was is easiest to the see the light and properly fixate. Thirty-five out of 40 patients reported this to be the LADARVision eye.

Speaker: The LADARVision system has a particularly good fixation light, making it easier for patients to fixate during treatment than on other systems.

New algorithms for minimizing aberrations

Brint: Are all of the refractive laser platforms making algorithm changes to minimize induced spherical aberration?

*(**Roundtable** continues on page 8)*

LADARVision system vs. CustomVue technology

Stephen G. Slade, MD

With or without a nomogram adjustment to the laser system, the LADARVision (Alcon, Fort Worth, Texas) system for performing a CustomCornea (Alcon) procedure provides measurements and results that are more accurate and that induce fewer higher-order aberrations than CustomVue (Visx, Santa Clara, Calif.) technology.

Apples to apples

We performed a contralateral eye study comparing the LADARVision system laser to CustomVue technology. As it is inherently difficult to compare separate studies, we treated one eye of each patient with the LADARVision laser and the other eye with the Star S4 (Visx) laser to see which provided the best results. The preoperative data for eye were similar (Table). Ablations were performed on the first group of patients with no adjustments to either laser to provide an "apples-to-apples" comparison. We found that the CustomCornea procedure provided better results than CustomVue, both in terms of traditional metrics and higher-order aberrations. The eyes treated with CustomVue were consistently undercorrected and the accuracy was better at 3 months with CustomCornea (Figure 1). The manifest refractive spherical equivalent (MRSE) difference was approximately 0.33 D between the CustomCornea eyes and the CustomVue eyes over 3 months (Figure 2).

Stephen G. Slade

The subjective responses of patients when asked which eye they preferred at 1 month, 15 of 22 patients (68%) preferred the CustomCornea eye to the CustomVue eye. Furthermore, when patients were asked at 3 months which eye had better quality of vision, 17 of 23 patients (74%) responded that the quality of vision in their CustomCornea eye was better than that of their CustomVue eye. Overall satisfaction with the CustomCornea procedure was better than with CustomVue.

Visual acuity not the entire story

Interestingly, one patient who had better visual acuity in the CustomVue-treated eye reported that they were happier with the quality of vision that they achieved in the LADARVision-treated eye. However, no patients reported that they were happier with the quality of vision they received from CustomVue when their visual acuity was better in the LADARVision-treated eye.

Preoperative Patient Demographics

	Mean Sphere (Range)	Mean Cylinder (Range)	Mean MRSE (Range)
CustomCornea	-3.15 D (-0.75 D to -7 D)	0.52 D (0 D to -1.25 D)	-3.41 D (0.88 D to -7.13 D)
CustomVue	-3.08 D (-0.75 D to -5.75 D)	-.052 D (0 D to 1 D)	-3.34 D (-0.88 D to -6.25 D)

Table information courtesy of Stephen Slade, MD.

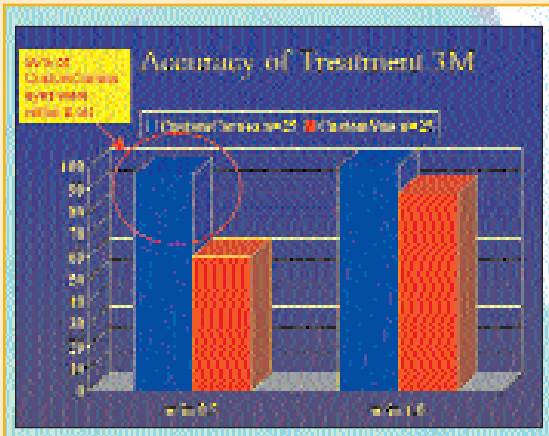


Figure 1. The eyes treated with CustomVue were consistently undercorrected and the accuracy was better at 3 months with CustomCornea.
Figures 1-4 courtesy of Stephen G. Slade, MD.

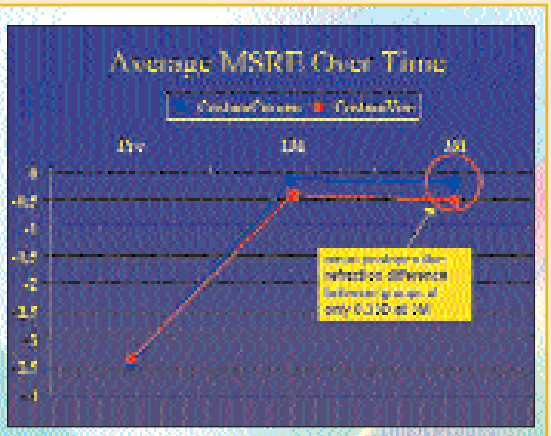


Figure 2. The manifest refractive MRSE differnce was approximately 0.33 D between the Custom Cornea eyes and the CustomVue eyes over 3 months.

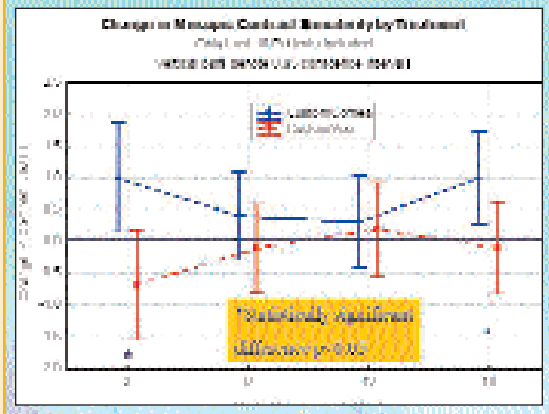


Figure 3. With nomogram adjustments to CustomCornea and CustomVue, patients reported better 1 month results with CustomCornea.

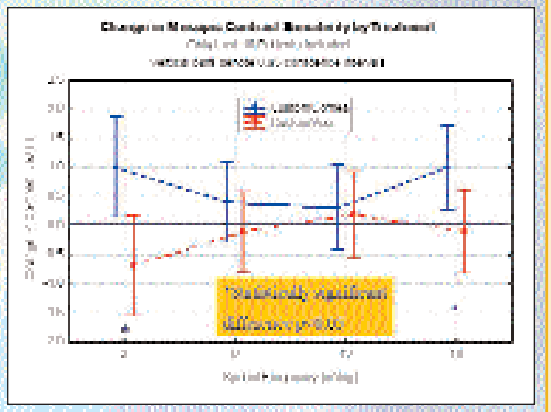


Figure 4. Contrast sensitivity was also better for patients treated with CustomCornea.

