EyeWorld
The News Magazine of the American Society of Cataract & Refractive Surgery
EYEWORLD SUPPLEMENT
JUNE 2006

Comparing wavefront-optimized to wavefront-guided LASIK

By Guy M. Kezirian, M.D., F.A.C.S.

While wavefront-guided LASIK may benefit some patients, new study results from the Food and Drug Administration (FDA) trial of the Allegretto Wave Excimer Laser System (WaveLight AG, Erlangen, Germany) suggest that in the majority of cases they offer no advantage over wavefront-optimized treatments. The trial was designed to directly compare the two approaches using the Allegretto laser. Results show that preoperative features can be used to identify the eyes that are most likely to benefit from wavefront-guided LASIK, and which eyes will do just as well with wavefront-optimized approach.

"Fifty-eight percent of eyes gained one line or more of vision compared with 62% of eyes in the wavefront-guided cohort."

Guy M. Kezirian, M.D., F.A.C.S., is president of Surgivision Consultants Inc., Paradise Valley, Ariz., and director of ongoing clinical trials for Allergretto Wave. He is a consultant for WaveLight AG.

Wavefront-Optimized LASIK is designed to treat the spherocylinder error without affecting the higher-order aberrations. Similar to conventional LASIK, Wavefront-Optimized LASIK is based on a phoropter refraction. Unique to Wavefront-Optimized LASIK is the ability to treat the refraction without inducing new aberrations.

Wavefront-Guided LASIK is based on aberrometry measurements and is designed to treat both refractive errors and higher-order aberrations.

The prospective study was designed to compare the two treatments and to determine which eyes, if any, benefited from Wavefront-Guided LASIK. The study was conducted by SurgiVision® Regulatory Consultants, Inc. of Scottsdale, Arizona at 5 centers in the United States. Patients were assigned to one of two cohorts based on alternating enrollment, treating both of the patient's eyes with either wavefront optimized or wavefront-guided LASIK. The randomization process successfully yielded comparable cohorts for all preoperative features including demographic, refractive errors and preoperative wavefront characteristics.

The study protocol hypothesized that the visual and refractive outcomes between the two treatment groups would be equivalent. This hypothesis was validated by the results. At the three-month post-operative mark 93% of eyes in both cohorts saw 20/20 or better without correction, and 76% of wavefront-optimized eyes attained 20/16 acuity compared to 64% of wavefront-guided eyes. (Figure 1 – PowerPoint slide 8).

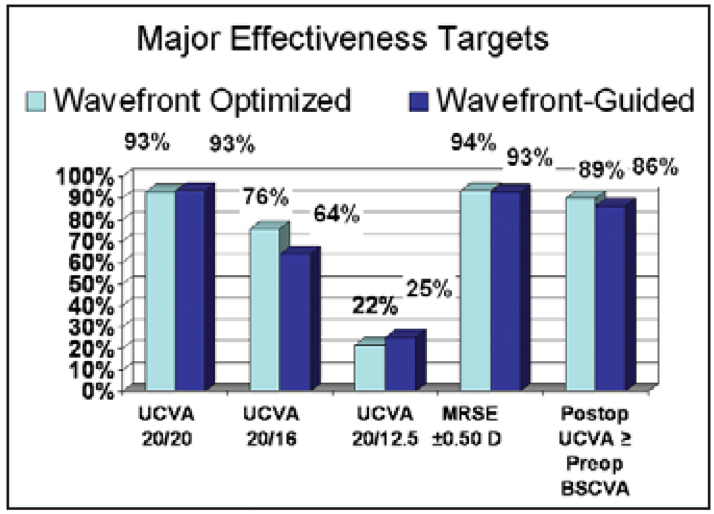


Figure 1: Comparison of major outcomes results for the two cohorts. The two groups performed similarly for Uncorrected Visual Acuity (UCVA), Manifest Refractive Spheroequivalent (MRSE) and Postoperative UCVA v. Preoperative Best Spectacle-Corrected Visual Acuity (BSCVA). Remarkably, over 85% of eyes in both groups saw as well after surgery without glasses as they did pre-operatively with glasses.

