Never before has ophthalmology had so many outstanding options for correcting refractive error. From wavefront-guided laser vision correction to multifocal IOLs, we are witnessing a dramatic improvement in visual performance and patient satisfaction.

Richard L. Lindstrom, M.D.
A retrospective study conducted by six international centers has found that wavefront-guided corrections are further enhanced by the incorporation of Iris Registration technology. To analyze the impact of iris registration, a population of 270 eyes was reviewed and compared. Patients included in the study had to have virgin eyes with pre-operative BCVA of 20/20 or better. Of the total cohort, 116 presented with a significant level of astigmatism, 1.5 D or more. This sub-group was further divided into Cohort A and Cohort B. Cohort A consisted of 57 eyes that were treated with wavefront-guided laser vision correction with iris registration; Cohort B consisted of 59 eyes that were treated with wavefront-guided without iris registration.

Post-operatively, 92% of Cohort A achieved 20/20 UCVA versus 82% of Cohort B. This 10% improvement in visual acuity is statistically significant. Additionally, Cohort A reported a 50% greater reduction in post-operative astigmatism compared to Cohort B. This difference is also statistically significant.

Overall, these initial results are very promising for this technology. Improvements like these have the potential to provide better and more predictable results as well as a reduction in retreatments.

We found that the outcomes have been better and taken less time when we used manual marking techniques.}

Optimizing outcomes

Our preliminary results with the technology have exceeded our expectations. While I was expecting good results in our low myopes with mild astigmatism, it has been particularly gratifying to see the results of our cases involving enhancements, as well as those with primary asymmetrical corneas. We found that the outcomes have been better and taken less time than when we used manual marking techniques.

Over the years as we have moved from conventional treatment to wavefront technology, and now to wavefront with iris registration, we have seen a steady improvement in outcomes for all of our patients, including our challenging astigmatic ones. For us, each step has been additive. With each succeeding improvement in technology we have seen a larger percentage of patients with 20/20 acuity or better.

The answer is “yes.” We have found that iris registration technology has brought an increased quality to our outcomes that have made it well worth bringing in to the practice.

For those of you who are just starting out with this new technology, I recommend using iris registration on every possible candidate — don’t just save this for the complicated high cylinder cases. You will be rewarded with excellent, predictable outcomes in even the most challenging cases.

Iris registration is not something to be overlooked when trying to maximize outcomes. This is an important factor because as patients go from a vertical to a supine position there is a documented rotational shift of the eye. While this can be compensated to a good degree by marking the eye in the traditional fashion, there can be inaccuracies with this method.

We have found that iris registration is a much more reliable technique that helps to ensure that we are treating refractive disorder, especially astigmatism, on-axis.

By J. Trevor Woodhams, M.D.
Real-World Experience with Iris Registration

Early clinical experience demonstrates importance of pupil centroid adjustment, in addition to cyclotorsion compensation

by Douglas D. Koch, M.D.

By matching iris features common to the WaveScan and laser iris images, the Iris Registration system for the VISX Star laser (AMO) calculates any cyclorotation that has occurred, and adjusts the treatment accordingly.

In a recent study of 64 eyes of 40 patients treated with CustomVue Fourier-driven ablations with IR enabled, the mean cyclotorsion was 2.1 degrees. This is similar to what has been reported in several other studies, and was not particularly surprising to me even given careful pre-operative marking. I was shocked, however, to see some eyes with cyclotorsion of as much as 6.6 degrees. In fact, about 14% of the eyes rotated inward or outward by 4.0 degrees or more.

Pupil centroid shift

An equally important but less well-understood aspect of iris registration is the ability to compensate for pupil centroid shift. We capture WaveScan images in a darkened room to obtain as large a pupil as possible. In some patients, the WaveScan pupil is 7 mm or even larger.

Under the laser, however, the pupil size often changes. With larger pupils, for example, any illumination from the ring light or oblique lights will bring the pupil well below the WaveScan size. Even by adjusting illumination in the laser suite, it is impossible to always match the size of the WaveScan pupil. Prior to IR, the laser tracker would lock on to the pupil and center the treatment around it.

