Supplement to

Sponsored by an unrestricted educational grant from Advanced Medical Optics, Inc.

Cataract & Refractive Surgery TODAY

April 2006

Piecing Together the

Laser Vision Correction Puzzle

Comprehensively designed and aligned wavefront treatments are improving outcomes, reducing enhancement rates, and making happier patients.

Next-Generation Laser Vision Correction

BY RICHARD L. LINDSTROM, MD

Over the past 5 years, there has been a major advance in the way we ophthalmologists perform laser vision correction (LVC). Wavefront technology has revolutionized the way we both view and treat refractive error. Wavefront analysis is now a critical component of LVC. However, the discussion continues as to how and when to use wavefront information. To date, there are two wavefront-based approaches to LVC: wavefront-guided and wavefront-optimized.

Wavefront-guided LASIK creates an ablation profile based on all optical aberrations, both lower- and higher-order, that are derived from an aberrometer. As a result, all aberrations are measured and treated. In the optimized approach, the treatment is based primarily on sphere and cylinder (lower-order aberrations), and the ablation profile is modified so as to induce less spherical aberration. The laser achieves this by placing additional treatment pulses around the periphery of the cornea, based on the average amount of spherical aberration in the population, not the amount specifically measured in the patient.

Results from an interesting new model developed to simulate the visual performance of the human eye shows that wavefront-guided LASIK provides most patients with the best visual quality possible, according to Captain Steven C. Schallhorn, MD, Director of Refractive Surgery at the Naval Medical Center, San Diego (*for more information, see* Modeling Quality of Vision After Laser Vision Correction, *page 12*). Wavefront-guided LASIK results in the lowest level of induced higher-order aberrations when compared to both conventional and wavefront-optimized LASIK. Fewer aberrations produce a higher quality of vision with less night-vision symptoms.

Based on the simulations from the model, Dr. Schallhorn and his colleagues concluded that although optimized LASIK is an improvement over conventional LASIK, it still leaves the patient with more higher-order aberrations than wavefront-guided LASIK. They also concluded that wavefront-optimized LASIK is no better than conventional LASIK for eyes with preoperative negative spherical aberrations (12% of the population).

In their opinion, wavefront-guided LASIK is the best procedure for the majority of patients, providing the highest quality of vision with the least chance of night vision symptoms.

Furthermore, they conclude that the patient with good preoperative BSCVA and minimal higher-order aberrations may benefit from iris registration and wavefront-guided treatment as much as or more than the complex patient who has significant higher-order aberrations. The former has more to lose from astigmatism miscorrection, treatment decentration, induced night vision symptoms, and increased higher-order aberrations.

The current generation of wavefront-guided ablations provide significant advantages over and above simply

adding an aberrometer to the process.

Wavefront-guided platforms, such as the VISX CustomVue, have made at least six meaningful advances that have enhanced clinical outcomes since their original FDA approvals. These exciting advances include: (1) the use of Fourier analysis (over Zernike polynomials); (2) Variable Spot Scanning (VSS—with improved algorithms, which include a nomogram boost and correction for a "cosine effect"—the current lasers are faster, spare more tissue, and generate a smoother surface); (3) options for enlarged optical zones; (4) improved blend zones; (5) iris registration; and (6) compensation for pupil centroid shift.

In short, the current generation of the VISX S4 excimer laser includes many more benefits than just the addition of a wavefront analyzer. These added elements allow surgeons to give patients the best possible outcomes for laser vision correction today.

CustomVue is, for me, the preferred platform for all patients in whom accurate measurements can be obtained.

Contents

4 ROUNDTABLE DISCUSSION: WAVEFRONT-OPTIMIZED OR WAVEFRONT-GUIDED?
Wavefront-optimized may trump conventional, but it is no match for a true customized correction, according to surgeons with experience on multiple laser platforms.
Panel Participants:
Andrew E. Holzman, MD, FACS
Sao (John) Liu, MD
Jeffery J. Machat, MD
Mark E. Whitten, MD

8 COMPARING CONVENTIONAL, CUSTOMIZED, AND WAVEFRONT-OPTIMIZED LASIK TREATMENTS
VISX CustomVue improves results over conventional ablations and produces the lowest rate of enhancements and higher-order aberrations.
By Perry S. Binder, MS, MD

10 LOOK TO WAVEFRONT-GUIDED SURGERY TO REDUCE ENHANCEMENT RATES
Cutting retreatment rates boosts patient satisfaction and has a major impact on practice flow and financial growth.
By Mark E. Whitten, MD

12 MODELING QUALITY OF VISION AFTER LASER VISION CORRECTION
One model suggests significant differences in aberrations after conventional, optimized, and wavefront-guided procedures.
By Captain Steven C. Schallhorn, MD

14 PROLATE CORNEAS NOT NECESSARILY THE BEST
Study data dispel the conventional wisdom that a prolate shape is necessary for superb visual outcomes.
By David R. Hardten, MD

Wavefront-Optimized or Wavefront-Guided?

Wavefront-optimized may trump conventional, but it is no match for a true customized correction, according to surgeons with experience on multiple laser platforms.

Panel Participants:

***Andrew E. Holzman, MD, FACS**, is Medical Director of Millennium Laser Eye Centers, a TLC Laser Eye Centers Partner in Tysons Corner, Virginia. Dr. Holzman may be reached at (703) 556-9155 x 232 or andrew.holzman@tlcvision.com.*

***Sao (John) Liu, MD**, is Medical Director of the Omaha Eye & Laser Institute in Omaha, Nebraska. Dr. Liu may be reached at (402) 493-2020 or johnliu@omahaeye.com.*

***Jeffery J. Machat, MD**, is Co-Medical Director of TLC Laser Eye Center in Toronto, Ontario, Canada. Dr. Machat may be reached at (416) 733-2020 or jeffmachat@hotmail.com.*

***Mark E. Whitten, MD**, is the Regional Medical Director of TLC Laser Eye Centers, Rockville, Reston, and Fairfax, in greater metropolitan Washington, DC. Dr. Whitten may be reached at (301) 654-9777; mark.whitten@tlcvision.com.*

Editorial note: None of the participants is a paid consultant for any of the laser companies discussed in this roundtable.