Comparison of postoperative UCVA v. preoperative best spectacle-corrected visual acuity (BSCVA) was statistically the same in both groups. We found that 89% of the eyes in the wavefront-optimized cohort had post-operative uncorrected acuity as good as or better than their preoperative BSCVA. This rate was 86% in the wavefront-guided group. Manifest refraction spherical equivalent (MRSE) results were also similar, with 93% of wavefront-guided patients within 0.5 D of target, and 94% of wavefront optimized patients reaching this level.

No eyes in this study lost 2 lines of BSCVA; in fact, most eyes gained BSCVA after surgery. In the wavefront-optimized group, 58% of eyes gained one line or more of vision compared with 62% of eyes in the wavefront-guided cohort.

These findings support the hypothesis that key safety and effectiveness outcomes between the two groups would be remarkably close. Both groups performed equally well.

Wavefront Results

The protocol included two hypotheses to test the wavefront outcomes. The first

Supported by an unrestricted educational grant from WaveLight AG

hypothesis was that eyes with higher amounts of preoperative aberrations would benefit more from the wavefront-guided treatments and would experience lower amounts of postoperative aberrations. The second was that eyes with higher amounts of postoperative aberrations would experience visual symptoms related to their wavefront errors, in the form of reduced low contrast acuity, decreased contrast sensitivity and subjective complaints of difficulties with mesopic visual function.

The answer to the first hypothesis was true; eyes with higher amounts of preoperative aberrations did benefit from the wavefront-guided treatments. This was interesting, but even more interesting was that wavefront-optimized eyes did not experience any increase in postoperative aberrations.

Results showed similar wavefront outcomes for both groups in eyes with less than 0.3 microns of preoperative

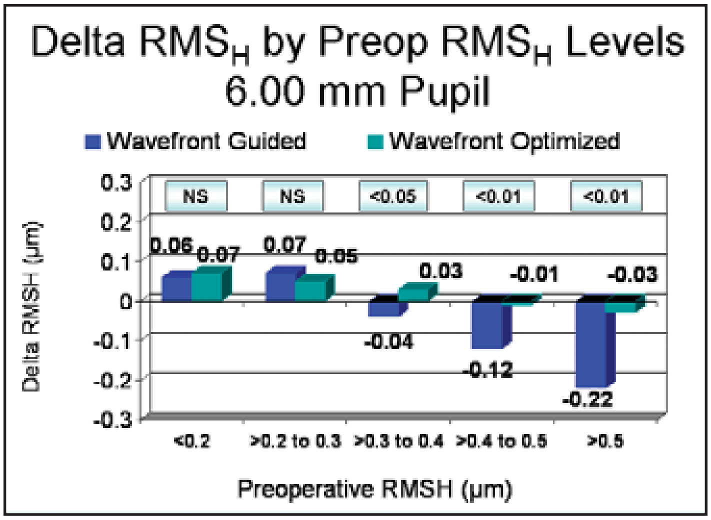


Figure 2: Change (Delta) in root-mean squared higher order aberrations (RMS_H) for the two cohorts, versus the preoperative RMS_H levels. The two cohorts had similar results in eyes with low amounts of preoperative aberrations, with very small changes of less than 0.1 microns. Eyes with higher amounts of preoperative RMS_H did better with Wavefront-Guided LASIK. Interestingly, eyes having Wavefront-Optimized LASIK also showed a slight decrease in aberrations if the preoperative aberrations were large.

RMS_H error. Eyes with 0.3 to 0.4 microns preoperative RMS_H did significantly better with Wavefront-Guided LASIK if refractive correction was under 4 D. Eyes with over 0.4 microns preoperative RMS_H did better with Wavefront-Guided LASIK through 7 D of treatment (Figure 3).

Interestingly, in cases with more than 0.4 microns of RMS errors, higher-order aberrations were also reduced in the wavefront-optimized group. This has not been previously reported. Wavefront-Optimized LASIK eyes did well despite the amount of treatment, as well. Evaluation of induced aberrations across the spheroequivalent treatment range shows minimal induction of higher-order aberrations with Wavefront-Optimized LASIK (Figure 3).