But if the pupil is larger or smaller than the originally measured pupil, its center may also have shifted after the wavefront measurements were taken. If the shift is more than 0.1 to 0.2 millimeters, the efficacy of the higher-order correction drops dramatically because the efficacy of the higher-order correction drops dramatically because the higher-order correction is similar to what has been reported in several other studies, and was not particularly surprising to me even given careful pre-operative marking. I was shocked, however, to see some eyes with cyclotorsion of as much as 6.6 degrees. In fact, about 14% of the eyes rotated inward or outward by 4.0 degrees or more.

In our study, the mean pupil center shift was 0.29 ± 0.14 mm (range 0.07 to 0.50). In some eyes, the shift was as much as 0.4-0.5 mm. (Figure 1) One would expect this to significantly affect the accuracy of the higher order correction, particularly if the patient happened to have a relatively high degree of wavefront error.

Refractive outcomes

We also compared a subset of 20 IR-treated eyes for which we had one-month outcomes to 78 eyes treated with Fourier-driven CustomVue in the nine months prior to obtaining IR. All eyes in both groups had surface ablation (PRK) treatments.

We were already achieving 20/40 uncorrected visual acuity in nearly all eyes before IR, so the small improvement in 20/40 rates is not that impressive. The important difference, however, was in the number of patients achieving 20/20 UCVA at one month: 90% of the IR group, compared to 60.3% of the non-IR group. (Figure 2)

The data suggest that we may be achieving more predictable results with IR, with a tighter standard deviation. (Figure 3). It makes sense that if IR allows one to apply the treatment exactly where it is supposed to be, especially with the greater precision and fidelity of Fourier-driven ablations, then results will be more accurate and more predictable.

My expectation was that IR would confirm the accuracy of corneal marking and eliminate the need for it, but that there would be little, if any, improvement in visual results. Instead, I have been surprised at the degree of compensation required, both for cyclotorsion and pupil shift. Based on my initial experience, I now believe IR has great potential for improving visual results.
Recent Approvals Provide More Options for this unique population of patients

By Richard L. Lindstrom, M.D.

When a high myope considers refractive surgery he rarely asks, “Should I have LASIK or a phakic IOL?” For the patient, the decision is whether to have surgery at all.

The surgeon, of course, has to consider many factors in deciding whether to recommend laser or intraocular surgery, including corneal thickness, keratometry, age, risks, etc. Until quite recently, many of us felt that the quality of vision with laser refractive surgery began to drop somewhere around -8 D. Customized laser vision correction is changing that calculation, and it’s shifting my comfort threshold higher.

Now that CustomVue treatments on the VISX Star laser (AMO, Irvine, Calif.) have been approved for high myopia, I know that I will start to choose LASIK over a phakic IOL much more frequently for higher degrees of myopia. There are several reasons including patient preference for the less expensive and invasive procedure, my own conviction that an intraocular procedure carries more long-term risks, and the excellent outcomes in high myopes.

The clinical trial demonstrated that we finally can achieve visual quality similar to that of phakic IOLs with custom laser refractive surgery up to -11 D.

For all these reasons, my recommendation — assuming that patients have enough tissue for LASIK or PRK, and that corneal surgery is not otherwise contraindicated — is that phakic IOLs be considered primarily for those patients who are outside the range of custom laser vision correction, or who are otherwise not good candidates for corneal surgery. For candidates within the range of custom, I will be increasingly likely to opt for CustomVue over a phakic IOL.

Psychology of a high myope

Patients who present in our offices for refractive surgery consultations tend to be more educated, more active, and more affluent than the population at large. Regardless of pre-operative refractive error, these individuals recognize that they are “handicapped” by their vision, and want to correct it so that they can...
"We do know that high myopes have sought out refractive surgery in numbers disproportionate to their representation in the population."

better perform their everyday work or leisure-related tasks.

High myopes are a unique subset of this already self-selecting group of patients. As people who are totally dependent on their glasses or contacts, their perception of a handicap and, therefore, motivation for surgery is higher. Of course, this slice of the population is a relatively small one.

Patients with myopic error of greater than 6 D make up only 14% of the U.S. myopic population, and those with greater than 10 D of myopia are only 2% of the pie.