Q: How do the visual acuity outcomes of wavefront-optimized versus wavefront-guided treatments compare?

Dr. Whitten: A couple of years ago, I was performing LASIK procedures with both the VISX CustomVue and WaveLight Allegretto laser platforms in roughly equal proportions. Since then, the CustomVue platform has undergone several improvements that have significantly improved my outcomes. With these improvements and the system's broadened FDA-approved parameters, I now use CustomVue more and perform fewer cases with the Allegretto.

To me, the decision of which laser to use is completely based on patient outcomes. When I compare the two platforms, my outcomes are better with CustomVue. I now reserve the Allegretto primarily for the small percentage of patients who are outside the CustomVue parameters, either because they have large amounts of astigmatism or because their manifest refraction differs from the WaveScan refraction.

Dr. Liu: My partners and I also introduced a WaveLight Allegretto laser into our practice in the hopes of achieving better results for our patients who were outside the VISX CustomVue parameters. After a few months of using the Allegretto laser, however, we realized it was not the answer.

Using the Allegretto's standard nomogram, our visual acuity results were significantly overcorrected by as much as 1.00 to 1.50D, especially in patients with astigmatism. Even after working with the manufacturer to implement some nomogram adjustments, we could not bring the results in line with our expectations.

My staff and I also experienced induced cylinder in a number of cases, which may have been related to centration problems.

Dr. Machat: I have extensive experience with a number of lasers. After treating nearly 2,000 patients with wavefront-optimized or prolate corrections, there was no question in my mind that I was getting better results than I achieved with the Technolas 217Z PlanoScan program or the VISX S3 SmoothScan program. However, when my staff and I upgraded our VISX laser to an S4 with CustomVue in late 2004, there was an equally great jump in results.

Q: Beyond visual acuity, how would you compare night vision and other qualitative outcomes?

Dr. Machat: The WaveLight system creates very smooth corneal beds and good qualitative vision, but I think the qualitative benefit doubles when you move to CustomVue. The two lasers take very different approaches to the treatment of spherical aberration. VISX CustomVue attempts to correct each patient's actual spherical aberration, based on his wavefront map. The WaveLight program optimizes the corneal shape to create a spherical-aberration–neutral cornea, based on data about the amount and effects of spherical aberration in a database of patients. For any given patient with a wavefront-optimized treatment, his spherical aberration might be a little over- or undertreated, which you would probably never notice. However, for one in 10 patients who have negative spherical aberration to start with, "optimization" is going to aggravate the condition.

My staff and I obtain preoperative wavefront maps on every patient, so when a patient is unhappy after his wavefront-optimized ablation, we can look back and see what is going on. In many cases, these patients have negative spherical aberration, and the treatment has made it worse. Sometimes, they have a lot of coma, which a wavefront-optimized treatment did not address at all. Thus, we began to correlate the symptoms of our patients with their preoperative wavefront maps and outcomes.

At one point, we were treating approximately half our patients with wavefront-optimized treatments and the other half with VISX wavefront-guided. When we compared the two groups, there was a dramatic difference in the clinical results. Not only did we have more 20/20 results in the wavefront-guided group, but we saw a reduction in glare and better night driving outcomes. In addition, with CustomVue, we simply do not see patients with significant, qualitative, postoperative visual problems, irregular astigmatism, or high coma, as we would occasionally see after Allegretto treatments. We now treat almost all our patients with CustomVue, and since making that change, we have not had any patients with significant postoperative night glare or other quality-of-vision problems.

> "It's important to realize that the optimization feature in the Allegretto laser kicks off above -6.00D."
>
> **—Jeffrey J. Machat, MD**

Dr. Whitten: My staff and I also no longer have any complaints about glare or halos after CustomVue treatments. I think this is due to the most recent upgrades to the VISX system, a combination of Fourier-driven algorithms and IR. These two features have made a huge difference in postoperative night vision problems. If I have to choose between some night vision problems with a wavefront-optimized procedure versus none with a wavefront-guided one, I'll take the latter.

Dr. Holzman: My staff and I have not had complaints about visual quality with either laser. However, we avoid treating certain patients with the Allegretto laser, specifically to prevent problems with glare.

Wavefront-optimized treatments induce negative spherical aberration in order to achieve a spherical-aberration–neutral result. As Dr. Machat noted, this type of treatment resolves spherical aberration in most eyes but would be expected to exacerbate the problem in the 10% to 12% of the population with negative preoperative spherical aberration. Interestingly, about 12% of patients in the WaveLight FDA study complained about marked, severe night driving glare after wavefront-optimized surgery. We do not know for sure that these were the patients with preexisting negative spherical aberration, because preoperative aberrometry was not included in the study data, but it seems likely.

My staff and I obtain WaveScan measurements on all patients preoperatively. Anybody with negative spherical aberration is steered away from the wavefront-optimized treatment and is treated with the VISX CustomVue.

Retreatment Rates

Clinician	Wavefront-Optimized (Wavelight)	Wavefront-Guided (CustomVue)
Jeffrey J. Machat, MD	16%	8%
Mark Whitten, MD	10-15%	<5%
Sao John Liu, MD	25%	4%

Figure 1. Retreatment rates improve when moving from wavefront-optimized to wavefront-guided ablations.

Q: How satisfied have you been with wavefront-optimized outcomes in high myopes?