Approximately 83% of eyes in this study had 0.3 microns or less of preoperative RMS errors. Figure 4 shows the recommended treatments based on these results.

Did Patients Notice the Difference?

We also looked into how important reduced postoperative aberrations were to visual function. Eyes in both cohorts were evaluated based on postoperative aberration amounts, preoperative aberration amounts and change in aberrations. Very few clinical differences were found and both cohorts performed similarly. Differences were detected at the 20/12.5 level, where lower postoperative aberrations led to better acuity.

The interpretation is that mean aberration levels in both cohorts fell below the clinical threshold for symptoms. An important corollary is that most patients do not notice slight reductions in wavefront errors if their preoperative aberrations are low.

We did not find any correlation between higher-order aberrations and contrast sensitivity between the wavefront-optimized and wavefront-guided groups, nor was there was any mean worsening of low contrast-acuity in either treatment group. This may be due to the low amounts of pre-op and post-op higher-order aberrations in both groups. Had either cohort experienced significant increases in higher order aberrations, changes likely would have emerged.

Clinical Implications: Patient Selection

This study holds significant implications for patient selection for LASIK. Results show that the overwhelming majority of patients, about 80%, do not need wavefront-guided treatments with a laser that offers a wavefront-optimized alternative.

Wavefront-guided treatments have significantly contributed to our understanding of aberrations and their effects on vision. Wavefront-optimized treatments apply that understanding and incorporate wavefront principles into every treatment. Wavefront-guided treatments are not often needed if wavefront-optimized treatments are available.

> ***"Eighty percent do not need wavefront-guided treatments with a laser that offers a wavefront-optimized alternative."***

This supplement was produced by EYEWORLD under an educational grant from WaveLight AG.

The clinical rationale for wavefront-optimiziation

By Theo Seiler, M.D., Ph.D.

After undergoing LASIK patients' most frequent complaints usually focus on glare and halos at night. Symptoms such as these can be very debilitating and can ruin an otherwise optimal outcome. Such glare and halos are the result of increased post-spherical aberration. The fact is that there is a linear relationship between increasing asphericity and mounting spherical aberration. To ensure that we preserve the best quality of vision for our patients the solution seems obvious: We must keep the ideal corneal asphericity, or Q factor, in mind. We must try to maintain an optimum corneal profile. Practitioners must aim not only to correct refraction but to preserve the cornea's natural prolate shape, which is steeper in the middle and flatter in the periphery.

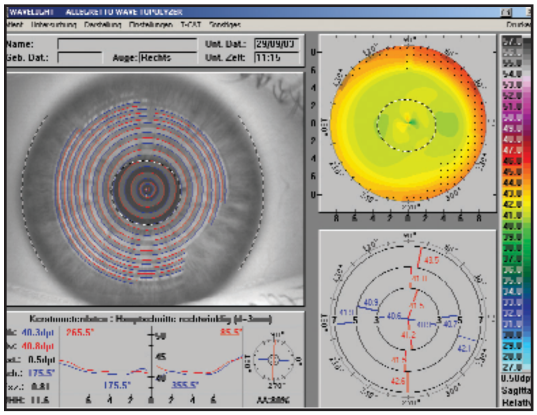


Figure 1: Large, true optical zone after a wavefront-optimized treatment.

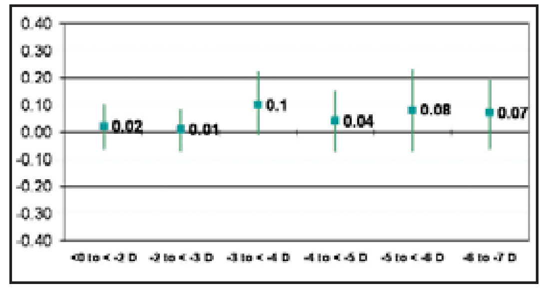


Figure 2: In ongoing clinical trials, the amount of induced spherical aberration following wavefront-optimized treatments was below 0.1μ in all eyes and directly related to pre-op spherical equivalent.