The bulk of the patients, and the opportunity for refractive surgeons, will always reside with lower myopes. Patients with myopic error of -2 to plano, and these patients tend to be among our most appreciative whether they have PRK, LASIK, or a phakic intraocular lens implant. After adjusting to their new vision, however, high myopes are just as likely or even slightly more likely to seek an enhancement to achieve the best vision possible. If they have the ability to be 20/20 or 20/15 and spectacle-independent, but aren’t quite there, most will want an enhancement.

On the other hand, it is true that the greater the disability the more the patient is willing to accept a mild compromise, particularly in terms of dryness or night vision symptoms. Higher myopes tend to be more forgiving of these side effects than their lower myope counterparts — possibly because they are also more likely to have experienced these problems preoperatively.

Dr. Lindstrom is adjunct professor emeritus in the Department of Ophthalmology at the University of Minnesota, and is in private practice at Minnesota Eye Consultants in Minneapolis. He is a consultant for AMO and eyeonics.

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**Rx Surgery: Penetration by Rx Error**

Figure 2: 12%-40% of myopes in the higher ranges have had surgery, compared to 5%-10% of moderate myopes, and less than 5% of low myopes.

**Patient Selection for Verisyse**

Patients who are not LASIK candidates, due to their myopia or thin corneas, may benefit from the Verisyse procedure

By Jonathan Christenbury, M.D., F.A.C.S.

The Verisyse phakic IOL provides excellent corrected vision for patients who are not candidates wavefront-guided LASIK. For these patients, I prefer to perform a phakic IOL procedure rather than a standard non-custom LASIK. In my experience, the vision quality is superior with Verisyse.

I prefer Verisyse over PRK for high myopia. In my experience, the vision result and comfort level are better with the phakic IOL. Most of my patients are 20/40 or better on the first post-op day with the Verisyse procedure. In addition, there is no risk of haze, which is not predictable and can be problematic with PRK. I try to avoid PRK or epi-LASIK in high myopia corrections.

**Ideal candidates**

Patients who are very near sighted or have corneas that are too thin for LASIK benefit from the Verisyse procedure. Patients should have best corrected vision of 20/40 or better. They also need to have realistic expectations. It is important that the patients realize that the Verisyse won’t correct astigmatism. Also, the patients must be willing to have touch-up PRK or LASIK at three to six months for any residual astigmatism or over- or under-correction.

**Reversibility**

One of the key advantages of the Verisyse is that the procedure is reversible. This gives patients more confidence because some may have hesitated to have permanent vision correction due to concerns about an irreversible result. However, with Verisyse patients are reassured because phakic IOLs can be removed if the patient is not satisfied with the results.

**Technique & results**

Generally, I perform the YAG peripheral iridectomies in both eyes and perform the first Verisyse implant (with topical anesthesia and some sedation) on the same day. Then, two weeks later, I perform the second eye Verisyse procedure. Marking the pupil location at the 3, 6, and 9:00 limbus is important for IOL positioning. Maintaining normal anterior chamber depth helps position the enclavation of the haptic at the proper radial location of the iris. No distorted pupils have occurred in our series. A small amount of astigmatism was induced from the scleral incision suturing in my first few cases. However, now that I am using topical anesthesia and I perform a clear cornea incision with absorbable sutures, I do not have problems with induced astigmatism.

Early on I also had some difficulty maintaining the anterior chamber. When I switched to Healon GV, this problem was eliminated. Careful viscoelastic removal has avoided any one-day post-operative IOP problems.

Looking at our one-month data for the Verisyse in more than 50 eyes, the majority of patients are 20/40 or better within the next day or in the first week (unless they have preexisting astigmatism). Several patients are 20/15 and one patient is 20/10 with a –9 D correction.

One week post-op, patients often report that their uncorrected vision in the Verisyse eye is as good or better than their vision in the other eye with the contact lens. We have had no surgical complications. Quality of vision is excellent. Patients report good vision in dim illumination with the Verisyse procedure. Night vision complaints are minimal, even if the scotopic pupil is larger than the Verisyse optic.

We have used Verisyse from -6.00 to -20.00 D. The Verisyse procedure is our procedure of choice for myopic patients who are not LASIK candidates.