Nomogram adjustments

For a group of 10 patients, we made nomogram adjustments to CustomVue to achieve results matching the LADARVision system and, with no nomogram adjustment to the LADARVision system, we performed contralateral surgery. Even with the nomogram change for CustomVue, the higher-order aberration data became more skewed in favor of the LADARVision system because, as ablations become larger, so do the amount of higher-order aberrations that are induced. Since CustomVue technology was undercorrecting patients, we increased the ablation sizes for the group treated with the nomogram on CustomVue, which results in more induced aberrations.

With no nomogram adjustments to CustomCornea procedure vs. the nomogram-adjusted CustomVue procedure, patients reported overall better visual results at 1 month (Figure 3). Additionally, contrast sensitivity was significantly better for patients treated with CustomCornea than with CustomVue (Figure 4).

These small studies show the power of contralateral eye studies in making direct comparisons between wavefront platforms. CustomCornea provided the best results for most patients in terms of reduced higher-order and spherical aberrations and better contrast sensitivity.

Stephen G. Slade, MD, is national co-director of the Laser Center in Houston, Texas. Dr. Slade is also a member of the editorial advisory board for Ocular Surgery News.

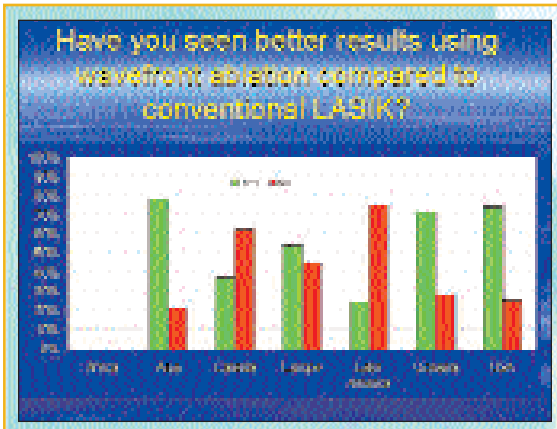


Figure 3. A survey performed by Kerry Solomon, MD, and colleagues shows that physicians in most countries had better results with wavefront ablation, compared to conventional LASIK.

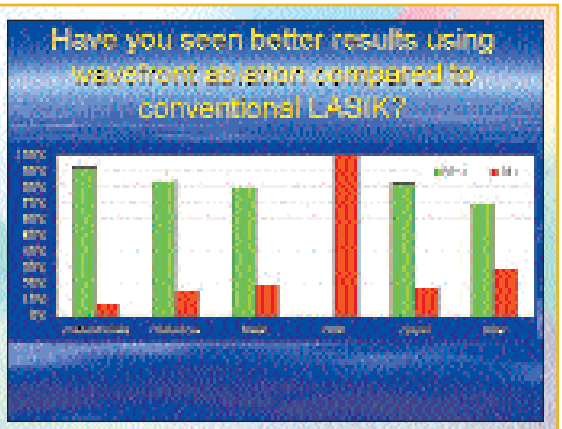


Figure 4. When asked to break their responses down into actual systems, more surgeons reported better results with CustomCornea compared to conventional LASIK.

Figures 3-8 courtesy of Kerry D. Solomon, MD.

*(**Roundtable**, continued from page 5)*

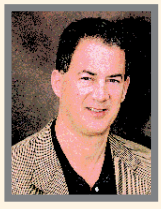
Durrie: The Alcon platform was developed in the United States during the U.S. clinical trials, so each time the algorithm changed, the clinical investigators performed another substudy to refine the algorithm. We collected preoperative wavefront measurements and compared them with postoperative data to determine how well the algorithm worked. The Alcon engineers recognized early in the trials that spherical aberration and coma were not being fully corrected. Based on this information, the algorithm was changed to dial up spherical aberration.

Although these substudies required more patients to be treated and took longer, I think it is why the Alcon platform seems to be correcting higher-order aberrations better than other systems.

Last year at the Wavefront Congress in Canada, some of the papers presented concluded that more pulses are required on the periphery in order to optimize the correction and reduce spherical aberration.

Alcon has improved their algorithms to make the postoperative higher-order aberrations as minimal as possible ...

— Mark G. Speaker, MD



Speaker: I have compared the postoperative wavefronts of patients treated with the LADARVision system to those treated with CustomVue technology and have been impressed by the fact that postoperative LADARWave measurements show significant reduction in preoperative higher-order aberrations. Alcon has improved their algorithms to make the postoperative higher-order aberrations as minimal as possible, from the standpoint of not only correcting preoperative higher-order aberrations, but also in preventing the induction of spherical aberrations when performing ablations on patients with myopia.

Steinert: Zero spherical aberration is not required to have good night vision. Most people have some element of spherical aberration. As a refractive surgeon, I have always struggled to understand why one patient following a typical myopic correction will have night vision issues and another patient treated exactly the same way will not. My hunch is that the patients who have postoperative night vision problems already have borderline-high spherical aberrations that become symptomatic after treatment. To use wavefront technology only for patients with preoperative high-order aberrations is incorrect. The concept of not inducing aberrations is one that should be applied to every patient.

A number of laser manufacturers are supposedly incorporating wavefront options into their refractive platforms, but those systems fail to consider preoperative baseline corneal curvature. If the lens is playing a significant role in a given

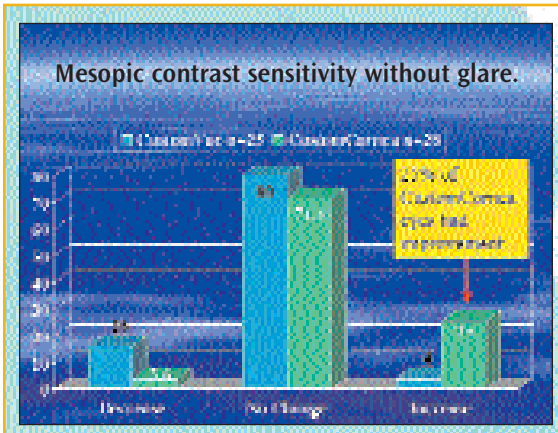


Figure 5. Three-month mesopic contrast sensitivity without glare (change from preoperative).