With conventional treatments a similar amount of laser energy is used in the center and on the sides. The problem is that as a result of the corneas' curvature, as the angle of the laser beam striking the eye changes, the amount of tissue removal changes. The laser energy in the periphery is spread over a larger area and is less effective at removing tissue.

These conventional treatments increase patients' spherical aberrations by factors up to 10 when compared to pre-op measures.

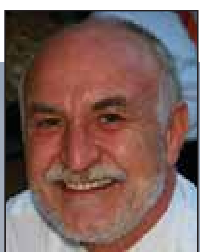
The wavefront-optimized aspheric ablation profile was developed to reduce the significant side effects of glare and halos that result from such spherical aberrations. . The Allegretto Wave system (WaveLight AG, Erlangen, Germany) takes two factors into account. First, the angle of the beam relative to the corneal surface and compensates for this, making superior vision results possible. With the system the number of spots applied to the periphery is increased based upon a proprietary algorithm. Second, the amount of spherical aberration that would have been induced by a treatment with conventional ablation profiles. As a result of this mid-peripheral overcorrection, the WaveLight system is able to obtain a spherical or slight prolate cornea inside the optical zone. Patients with this more prolate cornea resulting from this wavefront-optimized ablation profile have far fewer problems with glare, halos, and low-light vision.

Optical zones are another important factor in helping patients to attain the highest quality vision with LASIK. Functional optical zones created by conventional treatments (typical 3 -4 mm) tend to be significant smaller than those created with the wavefront-optimized approach (typical 6 - 7 mm). These larger optical zones are safer and result in fewer night-vision complaints. Because the treatment takes into account the cornea's aspheric shape, transition zones are optimized with the wavefront-optimized approach.

The problem is that optical zones created using traditional ablation profiles show a refractive gradient towards the edges, which results in optical distortions. In contrast, this refractive gradient is practically zero after wavefront-optimized ablations (Fig. 1). This is one of the most important outcomes, indicating a nearly physiologic optics of the cornea inside the treated zone.

As a result, patients treated with the wavefront-optimized approach report an excellent quality of vision and minimal halos. The latest proof of the optical superiority of wavefront-optimized ablation was presented by Kezirian, et al, who could show that the increase in spherical aberration due to myopic correction was minimal (Fig. 2). The amount of spherical aberration induced with the optimized approach for those treated for low myopia was as low as 0.01 D. Even for those with moderate corrections the amount of myopia induced remained minimal, with no more than 0.08 D induced.

Overall, we find that by maintaining a more prolate cornea with the wavefront optimized approach we can reduce the amount of spherical aberration induced compared to other lasers. As a result, with the wavefront-optimized approach we are able to maximize patient's night vision and help them to avoid problems with glare and halos.



"Patients with this more prolate cornea … have far fewer problems with glare, halos, and low-light vision."

Theo Seiler, M.D., Ph.D., is medical director at the Institute for Surgical Ophthalmology (IROC) in Zurich, Switzerland. Prof. Seiler is a consultant for WaveLight AG.

Revamping expectations for hyperopic patients

By Daniel S. Durrie, M.D.

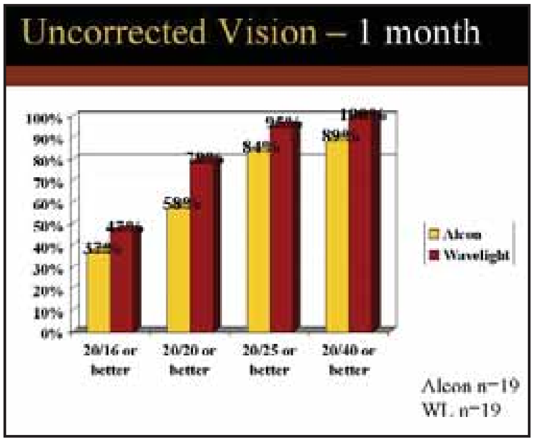


Figure 1: Comparing one months results for uncorrected vision in hyperopic treatments using the Alcon Ladarwave and the WaveLight ALLEGRETTO system.