Dr. Liu: This was the group we most wanted to treat with the Allegretto laser, because at the time, CustomVue was not approved for high myopes. But, we had a lot of trouble with overcorrections and induced astigmatism. We were also unsatisfied with the safety of this laser for high myopes. It requires large flaps, which produce more dry eye problems and consume more tissue. The ablation profile in the periphery is pretty steep for high corrections and ablates a lot of tissue, potentially putting patients at greater risk for corneal ectasia. For high myopes, it would be valuable to have a good procedure that preserves more tissue than a customized ablation. In our experience, however, wavefront-optimized corrections consume just as much tissue without delivering as good a correction as wavefront-guided surgery.

Dr. Machat: It is important to realize that the optimization feature in the Allegretto laser kicks off above -6.00D. In other words, there is no spherical aberration correction in high myopes, unless there has been a recent software update that I do not have. My understanding is that creating a prolate cornea in high myopes would require so many peripheral pulses that it would remove too much tissue, and the company opted not to do a partial prolate correction. This approach makes no sense to me, because high myopes are the very patients who are most at risk for night glare and would most benefit from at least a partial resolution of their spherical aberration. Instead, they are receiving a nonoptimized conventional procedure with the Allegretto. By contrast, customized platforms treat patients' actual spherical aberration up to the laser's full dioptric limit.

Dr. Whitten: I have never been told that the treatment of higher myopes is not wavefront-optimized, but it seems clear from my outcomes that there is something different happening above -6.00D. In general, I have achieved very good results with wavefront-optimized treatments on low-to-moderate myopes. At -6.00D and greater, however, I see a vast improvement in night-vision quality with customized treatments over the Allegretto software, and I have stopped using the latter for high myopes.

In any case, I am fairly skeptical of the value of creating a prolate cornea. In VISX's FDA CustomVue trial, they found that just as many of their 20/15 patients had an oblate cornea as a prolate one. I think it may be more important to give patients a true wavefront-guided treatment than to just make them prolate no matter what. (*For more information, see* Prolate Versus Oblate *on page 14.*)

Q: How do wavefront-guided and wavefront-optimized retreatment rates compare?

Dr. Liu: My staff and I were told that we should be able to achieve retreatment rates as low as 1% with the Allegretto laser. As I said earlier, though, many of our patients were overcorrected. After the first 75 patients or so, our retreatment rate was nearly 25%. We went through several nomogram adjustments after that, but they did not significantly improve our outcomes.

> "Although wavefront-guided procedures require a little more time on the front end, they save me time and energy in the long run, because I do not have to retreat customized-treated patients."
>
> **—Mark E. Whitten, MD**

Dr. Whitten: I consider my enhancement rate to be my most important measure of success, because happy patients do not need enhancements. With wavefront-optimized corrections, I have always needed to retreat approximately 10% to 15% of my patients. This rate used to be lower than my wavefront-guided retreatment rate, but each upgrade to the CustomVue system has reduced my need for enhancements. Now, with Fourier-driven ablations and iris registration (IR), my CustomVue enhancement rate is below 5%. (*For more information, see* Look to Wavefront-Guided Surgery to Reduce Enhancement Rates *on page 10.*)

Dr. Machat: My retreatment rate with wavefront-optimized corrections is about 16%, which is double the rate for wavefront-guided procedures, at approximately 8% (Figure 1).

Q: What is your approach to retreatments following wavefront-optimized ablation?

Dr. Holzman: My staff and I have been using the Allegretto laser for only 6 months, so I have not done many retreatments on the wavefront-optimized group as of yet. When I do need to enhance, I will opt for a wavefront-guided correction. Customized enhancements on the VISX system are very precise, with no overcorrections, and patient satisfaction is very high. I want to stick with what I know will succeed in any patient whose first outcome was not ideal.

Dr. Machat: My staff and I have not had great success with Allegretto retreatments, because the problem is often not strictly a refractive issue. If a patient has coma or negative spherical aberration, we have always had to use the VISX laser to enhance him with a customized correction.

In one case that comes to mind, the patient was treated with the Allegretto and was 20/20 in both eyes postoperatively, but he felt truly disabled by night glare. His wavefront maps showed that he had significant coma in both eyes as well as residual spherical aberration. His visual complaints correlated well with his wavefront error. My partner, who treated this patient, was concerned about a possible overcorrection. We decided to retreat one eye at a time with CustomVue. My partner did an amazing job and was thrilled that CustomVue not only resolved this patient's qualitative visual complaints, but also did not result in an overcorrection. The patient said it was "like somebody turned the lights on" and is now one of our happiest patients.

To me, the ability to fix qualitative problems like this is one of the truly amazing aspects of customized refractive technology. Although it is nice to have it as an enhancement option, I think we are better off avoiding qualitative problems by giving every patient a customized correction in the first place. I believe that customized treatments are rapidly becoming the new standard of care today and are the only way to consistently meet our patients' high expectations.

Dr. Liu: Retreatments on Allegretto patients are a significant expense that my staff and I are having to absorb right now. Because these patients were told they were getting a wavefront-optimized treatment the first time, we are giving them wavefront-guided enhancements. In addition to the cost, we spend a lot of time in following up with these patients. We have been counseling our overcorrected patients to wait to see if they regress, but when that has not happened over several follow-up visits, we eventually perform an enhancement.

Dr. Whitten: The impact on the practice of reducing your enhancement rate is huge, both financially and logistically. Although wavefront-guided procedures require a little more time on the front end, they save me time and energy in the long run, because I do not have to retreat customized-treated patients.

Q: How much do you think IR contributes to your results? Would you be happy operating without it?

Dr. Whitten: Practitioners may have thought initially that IR was nothing but marketing hype, but it has drastically improved my retreatment rate. Using IR, you can see that most patients cyclotort by 2° to 7° when they move to a supine position. There is no way you can reliably distinguish the difference of a few degrees in alignment, but that small amount of rotation can result in the incomplete treatment of cylinder. Wavefront-optimized treatments are not registered to the iris, of course, so you simply do not have the same precision in alignment, and you cannot know whether the cylinder is being treated in the correct meridian or not.