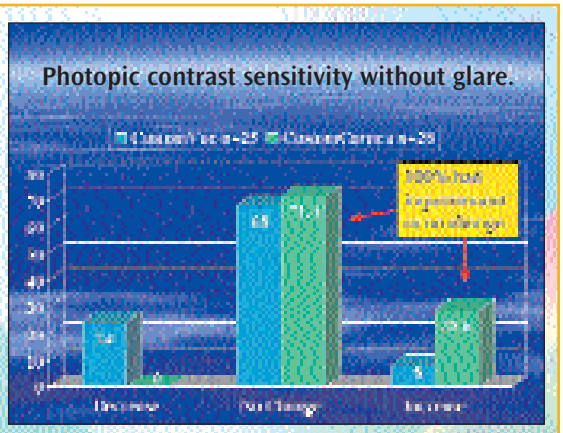


Figure 6. Three-month photopic contrast sensitivity without glare (change from preoperative).

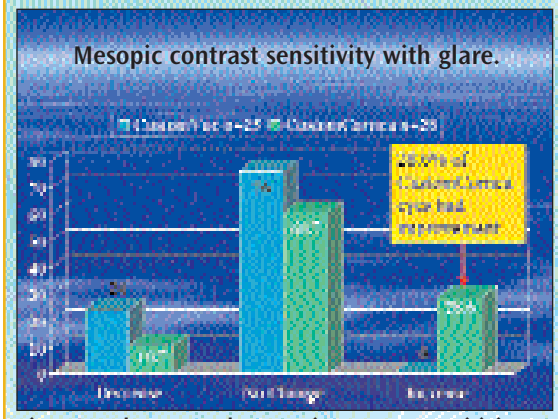


Figure 7. Three-month mesopic contrast sensitivity with glare (change from preoperative).

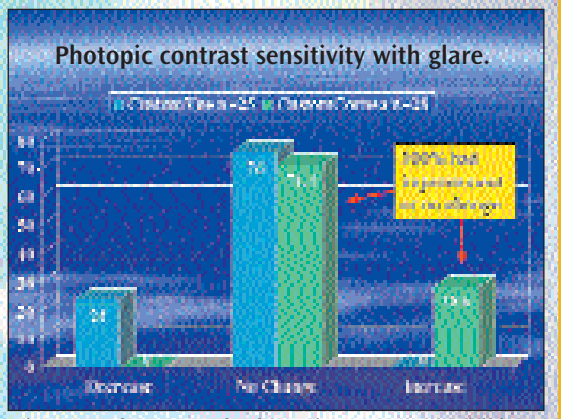


Figure 8. Three-month photopic contrast sensitivity with glare (change from preoperative).

patient, such a simplistic approach may end up making the patient worse rather than better. There are no substitutes for accurately measuring total wavefront error, not just guessing, and having an algorithm to drive the correction to compensate.

Donnenfeld: I would not call measuring preoperative baseline corneal curvature an algorithm. The LADARWave provides hard data as to the correct ablation profile for each patient.

The inability to measure wavefront aberrations and to place that wavefront on the cornea in a therapeutic way will not allow surgeons to achieve the best vision for patients. When adjustments must be made based on the simplistic idea of a mathematical formula that may not apply to all patients, the results cannot be accurate.

Every patient is different — the surgeon should perform wider measurements, capture these measurements and apply them to the cornea in the right position. An algorithm is no substitute for hard data that can directly be applied to the cornea.

My clinical experience is similar to that of the data compiled by Dr. Solomon in his comparisons of traditional vs. wavefront LASIK platforms (Figures 3 and 4).[2]

There is a definite improvement in Snellen acuity from conventional to wavefront, but the big difference occurs with quality of vision.

Our experience with the LADARWave system has been that patients' perception of quality of vision, both mesopic and scotopic, and contrast sensitivity were markedly improved (Figures 5-8). However, the quality of vision with CustomVue showed no significant improvement in quality of vision.[3]

Speaker: We presented our data at the 2004 American Society of Cataract and Refractive

Surgical Visual Benefit Index

Marc A. Mullie, MD

The lasers used by refractive surgeons have undergone progressive technological advances in the past 12 years. Currently, nearly all platforms used guarantee a greater than 90% chance of achieving 20/20 Snellen acuity after surgery. Wavefront-guided refractive surgery has pushed the visual system to new postoperative limits in the results that ophthamologists are able to achieve for their patients. However, the methods that are used in testing for high-contrast visual acuity are inadequate to assess the quantitative and qualitative aspects of vision after refractive surgery. Not all patients are satisfied with a 20/20 result.

Several image plane metrics describe the optical system of the eye after surgery, including point-spread function (PSF), Strehl Ratio, modulation transfer function (MTF) and optical transfer function (OTF). While these metrics are useful, clinicians require clinical descriptive metrics that test the entire visual system (i.e., optical, retinal, neural and higher cortical functions). No single metric can accomplish this testing adequately. In order to adequately describe and compare the refractive results with wavefront, the visual system must be pushed beyond high contrast Snellen acuity. Postoperative measurements must be as complex as the results.

David R. Williams, MD, and colleagues have developed an image plane metric called the "Visual Benefit."[1] In *Wavefront Customized Visual Correction: The Quest for Super Vision II*, the Visual Benefit is described as the measure of visual improvement at the retinal plane resulting from a perfect theoretical correction of the eye's higher-order aberrations or "the increase in retinal contrast at each spatial frequency that would occur if one were to correct all aberrations instead of just correcting defocus and astigmatism as one does with conventional refraction. More specifically, the Visual Benefit is the ratio of the eye's polychromatic (white light) MTF when all monochromatic aberrations are corrected when only defocus and astigmatism are corrected."[1]

The Visual Benefit may be a useful image plane metric to describe "how much" the optical system of the eye is improved by correcting the eye's aberrations.

Dr. Williams and colleagues wrote, "[Visual Benefit] is directly applicable to visual performance as assessed with contrast sensitivity measurements. That is, a Visual Benefit of 2 will lead to a two-fold increase in contrast sensitivity as well as a two-fold increase in retinal image contrast."[1] This measure is intuitively grasped as a useful measure of optical visual improvement.