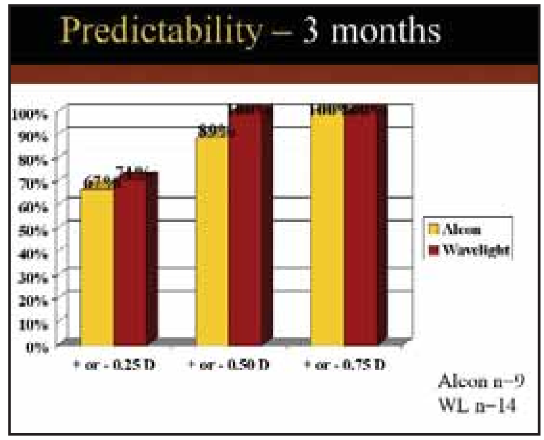


Figure 2: At three months the predictability with both platforms was excellent, however 100% of ALLEGRETTO WAVE patients were within 0.5D.

Over the years most practitioners have become a little complacent about hyperopic LASIK results. Many of us have come to accept that our hyperopic results just aren't as good as our myopic ones. Yet there is no good reason why this needs to continue to be the case. When you considered our good outcomes for myopia it seemed that most of these were the result of time spent on optimizing our algorithms. As a result, the same should be possible for hyperopic treatments.

I see no reason why our hyperopic lasers will not continue to improve. We recently set out to get baseline results on two promising hyperopic lasers that we used at our center-the Allegretto Wave (WaveLight AG, Erlangen, Germany) and the Ladar 4000 (Alcon, Fort Worth, Texas). We launched a randomized, prospective study to compare hyperopic outcomes with the two lasers.

The study included 50 patients. Of the 50, 25 underwent hyperopic conventional LASIK with the Alcon Ladar 4,000, and the remaining 25 underwent hyperopic wavefront-optimized LASIK with the WaveLight Allegretto. All flaps were made with the IntraLase laser (IntraLase Corp., Irvine, Calif.), which I have found in myopic cases to offer more predictable results.

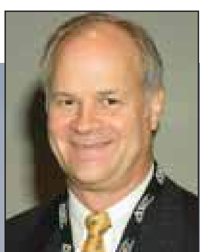
While the results of this ongoing study may change, we took a look at our early visual acuity results, which have exceeded our expectations. The visual outcomes, to date, show that the WaveLight laser looks as if it is an extremely good laser for hyperopia. Results for the Alcon, which has long been reputed as an excellent hyperopic laser, were also strong.

In particular, the early visual acuity results have been exceptional and have remained at a very high level out to the current three-month mark. From day one, post-op, 18% of patients that underwent the optimized procedure had 20/16 uncorrected acuity or better and 64% boasted 20/20 uncorrected acuity or better. In the Ladar 4,000 group none of the eyes attained 20/16 acuity and 24% were at the 20/20 level.

Likewise, at one week 29% of eyes that underwent wavefront-optimized LASIK had 20/16 uncorrected acuity or better versus 10% of Ladar 4000 patients. At one week 81% of optimized patients saw 20/20 uncorrected or better compared to 38% of the Ladar patients. All patients in the Allegretto optimized group attained 20/40 uncorrected acuity or better, as did 81% of those in the other group.

At the one-month mark, nearly half of patients, 47%, of those that had the wavefront-optimized procedure had 20/16 uncorrected acuity or better, as did 37% of those with the Ladar 4000 (Figure 1). Also, 95% of optimized patients had 20/25 acuity or better, as did 84% in the Ladar group. Remarkably, by three months post-op 87% of wavefront-optimized patients had 20/20 acuity. These results are particularly impressive because this is the first time we have been able to break the 70% mark, let alone the 80% barrier, for 20/20 hyperopic LASIK results. These outcomes are, in fact, comparable to what we have become used to finding for low myopia with conventional LASIK. At three months even wavefront-guided myopic results tend to run close to this level. Results with the Ladar 4000 laser at three months were also strong at 67%.