Jonathan Christenbury, M.D., F.A.C.S., is medical director at the Christenbury Eye Center, Charlotte, N.C.
Combining Technologies to Maximize Post-Refractive Lens Implantation Results

For many patients, mixing and matching ReZoom, ReSTOR, and Crystalens may best meet their visual needs

By Richard L. Lindstrom, M.D.

ow that we have three good refractive IOLs available, it behooves cataract surgeons to learn about the different options in order to offer at least one of them to their patients. Even better is to be prepared to offer a combination of technologies for that slice of the population that can benefit from a staged approach.

The refractive IOL options

The ReZoom multifocal IOL is a zonal aspheric refractive lens. Incoming light is directed across the entire focal plane to provide vision at all distances. In my experience, this lens provides excellent distance vision, functional intermediate vision, and very good reading vision.

The effective add is +2.6 D, which is similar to what most of us would prescribe for reading glasses after lens implantation. It has better distance vision than the ReSTOR (Alcon), and better near vision than the Crystalens (Eyeonics). Patients may experience some night vision symptoms, but these are significantly less than we encountered with AMO’s first multifocal IOL, the Array.

The ReSTOR multifocal IOL is a combined refractive/diffractive optic. It provides good distance vision and stronger near vision than any of the other options, with an effective add of +3.2 D, which may actually be too strong for some patients. None of the incoming light is focused on the intermediate zone, so intermediate vision is relatively weak with this lens. That can make computer use or other intermediate tasks awkward. Like the ReZoom lens, there are some mild compromises in distance vision.

There is also an accommodating IOL, the Crystalens. This IOL offers excellent distance vision with no measurable loss of contrast sensitivity. Intermediate vision is also very good, but the near vision is weak compared to the two multifocal alternatives. I think of the Crystalens as providing a +1.25 D add.

The typical outcome is J3 or 20/40 at near, which means that many patients will need a supplemental reading add for fine print or prolonged reading.

Strategy for combining technologies

Most patients will be happy with their outcome with the refractive lens implanted in the first eye. If that is the case, it makes sense to

Multifocal LASIK Ablations Show Promise

Unique ablation profile offers excellent distance, intermediate, and near vision for hyperopic presbyopes in clinical trials

A U.S. investigational trial of VISX WaveScan-guided multifocal treatments (AMO, Santa Ana, Calif.) for hyperopic presbyopia is currently about halfway completed, and the early results are very promising.

So far, we have treated 12 patients, with three-month follow-up available on five. Ultimately, 20 patients will be enrolled.

We treat only the non-dominant eye of each patient with the multifocal ablation, while the other eye receives a CustomVue hyperopic treatment. Both eyes are targeted for emmetropia.

A larger, multi-site clinical trial will be undertaken prior to seeking approval for this treatment from the U.S. Food and Drug Administration.

Study results

Pre-operatively, the mean sphere of the multifocal treatment eye was 1.67 ± 0.47 D (+1.0 to +2.5 D), with mean cylinder of 0.19 ± 0.17 D (0.0 to 0.5 D).

Distance vision in the multifocal eye has been at least as good as, if not better than, traditional hyperopic CustomVue treatments. At three months, 100% of the multifocal treatment eyes had 20/20 or better uncorrected distance vision, compared to none pre-operatively. Eighty percent had 20/20 or better uncorrected intermediate vision, compared to none pre-operatively. And all patients had near uncorrected vision of at least 20/40 post-operatively, compared to only one pre-operatively.

There was no loss of best spectacle-corrected visual acuity at any distance at three months.

A patient questionnaire shows that 60% of patients are satisfied or very satisfied with their uncorrected distance vision pre-op, compared to only 40% that were satisfied with their corrected distance vision pre-op. Twice as many patients (80%) were satisfied with their uncorrected near vision post-op compared to their corrected near vision pre-op.

The data confirm my anecdotal impression that these patients are very happy with their outcomes. I believe that we’ll see even greater patient satisfaction in the full trial when we can treat both eyes and, perhaps, increase the strength of the near add as well.