New visual function measurements needed

I believe we need a similar quantitative or semi-quantitative measure to describe "how much" the entire visual system has been improved by wavefront-guided surgery. Such an index should include several measures of visual function, each of which tests the whole system (optical, retinal, neural and cortical). I propose an index titled the "Surgical Visual Benefit Index" (SVBI). The SVBI could include five tests of visual function as follows:

1. Low-contrast acuity: Gain or loss
2. Postoperative uncorrected visual acuity (UCVA) to preoperative best-corrected visual acuity (BCVA) (efficacy): Gain or loss
3. Contrast sensitivity, both photopic and mesopic: Gain or loss
4. Higher-order aberrations: Gain or loss
5. Quality-of-vision questionnaire: Improvement or worsening

The SVBI could be constructed with weights to each term. It would range numerically from 0 to 10, but in theory could be less than 0 (poor result) or more than 10 (an extraordinary result). A significant increase in total higher-order root mean square would deduct points and a significant decrease would add points.

As an example, an eye that improves two lines of BCVA is two lines of postoperative UCVA better

than the preoperative BCVA; has improved photopic and mesopic contrast, decreased higher-order aberrations and decreased spherical aberrations; and has fewer halos at night and better night vision would score a perfect 10 (if lower coma was present, the score would be 11). An eye that improved one line of BCVA and one line better UCVA than preoperative BCVA, but had worse mesopic contrast sensitivity, more aberrations and worse night-vision ratings would score -3. In general, we could say that a score of less than 0 represents little to questionable benefit, 1 to 3 is marginal to good benefit, 4 to 6 very good benefit, 7 to 9 high benefit and over 9 exceptional benefit.

Combining the factors that surgeons now consider crucial to the overall success of wavefront-guided surgery into one index would benefit patients and help direct the improvement of the technology involved in refractive surgical outcomes.

Reference

1. Williams DR, Applegate RA, Thibos LN. Metrics to predict the subjective impact of the eye's wave aberration. In: Kreuger R, Applegate R, MacRae S, eds. *Wavefront Customized Visual Correction: The Quest for Super Vision II*. Thorofare, NJ: SLACK Incorporated; 2004:25.

Surgery (ASCRS) Annual Meeting comparing our outcomes with CustomVue and CustomCornea.[1] In these data, it was clear that both systems provided a marked improvement in Snellen acuity. I have no doubt that patients perceive an improvement in quality of vision with both systems, but there was a definite difference between the results obtained with CustomCornea and CustomVue with regard to the number of patients achieving 20/15 or better vision. At 6 months, 62% of the patients treated with LADARVision system achieved 20/15 or better, and 7% achieved 20/10. Only 42% of patients treated with CustomVue technology achieved 20/15 vision, a full 20% less than with LADARVision, and there were no patients treated with CustomVue technology system who were 20/10.

Brint: Did you compare higher-order aberrations, either induction or reduction, preoperatively and postoperatively between the two platforms?

Speaker: Although we are still in the process of performing that analysis, preliminary data show that there was no significant induction of higher-order aberrations in the LADARVision group and a small but statistically significant increase in the CustomVue group. It was also interesting to me that in the LADARVision group, 63% of patients improved one or more lines of best-corrected visual acuity (BCVA) at 6 months. In the CustomVue group, approximately 40% of patients improved one or more lines of BCVA. These better results for patients who were treated with the LADARVision system highlight the importance of registration and centration of the wavefront during treatment.

Durrie: Ophthalmologists are moving away from using high-contrast acuity as the only measurement. Although it still is important that a patient can identify the black-on-white letters on an eye chart to measure visual acuity, in the real world there are few black-on-white comparisons, making contrast testing more important. In looking at my patients, it is clear to me that patients who have night-vision symptoms also have loss of low-contrast vision and also have higher-order aberrations.

I have performed off-label treatments using the CustomCornea platform for 300 patients who have had previous refractive surgery and had significant higher-order aberrations. In all cases, their night-vision symptoms improved, higher-order aberrations decreased and contrast sensitivity improved. Before the introduction of wavefront-guided ablation, I never had patients tell me how good their night vision was after surgery. With CustomCornea, this is something that I hear frequently.

Speaker: Quality of vision cannot be underrated. For example, when I first began performing custom treatments and had patients who were slightly undercorrected by as little as 0.5 D after standard ablation, they were unhappy with that result and would insist on retreatment. Now, with CustomCornea, these same patients are happy even with 0.5 D of under-correction because the

entire quality of their vision, including fewer higher-order aberrations, better night vision and better contrast, is improved.

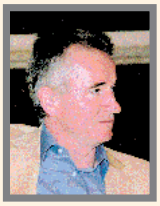
Mullie: Now that sophisticated aberrometers are available, a more advanced method of visual testing is needed that goes beyond the capability of Snellen high-contrast acuity (See "Surgical Visual Benefit Index," page 10).

Retreatments

Brint: What advice do you have for surgeons who want to retreat patients?

Now that sophisticated aberrometers are available, a more advanced method of visual testing is needed that goes beyond the capability of Snellen high-contrast acuity.

— Marc A. Mullie, MD



Durrie: First, I would advise surgeons to use the CustomCornea system because it has the best registration and tracking capabilities. Second, it is important that the wavefront data are accurate — this is especially important when performing retreatments because spherical aberrations are prevalent in these patients and so the measurements taken from the periphery of these eyes are often difficult to obtain. If I have a patient on whom I can obtain good wavefront data and who has spherical aberration, coma and/or secondary astigmatism, the patient seems to do well when treated with CustomCornea.

When performing retreatments with the CustomCornea system, I use a 0.75-D target offset to compensate for the mild overcorrection of the sphere seen in earlier cases.