Predictability at three months for the two lasers also appears good. With optimized LASIK 100% of patients were within .5 D, as were 89% of patients in the Ladar 4,000 group (Figure 2). We will not fully be able to determine the impact of these results until we have a chance to consider the full data set, including wavefont, contrast sensitivity, and topography results. We will be presenting the complete results on this during the upcoming ASCRS•ASOA Symposium & Congress.



"These early wavefront-optimized outcomes show there is no reason we cannot strive for results that may one day equal those of myopic LASIK."

Daniel S. Durrie, M.D. is director of the Department of Ophthalmology, Division Refractive Surgery, University of Kansas Medical Center, Overland Park, Kan. He has no financial interest in WaveLight AG

Optical Zone Comparisons

By Charles R. Moore, M.D., F.I.C.S.

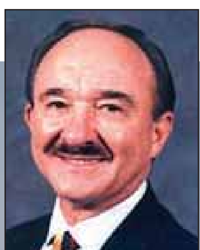
Refractive surgery these days is about creating enthusiastic patients with exceptional quality of vision. The fact is the quality of the patient's post-operative vision particularly at night, with the specter of glare and halos, is related in part to the true optical zone size. This is something which has been a key part of the Allegretto Wave system (WaveLight Laser Technologie AG, Erlangen, Germany) from the start, but which many other companies have been modifying in an attempt to keep up, for some time.

Precision Counts

In the past, we assumed that the optical zones predicted by lasers matched the zones ablated. However, too often the ablated optical zone was considerably smaller than the intended optical zone size. Unfortunately, this is true even with the newest laser technologies, such as the Visx Star S4. With this laser, the blend zone encroaches on the true optical zone.

When Visx first obtained approval of their wavefront-guided CustomVue platform, this did not include the measurement or treatment of higher-order aberrations. The Visx CustomVue platform was also only originally approved to treat up to 6 D of myopia and 3 D of cylinder, which has recently been expanded. The Allegretto Wave's wavefront-optimized approach was initially approved to treat myopia up to -12D and 6D of astigmatism as well for hyperopia up to +6D and 5D of astimatism.

It wasn't until Visx developed the Star S4 WaveScan, that they changed the algorithm to increase the optical zone size to more favorably compare to those created by the standard wavefront-optimized Allegretto Wave platform.



> "Large, true optical zones can result in better quality-of-vision at night when the pupil enlarges and help to prevent troubling night vision symptoms."

Charles R. Moore, M.D. Medical Director of International EyeCare Laser Center in Houston.
He is a consultant to WaveLight AG.

Topographical Evidence

The trouble is that when the effective optical zone is too small it can result in poor outcomes for patients. Consider the following cases, involving patients who had undergone standard Visx Star S3 standard treatment (Figure 3) and Star 4 CustomVue/wavefront-guided (Figure 2). In these treatments, the ablated optical zone sizes were significantly smaller than the predicted ones - all resulting in poor outcomes. To correct the problems that resulted, wavefront-optimized (Figure 4) enhancements were performed.

With the Allegretto Wave's wavefront-optimized (standard) program as seen in Figure 2, the resultant optical zone sizes meet the predicted ones.

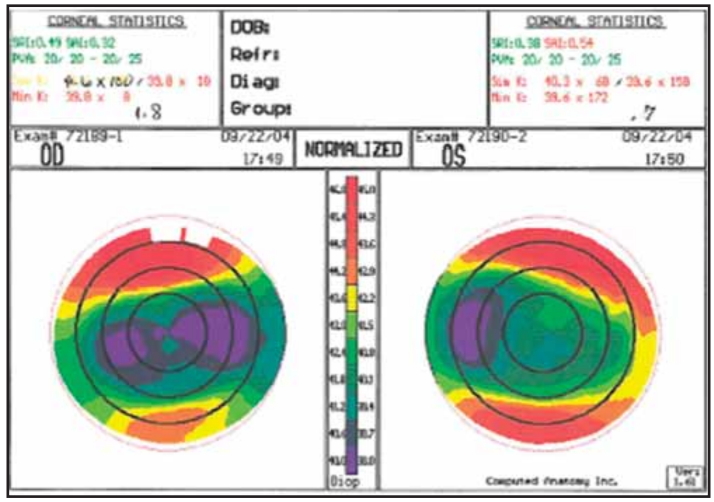


Figure 1: Corneal topography after Visx Star S3 Standard Treatment with an 8mm blended OZ.