> "With IR, your chances of aligning the treatment appropriately are much higher. It gives me much more confidence as a surgeon to know that the ablation is being delivered at just the right orientation to just the right spot."
>
> **—Andrew E. Holzman, MD, FACS**

Dr. Holzman: With IR, your chances of aligning the treatment appropriately are much higher. It gives me much more confidence as a surgeon to know that the ablation is being delivered at just the right orientation to just the right spot. My IR capture rate is somewhere between 90% and 95%, so I still continue to mark every patient's cornea just in case I cannot capture it, but I am much more comfortable when the iris registers.

Dr. Whitten: My staff and I are up to approximately a 98% to 99% capture rate. If there is a case where the iris does not register, we can often get it to register just by turning out the lights on the laser to make the pupil expand slightly. I always try lighting adjustments before giving up, because I think IR makes such a big difference.

Dr. Machat: To be able to take cyclotorsion and pupil centration into account when the wavefront map is matched up with the ablation pattern has brought wavefront-guided correction to a whole new level. Even in patients with 4.00 to -5.00D of cylinder—people I would have previously counseled to expect to need two procedures—we are now able to achieve full corrections in one treatment. IR gives me much greater comfort in treating hyperopia and mixed astigmatism, too. I think it is going to be very hard for anyone not using customized refractive technology and IR to have comparable results.

Comparing Conventional, Customized, and Wavefront-Optimized LASIK Treatments

VISX CustomVue improves results over conventional ablations and produces the lowest rate of enhancements and higher-order aberrations.

BY PERRY S. BINDER, MS, MD

In my refractive surgery practice, I have been using three different excimer lasers: the Alcon LadarVision 4000 (Alcon Laboratories, Inc., Fort Worth, TX); the VISX Star S4 (AMO, Inc., Santa Ana, CA); and the WaveLight Allegretto (WaveLight Laser Technologie AG, Erlangen, Germany). In order to obtain hard data about which laser treatments were producing better results, I compared a large number of my own cases, both customized and conventional (Table 1).

THE STUDY

I retrospectively reviewed myopic sphere and spherocylinder LASIK treatments for all three lasers in my practice. I personally performed all the surgeries, and I used the IntraLase FS femtosecond laser (IntraLase Corp., Irvine, CA) to create the flap in every case. I marked the corneas at the slit lamp for every conventional case with greater than 0.50D of astigmatism and for every customized procedure. I did not have Iris Registration available on the VISX CustomVue system (AMO, Inc.).

> "VISX had the lowest enhancement rate of any of the lasers tested."

In all cases, I obtained aberrometry readings pre- and postoperatively using the same aberrometer both times,

TABLE 1. ENROLLMENT IN A PRIVATE-PRACTICE LASER COMPARISON

TECHNOLOGY USED	NUMBER OF EYES		
	Spheres	Spherocylinders	Total
VISX Star S4 Conventional	23	108	131
VISX CustomVue	17	54	71
Alcon LadarVision 4000 Conventional	44	77	121
Alcon CustomCornea	47	45	92
WaveLight Allegretto	43	108	151

regardless of whether the patient underwent a customized ablation. The mean follow-up for the various groups ranged from 5.5 to 7.3 months.

For each of the five laser-treatment categories (VISX conventional, VISX CustomVue, Alcon conventional, Alcon CustomCornea, and Wavelight Allegretto optimized), my colleagues and I examined a variety of outcome factors, including reduction in sphere, reduction in cylinder, a refractive outcome within 0.50D of the intended correction, a UCVA of 20/20 or better, an enhancement rate, a BSCVA gain or loss of ≥ two lines, and a total higher-order aberration RMS change.

> "The data indicate that the VISX CustomVue performed the best in terms of correcting total RMS, spherical aberration, and defocus."

Within the higher-order aberrations, we also studied changes in defocus and spherical aberration. We examined the absolute values as well as the percentile change for each value. A subanalysis that we stratified by pupil size (≤ 6.5 or > 6.5mm) did not change the study's conclusions.

We are currently updating our data from this study with more eyes before we submit them for peer-reviewed publication, so they are not available here in detail. I can, however, share some of the highlights of the study.

VISUAL ACUITY

All of the lasers performed well—that is, they all improved patients' UCVA and BCVA and produced very predictable refractive changes. The Star S4 wavefront-guided ablations produced the best visual acuity results in eyes with a spherical refraction and no astigmatism (spheres), whereas eyes with myopia and astigmatism (spherocylinders) achieved their best acuity results with either the Allegretto laser or the VISX CustomVue. The LadarVision 4000 laser performed better than any other in reducing cylinder, regardless of whether the procedure was conventional or wavefront-guided.

Overall, the Star S4 wavefront-guided ablations produced better results compared with conventional VISX treatments. The LadarVision's wavefront-guided ablations did not improve on its conventional results.

Therefore, in terms of acuity, each laser displayed some advantages and some disadvantages. When we drill down into more detailed analysis, the results get very interesting.

For example, the Star S4 CustomVue and Allegretto lasers gave the highest predictability: ± 0.50D of emmetropia. Also, the Star S4 had the lowest enhancement rate of any of the lasers tested.

HIGHER-ORDER ABERRATION

All of the lasers induced higher-order aberrations in the majority of patients. However, in patients with a total preoperative higher-order RMS of > 0.3µm—roughly a 20% slice of the patient pie—wavefront-guided and wavefront-optimized procedures tended to achieve a reduction in RMS, whereas eyes with < 0.3µm total RMS tended to develop an increase after surgery. In other words, eyes with more aberrations preoperatively fared better with either a wavefront-guided or a wavefront-optimized treatment than with a conventional one. The Star S4 wavefront-guided treatments produced the best results with higher-order aberration, for both spheres and spherocylinders, across all categories.