Steinert: At the 2004 ASCRS annual meeting, I presented data that clearly showed a benefit to using surgeon offsets. I compared patients in whom no surgeon offset was used with patients who underwent retreatments with a surgeon offset. The first group of patients experienced a hyperopic shift that correlated to the amount of spherical aberration; as spherical aberration increased, so did the unintended hyperopic shift. This was particularly true when spherical aberration was approximately 0.8 µm root mean square (RMS) or higher.[5] This occurred even when there was a good match of manifest and wavefront refraction. My hypothesis is that using mid-peripheral treatment to reduce spherical aberrations causes a secondary healing effect of hyperopic shift. In the second group of patients, we started performing surgeon offsets of mostly 0.5 D. In other words, I was driving treatment in the myopic direction, and I found that the mean correction was more accurate as a result.

In the future, ophthalmologists will be able to better analyze aberrations and assign offsets that are driven by the amount of aberration present. I have become more aggressive with my surgeon offsets as aberrations increase because I want to avoid overcorrection.

In cases where there is a significant disparity between the manifest refraction and the wavefront refraction in terms of cylinder, patients often have vertical coma. When I am determining a wavefront for a patient and see that the cylinder is lower on the wavefront refraction than on the manifest refraction, I usually know I am on the right track. Upon viewing the orientation, the measurements line up as vertical and horizontal coma components.

Donnenfeld: I agree. With patients who have significant coma, the wavefront refraction is often undercorrecting their cycloplegic refraction. This tells the surgeon that most of the aberration is coma that is not detected by the wavefront. However, an offset must be used when the wavefront refraction is significantly more myopic.

I rarely find that I overcorrect patients using the LADARWave. This is most likely because, in capturing the wavefront image, I also capture the cycloplegic refraction.

When performing retreatments, surgeons must note that other systems do not capture cycloplegic measurements while obtaining the wavefront information. Under these circumstances, accommodation will be introduced to the equation and successful retreatment becomes almost impossible. Removing accommodation from the wavefront image on the LADARWave gives the surgeon more certainty on exactly what data are being collected for a patient's wavefront. When I perform surgery on virgin eyes using WaveScan measurements, I overcorrect patients by 1 D to 1.5 D. The LADARWave allows me to be almost always exact in my correction and I rarely have to use a physician adjustment.

I have performed many retreatments with

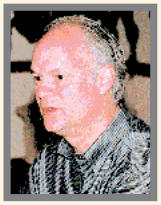
both CustomCornea and CustomVue and have found that retreatments with CustomCornea are better than any system I have ever used. Many of the complications that I encounter during these procedures are associated with decentration. If decentration occurs with CustomVue because of pupil movement and the surgeon retreats with the same system, he or she will add insult to injury. When decentration is a problem, registration is the key issue and if wavefronts can be applied to the area in question, the issue will be resolved. The registration on the LADARVision system allows for this resolution.

Speaker: I have found that when I am retreating patients who have a wavefront profile refraction of less than 1 D, it is helpful to carefully measure at the maximum ablation depth. I have seen planned retreatments for 0.5-D correction, but where the ablation depth was 38 µm or more. In these cases, the surgeon must be careful not to overcorrect the patient by scaling back the myopic component of the wavefront treatment to reduce the ablation depth, or by performing a standard enhancement.

Brint: When Dr. Durrie first started performing retreatments on patients who were plano, these procedures took 1 minute, a long time to many ophthalmologists. However, now that the CustomCornea software planning system is available, we can see what is being removed at every location on the cornea, even in the periphery. This shows us that 38 µm peripherally is not the same as an additional 38 µm centrally.

Durrie: Patients who are close to plano and have a large amount of spherical aberration may easily be overcorrected. This is partly due to the phototherapeutic keratectomy effect, from prolonged ablation times and aberration in the sphere, which is not yet understood. However, more of a physician adjustment is needed on all laser systems for these patients.

> … wavefront-guided correction provides the best results for the majority of patients in that it induces fewer aberrations and contrast sensitivity results are better.
>
> — Daniel S. Durrie, MD



Speaker: How do patients with 6-mm optical zones respond to retreatment with the LADARVision system?

Durrie: Patients with a 6-mm optical zone respond well, but only if a good wavefront reading is taken. I have performed upgrades on patients with 5-mm optical zones who had been treated back in the early 1990s, and the results have been excellent. These patients have lived with up to 2 µm of spherical aberration for many years, so they were more than satisfied with their improved night vision.

Donnenfeld: I treated patients from Europe who had their original treatments in the early 1990s. Their optical zones were 4 mm and they were functionally incapacitated by problems with quality of vision such as glare and halos. We enlarged the optical zones, reduced their higher-order aberrations and resolved their residual myopia. These patients were happier with their results than any other patients I have ever treated.

Clinical comparisons among wavefront platforms

Durrie: Based on my personal experience, I would recommend that whether a surgeon is using the Zyoptix, CustomVue or LADARVision platforms, wavefront-guided correction provides the best results for the majority of patients in that it induces fewer aberrations and contrast sensitivity results are better.

The 2004 ASCRS annual meeting was significant for me because I was able to hear surgeons who were using two different platforms offering their clinical comparisons. Everyone I spoke with reported better outcomes with the Alcon platform than any other system.

My most recent data came from using the IntraLase femtosecond laser (Irvine, Calif.) with the CustomCornea platform on patients with an average of 4.8 D of myopia. Fifty-five percent of patients had postoperative visual acuity of 20/12 and 20/10. I have never had results this good.

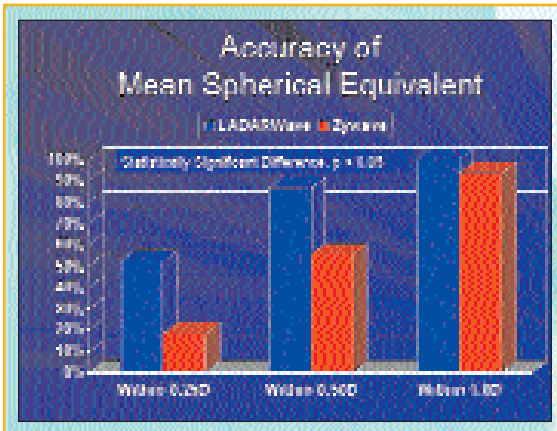


Figure 9. Comparison of the accuracy of mean spherical equivalent with the LADARWave and the ZyWave. *(Figures 9 and 10 courtesy of Marc A. Mullie, MD.)*

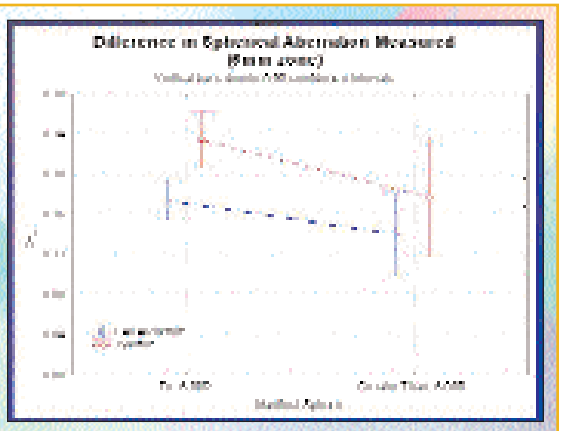


Figure 10. The ZyWave measures a significantly greater amount of spherical aberration at the 6-mm zone.