Coleman R. Kraff, M.D. is in private practice at the Kraff Eye Institute, Chicago. He is clinical instructor, Northwestern University Medical School, Chicago.
Redefining Refractive Surgery

All three premium lenses have strengths and weaknesses. The trick is matching the strengths with the patients’ needs. This would strengthen the intermediate vision and give them really good distance vision without the night vision symptoms they disliked.

If I’ve implanted a multifocal lens in the first eye and the patient is having difficulty with the night vision symptoms or, in the case of ReSTOR, misses the intermediate vision, I might utilize an accommodating lens in the second eye. It is often taught, but without any real basis in fact, that patients implanted with these new technology lenses must have the same optical system in both eyes. However, over many years of doing multifocal/monofocal combinations with the Array lens, and now accommodating/multifocal combinations with these IOLs, my experience is that patients generally adapt very well to the combination approach, particularly if there is some dissatisfaction following the first procedure.

Dr. Lindstrom is adjunct professor emeritus in the Department of Ophthalmology at the University of Minnesota, and is in private practice at Minnesota Eye Consultants in Minneapolis. He is a consultant for AMO, eyionics, and Alcon.

By Kerry K. Assil, M.D.

Since the Food and Drug Administration approval earlier this year, I have implanted 150 ReZoom lenses for both refractive and cataract cases. I have found that patients implanted with this lens enjoy excellent vision at all distances. The typical uncompromised distance acuity is 20/20 or better, and the majority attain a near acuity of J3 or better. I even have a subset of patients that surpass all expectations with these new lenses. Those patients have attained 20/15 distance acuity and J1 at near vision in both eyes.

One of these exceptional patients started out as a 4 D hyperope, with slightly steep corneas, on whom I was hesitant to do LASIK. Instead, I decided to do refractive lens exchange, and was happy to find that the patient was rewarded with phenomenal vision.

On the first post-op day the patient had 20/15 distance acuity and J1 plus in the first eye. At first I thought that the results were a fluke, however, when I did the second eye I was pleasantly surprised to find that the patient had the same outstanding outcomes. Such excellent outcomes underscore that there are no inherent limitations on acuity attained with these lenses.

So far we have found that the patients who are able to achieve these exceptional results tend to be young and have very healthy retinas. They are also those that have an almost nonexistent residual refractive error. In these cases there are almost no volunteered symptoms of glare and halos.

I have actually found that glare and halos are a rare occurrence with the ReZoom compared to other multifocal IOL designs. In fact, glare and halo affect only about 2% of patients. Most of these cases involve patients who have a significant amount of residual astigmatism — typically in the range of 1 D or more. To date we have not had to explant any of these lenses.

Moving forward, I believe that within the next two years we’re going to see the category of multifocal and accommodative IOL become the most talked-about single category in ophthalmology. In part this will be due to the favorable economic climate resulting from the CMS (the Centers for Medicare and Medicaid Services) ruling that makes it feasible for many more patients to afford these new presbyopia-correcting lenses. It is also very much the result of the new science of multifocal lenses that allows us to provide patients with a full spectrum of excellent vision at near, intermediate, and distance with lenses such as the ReZoom that, at times, may even surpass our best expectations.

Kerry K. Assil, M.D., is medical director of the Assil-Sinskey Eye Institute, Santa Monica, CA.
Key Criteria for Success with Custom Ablation

All custom platforms are not created equal. Careful analysis of the technology will pay off with improved patient outcomes.

By Michael C. Knorz, M.D.

“...In my personal experience with several wavefront-guided LVC systems...iris registration is key to optimal results.”

Optimal outcomes with customized ablation are dependent on several key factors including use of a high quality wavefront image, iris registration, and compensation for pupil centroid shift.

Customized ablations using the VISX CustomVue procedure (AMO, Santa Ana, Calif.) are better than other customized ablations for several reasons. The VISX system provides improved resolution because it employs Fourier rather than Zernike reconstruction. In addition, the STAR S4 IR system has iris registration that provides a perfect match of measured and treated areas.

Criteria for wavefront-guided laser vision correction

For the WaveScan procedure, the Fourier-based wavefront is preferred over the Zernike-based wavefront because with the Zernike decomposition of the measurement 150 points are reduced to about 20 points. Thus, many details are lost. However, when Fourier transforms are used a far more detailed image can be obtained.