Wavefront-optimized is a unique category. Rather than deliver an ablation based on an individual patient's wavefront map, the WaveLight Allegretto laser's algorithm is designed to deliver more pulses as the beam moves farther away from the visual axis. Based on data from large numbers of treated eyes,[1] this approach is supposed to minimize the induction of spherical aberration, the most commonly induced higher-order term and the one thought to cause the greatest problems with visual quality. Although the surgeon may enter any correction into the Allegretto laser, as with a conventional treatment, this laser optimizes that treatment to avoid the induction of spherical aberration.

Although the Allegretto laser performed as well as the customized laser platforms in terms of visual acuity and predictable results, it did not reduce the induction of spherical aberration. In fact, the data indicate that the VISX CustomVue platform performed the best in terms of correcting total RMS, spherical aberration, and defocus.

Perry S. Binder, MS, MD, is in private practice at Gordon Binder & Weiss Vision Institute in San Diego. He is a consultant for IntraLase Corp., but he acknowledged no financial interest in any product or company discussed herein. Dr. Binder may be reached at (858) 455-6800; psbinder@gbvision.com.

1. Mrochen M, Donitzky C, Wullner C, Loffler J. Wavefront optomized ablation profiles: theoretical background. *J Cataract Refract Surg.* 2004;30:775-785.

Look to Wavefront-Guided Surgery to Reduce Enhancement Rates

Cutting retreatment rates boosts patient satisfaction and has a major impact on practice flow and financial growth.

BY MARK E. WHITTEN, MD

Until recently, I performed laser refractive surgery with both the WaveLight Allegretto (WaveLight Laser Technologie AG, Erlangen, Germany) and VISX Star S4 (AMO, Inc., Santa Ana, CA) lasers. After comparing outcomes with the two lasers, however, I have shifted to using wavefront-guided CustomVue surgery with the Star S4 laser for nearly 100% of my refractive surgeries.

RETREATMENTS AS A METRIC

In comparing the two laser systems, the most important metric I took into account was my enhancement rate. That single number reveals more about a refractive surgeon's success than visual acuity outcomes, wavefront error, or any other measure, because it is tied directly to patients' satisfaction.

Most people would consider me to be relatively aggressive when it comes to performing retreatments. When my patients return to complain about their vision after LASIK, I do not check their visual acuity to determine whether it is worth performing an enhancement. I consider the fact that they are complaining about their vision. Most people do not unnecessarily subject themselves to surgery. They do not choose to endure an operation, several hours of postoperative discomfort, and a couple of weeks of using artificial tears unless they really want to correct a problem. Therefore, I take patients' complaints quite seriously, whether their vision is 20/25 or 20/40. This philosophy makes my retreatment rate higher than that of a physician who only enhances patients whose vision is 20/40 or worse. Also, because I do not charge for enhancements, my patients are more likely to seek one than those who must pay out of pocket.

> "When visual problems are related to higher-order aberrations, you cannot cure them with anything other than wavefront-guided surgery."

Procedure	Enhancement Rate
Conventional Ablation	20-25%
Wavelight Allegretto ("Wavefront-Optimized")	10-15%
VISX CustomVue with Fourier Upgrade	~10%
VISX CustomVue with Fourier & Iris Registration Upgrades	<5%

Figure 1. Advancements in the CustomVue platform, including the Fourier upgrade and Iris Registration, have reduced retreatment rates.

TECHNOLOGY HAS HELPED

Years ago, when I was performing conventional refractive surgery, my enhancement rate was 20% to 25%. When the VISX CustomVue software became available, that rate dipped into the high

> "I believe that the days of treating everybody the same are over. The future of laser vision correction lies in truly individualized treatments, not similar treatments for similar prescriptions."

teens—a significant improvement, but there were still a lot of patients whom I retreated. Furthermore, this rate was a bit higher than the 10% to 15% enhancement rate I had achieved with the Allegretto's wavefront-optimized treatments.

After I received the Fourier upgrade to my Star S4 CustomVue platform, my enhancement rate dropped to approximately 10%. When iris registration (IR) came along, it allowed me to align treatments much more precisely than I could with marking alone. This ability makes a big difference in the accurate correction of cylinder, in my opinion. Now that I use IR on nearly every case, my CustomVue retreatment rate is less than 5% (Figure1).

So, although my enhancement rate with the WaveLight Allegretto has stayed about the same, VISX's technological improvements have continued to reduce my rate of enhancements and improve my outcomes. Incidentally, I think the fact that AMO, Inc., supplies free retreatment cards for its CustomVue cases indicates how confident the company is about its software.

IMPACT ON THE PRACTICE

The impact of reducing my enhancement rate has been huge, both financially and logistically. As refinements in wavefront-guided software have progressed, the number of surgeries I perform every day has changed. Executing fewer retreatments opens up my schedule for seeing more new patients, which generates more revenue.

Wavefront-guided surgery takes slightly longer initially, because the surgeon has to obtain wavefront images and develop a treatment plan rather than just plug a refraction into the laser. In the long run, however, it saves me time and money, because I rarely have to enhance my customized-treatment patients. I also no longer have the energy drain of constantly dealing with patients who are complaining about their qualitative vision. As any surgeon, referring optometrist, or ophthalmologist knows, just one patient with night-vision problems can mess up an entire day's schedule. Going through the process of reassuring that patient, retesting him, and doing what it takes to fix his problem is enormously time consuming for the physician and is stressful for the patient as well.

A BETTER FIX

My preference, of course, is to avoid the need for enhancements in the first place. My outcomes data show that wavefront-guided surgery with Fourier-driven ablations and IR is the best method. There will always be patients who for some reason do not heal as expected and need a retreatment, but that number can be dramatically reduced with the latest customized laser technology.

Fortunately, customized enhancements are very effective. I still retreat patients with qualitative visual problems from conventional surgery they underwent years ago as well as high myopes who had wavefront-optimized surgery more recently.

The advantage of CustomVue is the ability to treat patients who have quality-of-vision problems, regardless of how they acquired them. A wavefront-optimized treatment that treats every eye the same way certainly cannot do that.