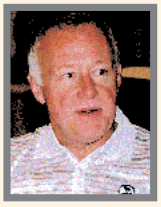
Additionally, approximately 50% of the patients who I treated gained one or more lines of BCVA. The patients reported a decrease in problems with night driving and in glare and halos.

The success that Alcon has had with their platform has put considerable pressure on the other laser systems.

Steinert: Spot size is an important factor in a laser because we can only treat aberrations that are as small as our laser spot. While registration seems to be the new focus, ophthalmologists must remember that the patterns of spots applied to the cornea are also important. In this respect, the LADARVision has an advantage because of its consistently small spots and accurate scanning control capabilities.

There is still curious disparity among the aberrometers — I have found, as have many others, that the same eye measured with different aberrometers yields different measurements. I have measured the same eye with the WaveScan, ZyWave and LADARWave and have not found the same measurements. I have consistently found that the LADARWave measurements show more aberration in terms of RMS error than the WaveScan. Pupil size is not the only reason for these disparities.

> ... if I cannot measure the aberration, I cannot treat it. The best way to tell which systems measure aberrations most correctly is to look at surgical outcomes ...
>
> — Roger F. Steinert, MD



Mullie: In terms of agreement with the manifest mean spherical equivalent, the LADARWave is statistically significantly better (Figure 9). The percentage of wavefront derived refractions within 0.25 D of the manifest is just over 50% with the LADARWave, but only 18% with the ZyWave system. All of the LADARWave values are within 1 D of the manifest refraction, but only 93% of the ZyWave data fall into this range. Also, the ZyWave measures more spherical aberration than LADARWave (Figure 10).

Steinert: Regardless of what I tried to compensate for pupil size, if I cannot measure the aberration, I cannot treat it. The best way to tell which systems measure aberrations most correctly is to look at surgical outcomes and, based on outcomes, I believe that the LADARWave measurements are more accurate.

The numerical measurements of RMS are so much lower on the WaveScan that there are fewer factors driving the laser to correct it.

Mullie: Also of importance is the reproducibility of the measurements taken. I have noticed that the LADARWave selects three out of the five measurements, and invariably they are close to one another. There is

much more variability in the measurements of the ZyWave — the standard deviation seems to be significantly larger on the ZyWave compared to the LADARWave.

Durrie: I performed a study using six different aberrometers on patients with the same pupil diameter. We input the measurements into the CTView software program (Sarver and Associates, Inc., Celebration, Fla.). The differences that we found among the six aberrometers were significant.

Zernike vs. Fourier

Brint: All of the aberrometers that drive lasers in the United States are based on the Hartmann-Shack system. Two mathematical formulas, Zernike and Fourier, have been used for many years. Laser manufacturers have traditionally relied on the Zernike system, which can measure an infinite number of aberration orders. The information that the Zernike data provide is based on the law of diminishing returns to the eighth order. In hindsight, it is possible that there is no need to go above the sixth order because the information obtained from the seventh and eighth orders is minimal to none.

There have been proposals that a switch be made to Fourier, which is said to provide information equal to the 20th Zernike order. However, because so little information in these higher orders is useful, it seems that there would be little advantage to using Fourier. It has also been suggested that basing ablations on aberrations in the higher orders up to the 20th can actually do more harm than good.

At the ASCRS annual meeting, Julian Stevens, MD, presented preliminary results using the Fourier system with CustomVue technology.[6] In his presentation, he stressed that the tear film must be perfect so that the surgeon does not pick up artifacts that would result in a poor ablation.

Donnenfeld: Surgeons must use the available resources to the point that achieves the best return on investment. Currently, Zernike polynomials provides excellent results. I predict that the improvements in excimer laser outcomes over the next couple of years will not be based on extending the Zernike readings or switching to Fourier analysis, but on better registration and reproducible peripheral wavefronts.

Mullie: Most of the wavefront systems use video-based trackers, which are often highly inaccurate. Before we consider treatment based on Fourier patterns, the tracking methods must be improved. Lasers still require precise tracking to be able to produce accurate wavefronts treatments. Other than the LADARVision system, no other laser systems currently have this capability.

Durrie: Ophthalmologists are now treating patients who could not be treated 5 years ago. First, clinicians have the ability to treat coma. These patients have a decentered apex and are not seeing through the center of their corneas. Second, spherical aberration can be treated, which is the slope of the refraction across the pupil. In the past, the assumption was that all patients had the same slope, but we were wrong — not all patients have the same refractive error at 6 mm as they do at 3 mm. This can now be dealt with and low-contrast and night vision is improved.

Zernike analysis has helped improve surgical outcomes. If better analysis comes along, I am sure it will be employed. However, the ability to treat spherical aberration and coma using Zernike analysis has benefited patients significantly.

There have been proposals that a switch be made to Fourier ... However, because so little information in these higher orders is useful, it seems that there would be little advantage to using Fourier.

— Stephen F. Brint, MD

Steinert: The eye is just a part of an overall optical system that includes excellent image processing — this is often forgotten until patient surveys show how happy people are when their visual acuity is improved. Patient perception must be considered when deciding to what order to correct aberrations. When the point has been reached where a patient can no longer tell the difference in visual results, there is little to no return on investment.

I hope to see ongoing effort toward developing better visual metrics to apply to wavefront, whether contrast sensitivity under certain lighting conditions or tests that are yet developed. Most ophthalmologists had never heard of wavefront 6 years ago and look where we are now.