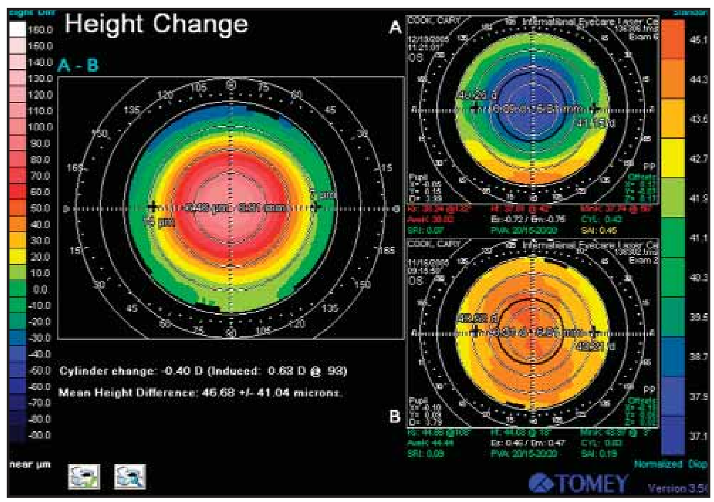


Figure 2: Large, true optical zone after a wavefront optimized treatment.

Wavefront-Optimization and Optical Zones

The Allegretto Wave system's large true physiological optical zone, results from its optimized approach. Using built-in wavefront principles anda proprietary algorithm to minimize induction of C 12 and mantain the balnce of the natural wavefront. The Allegretto Wave delivers a larger number of pulses to the peripheral cornea, compensating for the more tangential energy delivered in this area. This 30% to 40% increase in peripheral corneal ablation helps to preserve the pre-operative aspheristy, which results in less postoperative shrinkage of the optical zone.

By maintaining the natural corneal shape during LASIK, transition zones are minimized and a wide, uniform central optical zone is created. This leaves room for the pupil to expand in mesopic conditions, without the patient having to visually deal with zones of competing powers. This can result in

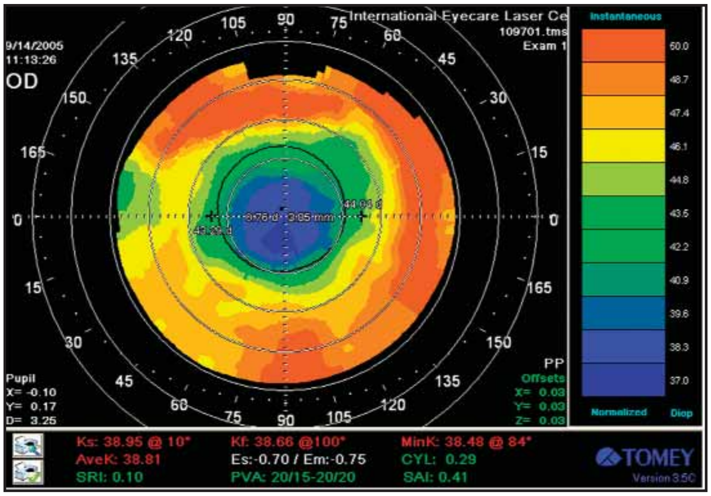


Figure 3: Patient who underwent a Visx Star S4 CustomVue wavefront-guided treatment. Note that the resulting optical zone size was significantly smaller than the indended optical zone size (6.00x5.00mm)