If a patient is merely under- or overcorrected, I might enhance his outcome using the Allegretto or a conventional laser platform, if that is how he was initially treated. For anyone who exhibits problems with night vision or other qualitative issues, however, a wavefront-guided retreatment is a must. When visual problems are related to higher-order aberrations, you cannot cure them with anything other than wavefront-guided surgery.

CONCLUSION

I believe that the days of treating every patient the same are over. I know that every patient who sits in my chair is unique. When you study wavefront maps, you realize very quickly that two spherical myopes with the same -4.50D prescription will have very different wavefront profiles. Thus, I believe the future of laser vision correction lies in truly individualized treatments, not similar treatments for similar prescriptions.

Mark E. Whitten, MD, is the Regional Medical Director of TLC Laser Eye Centers, Rockville, Reston, and Fairfax, in greater metropolitan Washington, DC. He is not a consultant to VISX/AMO or Wavelight Laser Technologie AG, *and he acknowledged no financial interest in any product or company mentioned herein. Dr. Whitten may be reached at (301) 654-9777; mark.whitten@tlcvision.com.*

Modeling Quality of Vision After Laser Vision Correction

One model suggests significant differences in aberrations after conventional, optimized, and wavefront-guided procedures.

BY CAPTAIN STEVEN C. SCHALLHORN, MD

Because of significant advances made in excimer lasers and microkeratomes, LASIK is achieving better results than ever before. It is now common for patients to attain 20/20 or better UCVA after their procedure. Looking beyond a satisfactory refractive outcome, surgeons and manufacturers have placed a new emphasis on the quality or clarity of vision after surgery. This greater pressure for better outcomes has resulted in the development, approval, and use of wavefront-guided refractive surgery. One of the newer procedures available is called *optimized LASIK*. My colleagues and I conducted a simulation of the outcomes of conventional, optimized, and wavefront-guided LASIK based on changes in higher-order aberrations to predict differences in visual performance.

Conventional LASIK typically induces a significant amount of higher-order aberrations, the most notable of which is spherical aberration. Wavefront-guided procedures, however, reduce the induction of higher-order aberrations, as shown in numerous clinical trials.[1-4] By inducing fewer aberrations, patients' quality of vision (as measured by contrast sensitivity and patient questionnaires) after wavefront-guided LASIK is better than with conventional treatments. Building on the observation that spherical aberration is one of the most significant aberrations induced by conventional LASIK, optimized LASIK was designed to be spherical-aberration–neutral. It achieves this goal by adding an aspheric profile to the ablation pattern. In addition, optimized LASIK offers a lower per-procedure cost and requires no aberrometry measurement for patient treatments.

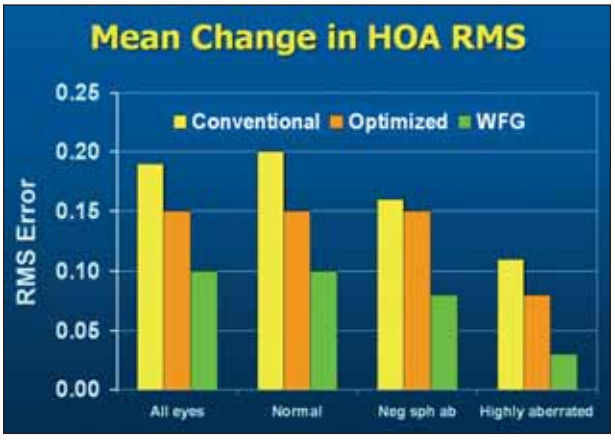

Figure 1. The model shows that wavefront-guided LASIK provides a dramatic improvement in results over both conventional and wavefront-optimized ablations.

VISUAL PERFORMANCE MODEL

To help predict visual performance differences between conventional, optimized, and wavefront-guided LASIK, my colleagues and I developed a model that simulated changes in aberrations for each. We used pre- and postoperative data from two groups of patients: 500 conventional LASIK eyes, and 170 eyes that underwent the customized procedure. We performed all wavefront analysis with a 6-mm entrance pupil. We made two important assumptions regarding optimized LASIK: (1) that it is completely spherical-aberration–neutral (ideal case), but that (2) it induces other, nonspherical higher-order aberrations, the same as conventional LASIK. I believe this second assumption is reasonable, because optimized is not "optimized" to reduce the induction of other high-order aberrations.

The amount of higher-order aberrations induced by a procedure depends upon the amount present prior to surgery. Patients with few higher-order aberrations preoperatively are much more likely to have induced aberrations after surgery. This is true even with wavefront-guided

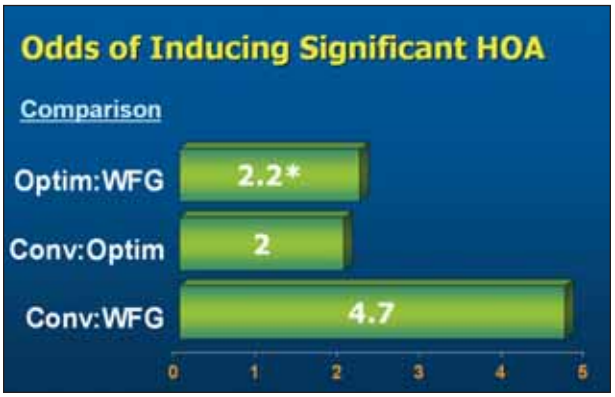

Figure 2. With a wavefront-optimized approach, you are 2.2 times more likely to induce significant higher-order aberrations postoperatively than with a wavefront-guided approach.

LASIK. However, particularly for wavefront-guided LASIK, there can be a reduction of preoperative higher-order aberrations if there were significant aberrations present before surgery.

METHODOLOGY

Based on the distribution of higher-order aberrations found in a normal population, we generated 10,000 wavefront maps. Using these model eyes, we randomly assigned the postoperative higher-order aberrations to be within ± 1 standard deviation of induced aberration, depending on the type of surgery and the amount of preoperative higher-order aberrations present.