The role of tracking also must not be forgotten. Even with correct wavefront diagnostics, the

intended corneal treatment patterns are not achieved with the wrong latencies, response times and tracking frequencies. As spot size becomes another 0.5 mm smaller, the demand to properly place each spot increase.

Durrie: These data show the need to match the spot size with the tracker speed, which the LADARVision does well. **[AU: To what data are you referring?]**

Pearls

Brint: I would like to discuss pearls for surgeons who are using customized platforms.

Let's say a patient comes into the office and the normal patient workup is performed, which included manifest refraction and cyclorefraction, etc. The preoperative measurements reveal no surprises in topography, pachymetry and wavefront. However, the wavefront that is obtained the day of surgery shows more than 0.75 D of difference with what was obtained previously. What is our nomogram for this patient?

My ideal patient has a wavefront refraction that is slightly less myopic than the manifest refraction. For example, if the manifest refraction is -4 D with the appropriate amount of cylinder, the ideal wavefront refraction is -3.8 D. No adjustments are needed for a patient with these refractions.

For the past 6 months for my custom treatments, I have been using Optimized Nomograms software (Refractive Consulting Group, Westlake Village, Calif.), which suggests that for a patient who has manifest refraction of -4 D, the offset should be between 0.15 D and 2 D.

If there is a 0.75 D difference (manifest refraction of -4 D; wavefront refraction of -3.75 D), and the patient has presbyopia, I want to be careful not to overcorrect. Thus, I adjust the refraction no more than the Optimized Nomograms software instructs. I may even back off more than the software advises, because the nomogram takes the wavefront reading as an absolute measurement and so will always adjust somewhat.

For a younger patient, I might split the difference and add in -0.37 D to compensate for the manifest refraction of 4 D and the wavefront refraction of 3.75 D. I use this nomogram only when the wavefront refraction and the manifest refraction are close to one another.

Donnenfeld: When I see a patient on the day of surgery, I consider three main points when choosing my offset. First, a personalized nomogram is as important for the customized platforms as with the older generation lasers. Adjustments should be made based on comparisons of the clinical vs. expected results.

> The wavefront measurements that I get with the LADARVision system coincide with the manifest refractions more than with any other system that I use.
>
> — Eric D. Donnenfeld, MD

Second, I adjust for a patient's age because older patients ablate faster than younger patients. I also adjust my nomogram for visual needs. I am comfortable having a 0.25 D offset for a 20-year-old patient, but would never do this for a patient in his/her 40s.

The third consideration is whether the patient's wavefront and manifest refraction differ greatly. Like Dr. Brint, when the patient's wavefront is less myopic than the manifest refraction, I am usually comfortable treating based on the wavefront measurements. Usually, higher-order aberrations explain the decreased spherical equivalent, most likely because of decreased cylinder. It is more challenging, however, when the patient does not have a significant amount of higher-order aberrations and is still undercorrected. For this type of patient, I use an offset and add some minus.

For patients who have a more myopic wavefront than manifest, it is important not to overminus because this will result in hyperopia. For these patients, I often repeat their wavefronts and let the cycloplegia work longer to get better results. I will also check to be sure that while I am taking their wavefront measurements, they are looking into the distance and not accommodating. I am able to do this easily using the LADARVision system.

These concerns are more theoretical than actual, because with the LADARVision system, I rarely need to use physician adjustments, other

than for a patient's age. The wavefront measurements that I get with the LADARVision system coincide with the manifest refractions more than with any other system that I use.

Mullie: A personalized nomogram is important. For example, in my surgery, I keep the humidity at approximately 40% and I find I tend to get slight undercorrections with the LADARVision, while most surgeons report overcorrections, so I routinely add -0.25 D to even -0.50 D to the offset to improve my results.

Speaker: I routinely use a nomogram based on age and amount of correction, and my results have been excellent. Less adjustment is required with LADARVision than with CustomVue technology. With the LADARWave, we capture five images and treat based on an average of three, but cannot do this on the WaveScan system because there is too much variability in the individual measurements due to accommodation. As a result, the surgeon must treat based on only one measurement with CustomVue technology.

I find that if there is a significant discrepancy between the wavefront measurement and the cycloplegic refraction, the manifest does not worry me, because accommodation or higher-order aberrations may be the explanation. However, if a big difference between wavefront and the cycloplegic refraction exists, we usually find better agreement if we go back and do a so-called wavefront-adjusted cycloplegic refraction. **[AU: Please explain this comment.]** I have few problems using the LADARVision system in terms of the accuracy of the wavefront measurements. It has been consistent and reliable.

I also find it helpful to ask patients to use Systane lubricant tears (Alcon Laboratories) four to six times per day starting 1 week preoperatively to improve the condition of their tear film. As a result, the image quality on the LADARWave is better and more consistent. Without stabilizing the tear film, it may be difficult to get a good image due to a thin tear film or rapid break-up time.

Durrie: I also must let my patients know that they cannot wear their soft contact lenses at least 3 days preoperatively, because their corneas may become warped and the wavefront will pick that up. For patients who use gas permeable lenses, I prefer that they take them out for 3 weeks preoperatively.

Speaker: Wavefront analyzers are so sensitive that any residual warpage of the cornea from contact lenses becomes more significant. In the past, as long as the patient's spherical equivalent and astigmatism were correct, the surgery would go well, but now, if a lens fits tightly and is creating a lot of distortion, this will transmit into the final results.

Donnenfeld: The accuracy of the LADARVision system is such that significantly fewer adjustments are required compared to other systems. I appreciate the reliability of the aberrometer data as it can be applied directly to the laser. The LADARVision system provides surgeons with the comfort that they are treating the patient appropriately.

Speaker: For surgeons who do not have much experience with performing customized ablations, CustomVue technology requires that the staff be skilled in operating the aberrometer to ensure that accommodation is controlled. Although technicians must be trained on the LADARVision system, the machine is less dependent on technician skill, which is another advantage to using this system.

Brint: The more adjustment that a surgeon must make translates to more room for error. It is virtually impossible to develop a consistent nomogram based on a random reading.