It is also imperative that the ablation matches with what has been measured. Because the eye rotates, treatment must compensate for the cyclotorsion, or the rotational movement of the eye around the Z-axis. Cyclotorsional movement studies show that cyclotorsion is in the range between 2 to 4 degrees, and in many cases it can go up to more than 10 degrees when the patient switches from an upright to supine position. Even small movements, like 2 or 5 degrees, will cause a significant reduction in image quality.

In my personal experience with several wavefront-guided LVC systems, including the Zyoptix (Bausch & Lomb, Rochester, NY) that I used since 1998, and the VISX CustomVue, iris registration is key to optimal results. First the iris image is captured and verified on the VISX laser system. Then the amount of torsional rotation is calculated, and the treatment axis is adjusted.

Compensation for pupil centroid shift is also an important component of custom ablation success. Without this compensation, the WaveScan measurement of the center of a dilated pupil often differs from the center of the laser ablation treatment.

Therefore, VISX iris registration means not only mean cyclotorsion and compensation but also perfect alignment of the WaveScan image under the laser. The same spot is measured and treated. To do this, there is compensation for both eye rotation and pupil offset.

Results for the CustomVue treatment are excellent, and superior to other custom ablations.

Looking at a consecutive series with my Bausch & Lomb patients, I was very happy with 60% of them seeing 20/20+ uncorrected at six weeks. However, when I switched to the VISX system and compared the data at six weeks, I was surprised to find it is much better.

More than 80% of patients are seeing 20/20 or better because there is the perfect match. Safety is another criterion for any wavefront-guided procedure. At six weeks, 60% of patients gained one line of best-corrected spectacle acuity.

Retreatments

CustomVue re-treatments correct the residual refractive error and also minimize the higher order refractive errors.

For example, one patient (with a -5 D sphere) had received LASIK in both eyes using the B&L 217z100. Post-op, the patient was plano with UCVA of 20/20, and experienced halos around lights. The wavefront map prior to retreatment showed that there were higher order aberrations including coma and a good amount of spherical aberration.

Prior to the CustomVue retreatment, the patient had -1.55 D sphere, and -0.16 D cylinder/79 degrees. Post-retreatment, the patient was plano with UCVA of 20/20. The patient reported “perfect vision.”

Although the patient still has trefoil and some coma and aberrations, the coma term was reduced, and the patient was subjectively much better.

The CustomVue retreatment also can be used effectively to treat small aberrated eyes after initial LASIK surgery to improve the quality of vision.

Michael C. Knorz, M.D., is professor of ophthalmology at the University of Heidelberg, Germany, and medical director of the FreeVis LASIK Center, University Medical Center, Mannheim, Germany.

Figure 1: At six months post-op more than 80% of patients treated with CustomVue are seeing 20/20 compared to 60% of patients treated with B&L 217z100.

Figure 2: More patients experience either no change or a gain in BCVA with CustomVue treatment than with treatment from the B&L 217z100.

Figure 3: After retreatment with CustomVue, the patient was plano with UCVA of 20/15.
Lamellar Epithelial Debridement: Improved Healing Rates With the Latest Technology

Removal of the epithelium with a microkeratome may help to speed healing and optimize outcomes

By Eric D. Donnenfeld, M.D.

Surface ablation has dramatically increased over the past five years. Nationally, rates of surface ablation are approaching 10%. In my own practice, our rate is a little above 10%, which is almost double the amount of surface ablation we were doing just two years ago.

There are many reasons for this trend including improvements in surface ablation such as gradual blend zones, and Mitomycin C for haze.

In addition, the advantages of surface ablation include no flap-related complications, no striae, no irregular flaps, and no DLK. However, the trend towards surface ablation has been expedited by deeper ablations due to larger ablation zones, increased concern of ectasia, the concept that we may have improved visual results with no flap-related aberrations, and that Bowman’s membrane is a more regular surface to ablate than a stromal bed.

Now, new surface techniques such as lamellar epithelial debridement that minimize pain while speeding healing are also helping to peak interest. We have been using the lamellar epithelial debridement procedure for some time.