The model correctly predicted that conventional LASIK significantly increased higher-order aberrations and also that wavefront-guided LASIK induced fewer aberrations than conventional. The model then forecast that optimized LASIK would induce fewer higher-order aberrations than conventional but more than wavefront-guided. In cases where the model eye had negative preoperative spherical aberration, an event that can occur in approximately 12% of the population, we found that the optimized approach was equivalent to conventional surgery.

Wavefront-guided LASIK ultimately fared the best in this simulation. In the cases we studied, it did not matter whether (1) there was a normal amount of higher-order aberrations present preoperatively, (2) if the eyes were highly aberrated, or (3) if negative spherical aberration were present. In all cases, the model predicted that the wavefront-guided approach induced fewer aberrations compared with either the optimized or conventional techniques.

CLINICAL PERSPECTIVE

To assign a measure of clinical relevance to the results, we deemed significant an induction of 0.1µm of higher-order RMS (for a 6-mm pupil). Using this benchmark, we found that conventional LASIK was twice as likely as optimized and five times more likely than wavefront-guided to induce a significant amount of higher-order aberration. Furthermore, the same advantage that optimized LASIK has over conventional, wavefront-guided has over optimized. Optimized LASIK was twice as likely as a wavefront-guided procedure to induce a significant level of higher-order aberration (Figures 1 and 2).

It is apparent from our model as well as from a growing body of clinical experience[5-8] that a wavefront-guided procedure is beneficial for those patients with a high degree of preoperative higher-order aberrations. Wavefront-guided LASIK can reduce (ie, treat) preexisting higher-order aberrations in these cases.

Particularly relevant, however, is predicting the outcomes of patients who have few preoperative higher-order aberrations (who represent the majority of patients in a normal population). Based on the model, it appears that patients with low levels of preoperative higher-order aberrations would have the best chance for a high quality of vision after undergoing wavefront-guided LASIK. It may be even more important to utilize a wavefront-guided procedure with this type of patient, because they may not adapt as well to an even greater amount of induced higher-order aberrations.

A limitation of this study is that the model is based on the observed change in higher-order aberrations of conventional and wavefront-guided LASIK. We did not have clinical data from optimized LASIK to validate our assumptions. This omission is being addressed in further studies.

Captain Steven C. Schallhorn, MD, is Director of Cornea Services at the Naval Medical Center in San Diego. He is a consultant for VISX/AMO, Inc., *but states that he holds no financial interest in any of the products or companies mentioned herein. Dr. Schallhorn may be reached at (619) 532-6702; scschallhorn@nmcsd.med.navy.mil.*

1. Brint SF. Higher order aberrations after LASIK for myopia with alcon and wavelight lasers: a prospective randomized trial. *J Refract Surg.* 2005;21:6:S799-803.
2. Caster AI, Hoff JL, Ruiz R.Conventional vs wavefront-guided LASIK using the LADARVision4000 excimer laser. *J Refract Surg.* 2005;21:6:S786-791.
3. He R, Qu M, Yu S. Comparison of NIDEK CATz wavefront-guided LASIK to traditional LASIK with the NIDEK CXII excimer laser in myopia. *J Refract Surg.* 2005;21(5 Suppl):S646-649.
4. Kim TI, Yang SJ, Tchah H. Bilateral comparison of wavefront-guided versus conventional laser in situ keratomileusis with Bausch and Lomb Zyoptix. *J Refract Surg.* 2004;20:5:432-438.
5. Alio JL, Montes-Mico R. Wavefront-guided versus standard LASIK enhancement for residual refractive errors. *Ophthalmology.* 2006;113:2:191-197.
6. Durrie DS, Stahl JE, Schwendeman F. Alcon LADARWave customcornea retreatments. *J Refract Surg.* 2005;21:6:S804-807.
7. Schwartz GS, Park DH, Lane SS.CustomCornea wavefront retreatment after conventional laser in situ keratomileusis. *J Cataract Refract Surg.* 2005;31:8:1502-1505.
8. Castanera J, Serra A, Rios C. Wavefront-guided ablation with Bausch and Lomb Zyoptix for retreatments after laser in situ keratomileusis for myopia. *J Refract Surg.* 2004;20:5:439-443.

Prolate Corneas Not Necessarily the Best

Study data dispel the conventional wisdom that a prolate shape is necessary for superb visual outcomes.

BY DAVID R. HARDTEN, MD

A retrospective analysis of the VISX CustomVue (AMO, Inc., Santa Ana, CA) FDA clinical trial data demonstrates that wavefront-guided ablations produce excellent outcomes regardless of whether the postoperative corneal shape is more prolate or more oblate. This finding runs contrary to conventional wisdom and seems to indicate that topography is not the determining factor in postoperative quality of vision.

PROLATE VERSUS OBLATE

Whether the cornea is prolate or oblate is determined by its Q-value, a measure of how the cornea's shape deviates from a perfect sphere. Prolate corneas, which have been compared to eagles' corneas, are bullet-shaped and have a steeper central cornea as well as a Q-value of greater than 0.0 based on corneal topography. Oblate corneas are shaped more like a hamburger bun—flat in the middle with increasing steepness on the periphery. Oblate corneas have a Q-value of less than 0.0 based on corneal topography.