Donnenfeld: In the past, when I used the Star S4 (Visx) laser more often, I would use a +0.75 D adjustment in one eye and a -0.75 D adjustment in the other eye looking for plano in both eyes because the patient was accommodating. Using these adjustments made me feel uneasy about the treatment and I do not think that my outcomes were as good as they could have been.

When performing surgery on virgin eyes,

With the LADARWave, we capture five images and treat based on an average of three, but we cannot do this on the waves can because there is too much variability ...

— Mark G. Speaker, MD

more adjustments in the platform will usually yield less accurate results. When the surgeon is adjusting for factors other than age and his or her own nomogram, this takes away some reliability of the laser. When a surgeon cannot rely on his or her own data and must adjust for translation into the laser, clinical outcomes suffer.

Future

Brint: How do you think centration will change in the future?

Donnenfeld: Currently, accurate limbal registration is the most important step in laser surgery. I have made a point to train my technicians in this step and I always check the limbal registration manually to ensure that the preoperative limbus is the same on which I am performing the ablation. However, there is still room for some human error.

My colleagues and I performed a study that showed a 44-µm difference between technicians in matching the limbus. This measurement is significantly better than the 177-µm difference in pupil movement we showed in the same study with pupil tracking systems.[7]

Alcon is working on incorporating a computerized limbal recognition system, which will enable surgeons to more accurately recognize the limbus. Computerized limbal recognition will allow for even more accurate preoperative wavefront measurements, that when applied surgically, will produce extraordinary refractive results.

In the next 6 months, surgeons should be able to see improved surgical outcomes based on this new feature to the LADARVision system. Computerized limbal registration will widen the gap in quality of vision obtained with limbal registration vs. pupil tracking system, making the latter an obsolete form of measuring the eye during the ablative process.

Brint: CustomCornea surgery-planning software is newly available for the LADARWave. We are using this software for every custom case. The software allows us to see the profile of the ablation before it is made — both the thinnest and the thickest sections. Prior to having the software available to us, we were unsure how much tissue would be removed and where it would be taken from. I have found this software helpful for when I am working on a marginal cornea or performing retreatments, because the intraoperative pachymetry gives me an idea of how much tissue is left in the bed for removal.

The CustomCornea software also offers the surgeon the advantage of treating each eye individually. Before the CustomCornea planning software was available, I had to use the same target offset for both eyes to avoid the complicated process of treating the fellow eye as a new patient.

Steinert: I agree. With CustomCornea software, I have one nomogram for primary treatments and a completely different nomogram for enhancements. This makes planning easier and more precise.

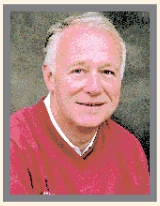
Durrie: I would like to have even more flexibility with the laser also. Alcon has developed expansion software for their laser. I participated in a study performing customized ablation on 85 eyes with high myopia and high astigmatism. Of 15 eyes that were 7.0 D with -9.75 D spherical equivalent, 100% were 20/20 postoperatively, with 62% achieving 20/16 vision. I have never seen results this good in patients with high myopia. Additionally, low-contrast acuity improved and symptoms of glare and halo decreased for these patients.

The LADARVision expansion software was approved by the Food and Drug Administration in June. Now that it is available, surgeons will be able to correct more cylinder and myopia and will be able to treat more patients who may not have previously been candidates for laser correction.

Brint: A solid-state laser with a 1,000-Hz laser and a 0.25-mm Gaussian beam is being developed. The treatment time is not shortened and this small of a beam will require a phenomenal tracker. Considering the accuracy that we have with our small-spot lasers and the upcoming software to improve them, will solid-state lasers have

With CustomCornea software, I have one nomogram for primary treatments and a completely different nomogram for enhancements. This makes planning easier and more precise.

— Roger F. STeinert, MD



a place in the future?

Mullie: Ophthalmology must find the right balance in spot size repetition rate. Studies show that a 1-mm or smaller spot size enables surgeons to correct up to fifth-order aberrations in virgin eyes. **[AU: Please provide reference.]** I am not sure that the extremely small spot size and high repetition rate are going to improve our results that much. As the repetition rate increases, extremely fast and accurate trackers will be required. Otherwise, the potential for error in spot placement will be high in the presence of microsaccades.

Durrie: When considering solid-state lasers, it is important to question how a wavelength of 213 MHz (solid-state lasers) vs. 193 MHz (excimer lasers) will affect ocular tissue in regard to wound healing. These new lasers will have to go through Food and Drug Administration approval, so more data will be required before they are even a viable option in the United States.

I do not think that the curve on excimer lasers has flattened yet. As registration becomes more automated, there will be more capabilities on excimer lasers. The industry has a long way to go before solid-state laser platforms are a realistic option.

Donnenfeld: The most interesting aspect of a solid-state laser is its convenience. However, there is nothing, in terms of improving surgical results, that can be accomplished with a solid-state laser that cannot be done with an excimer laser.

I agree that tissue reaction will be a significant factor in whether these lasers are approved in the United States and I would estimate that the approval process would take at least 5 years.

Durrie: I have heard surgeons say that solid-state lasers will cost less than excimer lasers. However, I already own a solid-state laser, the IntraLase, and it is more expensive than an excimer laser. By the time these lasers go through the regulatory, service and manufacturing process, the cost savings may disappear. Whatever takes the place of our current platform must prove better visual outcomes and, currently, that target has been set high by CustomCornea.

Mullie: One of the most important variables that must be controlled with laser treatment is treatment time. A 1,000-Hz laser with a 0.25-mm spot size will take the same amount of time to treat as the current excimer lasers. I would like to see a 1-mm spot moving at 300 Hz to 400 Hz.

Durrie: Dr. Mullie makes a valid point about treatment time. Increasing the speed of the laser could reduce the variability of outcomes. The shorter the amount of time that the flap is lifted the better. Currently, the treatment times with Zyoptix are longer than with CustomCornea, and I see recovery times that reflect this. Bausch & Lomb is currently working on improving the treatment times with Zyoptix.

Brint: This has been an interesting discussion on custom ablation technology and the capabilities that it provides now and may provide in the future. I would like to thank the faculty for their participation, Alcon Laboratories, Inc. for its support and OCULAR SURGERY NEWS for organizing this roundtable discussion.

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