With this technique, practitioners can create an epithelial flap, and then may choose to leave the flap on for traditional epi-LASIK or remove it. In our practice, we find it preferable to remove the epithelial flap that we create using the Amadeus II microkeratome (AMO, Santa Ana, California). Early on, we started doing this serendipitously in the few cases that required us to remove torn lamellar flaps.

We found that with this technique patients had exceptionally good quality of vision. They experienced a little bit more discomfort after the refractive procedure than with traditional epi-LASIK, but they healed dramatically faster.

With removal of the epithelial flap the procedure is in some ways similar to a surface ablation PRK. However, the difference with this technique is that there’s very little damage to the peripheral epithelium. The epithelial borders are regular and the diameters are exactly those that we determine. Because of this the healing is dramatically faster.

In addition, there is no alcohol-induced damage to the epithelium and stroma that is seen with LASEK. Even with 9 mm ablation zones we usually find that the epithelium closes within three days.

I have also found that unlike with PRK, there is no epithelial healing suture line. This elevated area of epithelium in the central visual axis, which commonly occurs with PRK, may take up to ten days to smooth out. During this time, the PKR patient has significant reduction in quality of vision.

On the other hand, with the lamellar epithelial debridement we found the patient seemed to regain very good quality of vision soon after the procedure.

Comparing Healing Rates

To better quantify our results we recently compared our healing rates for 20 patients undergoing lamellar epithelial debridement in one eye and epi-LASIK in the other. We found that with the removal of the flap, patients saw the return of their BCVA several days sooner.

This is a result of the fact that with epi-LASIK the epithelial flap needs time to remodel and is irregular for a short period of time. While the epithelium is remodeling, quality of vision is diminished. With the lamellar epithelial debridement, the epithelium lays down quickly, in a smoother fashion, and the vision returns more rapidly as a result.

We also compared results with lamellar epithelial debridement to those with PRK. When we looked at healing rates for day three and day seven we found that they were much faster with epithelial debridement — with epithelial defects closing approximately 1½ days sooner.

Both, UCVA and BCVA were significantly better with flap removal. While to physicians a delay in healing may not seem like much, this enhanced healing rate can make a significant difference to our patients. It’s the difference of someone having surgery on a Thursday afternoon and going back to work on Monday versus having to take off Monday and Tuesday, and wait until Wednesday.

Some epithelial lamellar debridement patients heal even sooner than this. We have several patients who with epi-LASIK were able to function the next day. For example, we had one patient whose pre-operative uncorrected visual acuity was 20/400. One day postoperatively her acuity was 20/25.

When we looked at patient comfort we found that while initial comfort was greatest with traditional epi-LASIK, patients who underwent flap removal still enjoyed much more comfort than those who underwent PRK.

Based on our results, we concluded that the epithelium can be removed successfully with the Amadeus II microkeratome, with no discernible damage or pathology to the epithelium or the under-laying corneal stroma. In addition, we determined that with lamellar epithelial debridement patients have greater comfort than PRK, and have more rapid visual rehabilitation.

Uncorrected visual acuity

When we looked at healing rates...we found that they were much faster with epithelial debridement...closing approximately 1½ days sooner.”

Overall, there doesn’t appear to be any downside to choosing lamellar epithelial debridement instead of PRK. I believe that it’s an advance that we can all readily offer to our patients. We then need to discuss what the patient believes is more important to them, discomfort or visual rehabilitation speed, to ultimately help them to decide what procedure is best for them.

Eric D. Donnenfeld, M.D., is in private practice with Ophthalmic Consultants of Long Island, NY. He is a consultant for Advanced Medical Optics, Alcon, Bausch and Lomb, and TLC laser eye centers.
he visual quality of wavefront-guided LASIK is better than either conventional or optimized LASIK, according to results from a model that simulates visual performance. Based on the simulations from a model, we concluded that while optimized LASIK is an improvement over conventional LASIK, it still induces more higher-order aberrations (HOAs) than wavefront-guided LASIK. We also concluded that optimized LASIK is essentially the same as conventional LASIK for eyes with pre-op negative spherical aberrations (12% of population).