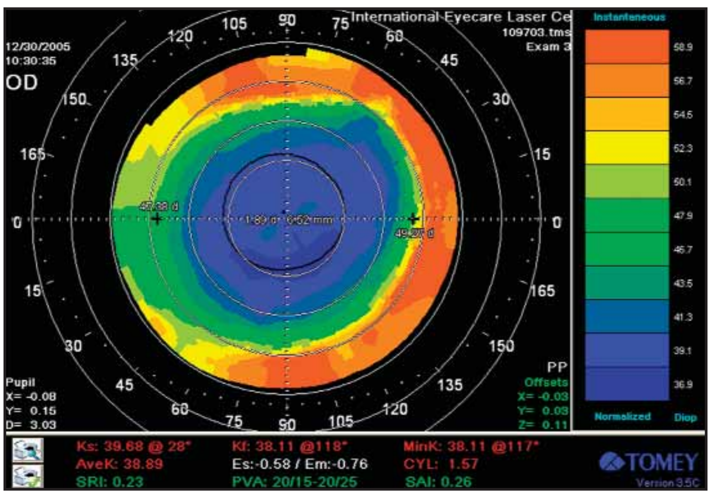


Figure 4: Post op topography after a wavefront-optimized enhancement. The retreatment created an optical zone of 6.62mm as compared to 3.82mm with her original wavefront guided Visx S4 CustomVue treatment.

better quality-of-vision at night when the pupil enlarges and help to prevent troubling night vision symptoms.

It is also possible, if you have a case with a thin cornea in which you are concerned about tissue preservation, of course to electively create a smaller true optical zone.

However, it is the increased optical zone sizes, available with the Allegretto Wave, for the treatment of hyperopia and hyperopic astigmatism in postoperative radial keratotomy cases that make it possible for surgeons to safely treat complicated cases.

A Case of Multiple Refractive Procedures

It is even now possible to expand the optical zone in patients who have been previously treated with a conventional laser - even in patients who have been treated many times before.

We recently had a case involving a patient who had initially undergone RK to correct myopia back in 1993. After RK enhancements her vision ultimately was 20/50 in the right eye and 20/25 in the left eye.

A decade after her initial surgery, in 2003, the patient, who's UCVA had slipped to 20/60 with monocular diplopia underwent a wavefront-guided procedure with the Visx Star CustomVue. Following her wavefront-guided custom treatment with the Visx Star S4, her UCVA was at the 20/25 level, but the patient was unhappy with her quality-of-vision. The reason appeared to be a too small optical zone, which measured just 3.85 mm instead of the intended 6.0 x 5.0 mms (Figure 2). The patient's UCVA in her right eye had regressed to 20/100 and she had a best spectacle-corrected visual acuity (BSCVA) of 20/40-2.

However, just one month after undergoing an optimized retreatment with the Allegretto Wave in 2005, her UCVA was 20/25.

By the three-month postoperative mark, the patient was telling us how pleased she was by her improved quality-of-vision. Her binocular UCVA was now at 20/16 and her uncorrected monocular acuity in her right eye was at 20/25-1. Meanwhile, her predicted optical zone size of 6.5 mm was actually exceeded by her postoperative measured optical zone size at 6.62 mm. (Figure 4). By increasing her optical zone diameter and smoothing her ocular surface, we were able to vastly improve her quality-of-vision. This is typical of what we have been able to accomplish with the Allegretto Wave.

Conclusion

Overall, in my experience with the Allegretto Wave, I have found that treatment with this laser has resulted in better quality-of-vision post-LASIK for many patients than what they attained preoperatively with spectacles or contact lenses. No matter what the pupil size, my patients do not report glare or halos postoperatively. With the help of the Allegretto Wave, which I have found to be the best in terms of achieving an enhanced, uniform optical zone, I have had first-rate outcomes and very satisfied patients.

Revamping expectations for hyperopic patients (Continued)

Our next step in this project will be to include 25 patients who have undergone wavefront-guided LASIK in the series. It appears as if we are already making headway. It seems as if we no longer have to limit ourselves to the old way of thinking about hyperopia outcomes. Patients in both arms of the study have had excellent results. We hope that in our upcoming presentation as we consider the rest of the study data set that it helps us to reach the next step in development for hyperopia. These early wavefront-optimized outcomes show there is no reason we cannot strive for results that may one day equal those of myopic LASIK.