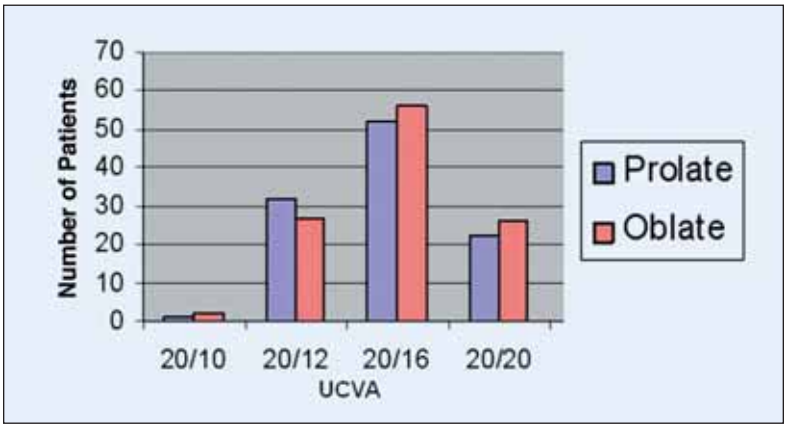

Figure 1. Postoperative UCVA shows no difference in results for prolate versus oblate corneas.

> "Wavefront-optimized surgery attempts to preserve the original prolate geometry of the cornea. This and other topography-based approaches do not incorporate aberration data from the entire optical system, but instead aim to produce a particular topographical shape."

As laser vision correction technology has evolved, refractive surgeons have altered their opinion of the desired corneal shape. Conventional laser vision correction procedures use the Munnerlyn formula to determine the ablation pattern. This nomogram usually results in a more oblate cornea with induced positive spherical aberration. Despite the limitation of conventional surgery, millions of successful procedures have been performed with this standard laser vision correction shape.

Wavefront-optimized refractive surgery attempts to preserve the original prolate geometry of the cornea. This and other topography-based surgical approaches do not incorporate aberration data from the entire optical system, but instead aim to produce a particular topographical shape. Proponents of wavefront-optimized corrections argue that the prolate shape is impor-

tant to reduce spherical aberration and provide a better quality of vision.

Wavefront-driven customized laser vision correction, on the other hand, attempts to measure and correct all the optical aberrations in the eye. The ablation shape is different for every eye, depending on the aberrations in that eye, and may result in a prolate- or oblate-shaped cornea.

Results from the VISX US FDA clinical trial for CustomVue[1] confirmed that wavefront-driven ablations produce better outcomes than conventional treatments. We know that wavefront-driven correction often results in improved visual quality, with benefits for night vision and contrast sensitivity, even in patients with large pupils.

But, are the best outcomes necessarily prolate?

> "The Q-value of the corneal topography does not appear to be the major determining factor in patients' postoperative quality of vision. Wavefront-driven ablations, which use the entire optical system to determine the optimal correction for each individual, provide excellent results regardless of a prolate or oblate outcome."

ANALYZING THE DATA

To answer that question, my colleagues and I retrospectively analyzed the CustomVue clinical trial data. Interestingly, this analysis, of 293 patients 6 months after they underwent wavefront-driven LASIK, shows no correlation between corneal shape (Q-value) and refractive results.

We found similar numbers of prolate and oblate eyes at all outcome points, and there was no relationship between corneal shape and postoperative UCVA (Figures 1 and 2) or BCVA. Contrast sensitivity results, under both photopic and mesopic conditions, were also similar for the oblate and prolate groups.

If the concept of the superiority of prolateness is correct, one would expect an analysis of patients in the clinical trial to show that those with prolate corneas had significantly better outcomes than those with oblate corneas. Instead, we saw an equal distribution of oblate and prolate corneal shapes across all outcomes. Based on the VISX data, a prolate cornea is not inherently beneficial.

Additionally, my colleagues and I examined individual cases of patients who had a postoperative UCVA of 20/12.5 or better. These patients had excellent acuity that approached the physiological limits of vision as well as excellent contrast sensitivity. However, it did not seem to matter whether their eyes were prolate or oblate, or even whether they had some remaining spherical aberration.

For example, one patient with a Q-value of -0.40D—well into the oblate side of the spectrum—had a UCVA of 20/12.5 at 6 months, with 0.20µm of spherical aberration. Although there was also a prolate cornea with 20/10 vision, we also had a patient with an oblate cornea (Q-value, -0.30D) who achieved 20/10 vision.

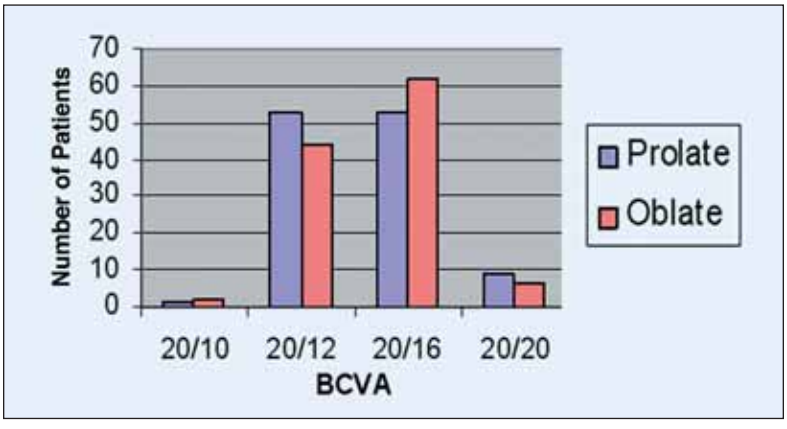

Figure 2. Postoperative corneal shape has no impact on BCVA.

CONCLUSION

From this information, the conclusion is that the Q-value of the corneal topography does not appear to be the major determining factor in patients' postoperative quality of vision. Wavefront-driven ablations, which use the entire optical system to determine the optimal correction for each individual, provide excellent results regardless of a prolate or oblate outcome.

Dr. Hardten is a founding partner of Minnesota Eye Consultants and Director of its Clinical Research Department. He is a paid consultant for AMO, Inc., but he acknowledged no financial interest in the company or its products. Dr. Hardten may be reached at (612) 813-3631; drhardten@mneye.com.

1. Jabbur NS, Kraff C; Visx Wavefront Study Group. Wavefront-guided laser in situ keratomileusis using the WaveScan system for correction of low to moderate myopia with astigmatism: 6-month results in 277 eyes. *J Cataract Refract Surg.* 2005;31:8:1493-1501.