**Visual performance**
For this study we sought to determine if the visual performance of optimized LASIK was equivalent to wavefront-guided LASIK. We recognize that conventional LASIK induces higher order aberrations, most prominently spherical aberration. Wavefront-guided LASIK reduces the induction of higher order aberrations, and in patients with a significant amount of higher order aberrations, can reduce higher order aberrations. Optimized LASIK, which has a treatment based on sphere and cylinder, minimizes the induction of spherical aberration.

**The model**
We developed a robust model that simulates visual performance of the three procedures: conventional, optimized, and wavefront-guided LASIK. The model assumed a perfect correction of sphere and cylinder. Previous work has shown us that the induction or reduction of higher order aberrations is related to the pre-operative level of higher order aberrations and the type of surgery.

We also assumed the best case scenario. Optimized surgery is “neutral” regarding spherical aberration, meaning that it doesn’t induce or reduce that aberration, but that higher order aberrations are increased or decreased the same as conventional surgery. Optimized surgery was only “optimized” to reduce the induction of spherical aberration.

The data set for the model included two cohorts of patients: conventional LASIK (295 eyes) and wavefront-guided LASIK (193 eyes). (CustomVue wavefront-guided LASIK was used with the Zernike reconstruction without iris registration.) All eyes had a 6-mm pupil diameter for wavefront analysis, and Zernike terms through 6th order were utilized.

Wavefront data was collected on pre-op and one month post-op for the conventional LASIK and wavefront-guided LASIK eyes. Using the HOA distribution, a Monte Carlo generation of 10,000 random pre-op wavefront maps was performed.

We determined the distribution of induced Zernike terms. For the model, the post-op higher order aberration terms were randomly assigned to be within ±1 standard deviation of the measured induced aberration, dependent on surgery type and the level of pre-operative HOA. For the optimized eyes there was no change in spherical aberration.

Both conventional LASIK and wavefront-guided LASIK induced higher order RMS as a function of pre-op levels. (Figure 1) The amount of aberration that is induced by a procedure is variable and dependent on the amount of pre-existing aberrations. For example, if there are low amounts of pre-operative higher order aberrations, there is a greater tendency to induce more. This applies to conventional LASIK as a function of pre-operative higher order aberrations on the X-axis and the change in higher order aberrations pre-op to post-op, the RMS.

Wavefront-guided LASIK induced fewer higher-order aberrations, however the same principle applies. For example, if there are very few pre-op higher order aberrations there tends to be an increase in higher order aberrations post-op, even with wavefront-guided LASIK. However in eyes with more pre-op higher-order aberrations there is less induction, or even a reduction, in the higher order aberrations. This information was all taken into consideration to develop the post-op model of these 10,000 generated eyes.

An important outcome of the model was that the odds of inducing significant higher order aberrations were five times more likely with conventional LASIK compared to wavefront-guided LASIK. A significant increase was defined as 0.1 microns, or higher, HOA RMS when measured with a 6-mm entrance pupil. The odds of inducing significantly greater aberrations were 2.2 times more likely with optimized LASIK compared to wavefront-guided LASIK. (Figure 2)

**Case example**
Looking at a case example using the Model Simulation illustrates the results. Patient one, a 30-year-old male, had a high level of pre-op HOA. He had -4.50 D sphere, a little bit of cylinder, and 0.55 microns of higher order RMS (over two standard deviations above the mean). Conventional LASIK does not induce very much HOA because he has a good deal already. Optimized LASIK does not induce any. Because the patient has a great amount of HOA, wavefront-guided LASIK reduces them.

The model essentially shows that the visual quality of optimized LASIK is better than conventional. However, the visual quality of wavefront-guided is better than optimized. Therefore, clearly wavefront-guided visual quality is much better than conventional.

By Capt. Steven C. Schallhorn, M.D.
Considering Real-World Outcomes: Wavefront-Guided vs. Optimized Ablation

Wavefront-guided ablations provide significantly better results than either optimized or conventional ablations

By Jeffrey J. Machat, M.D.

“...it is apparent from our results that the WaveLight-optimized approach...is not comparable to custom ablation profiles.”

These days, as refractive practitioners we no longer have to confine ourselves to the standard LASIK approach which has continued to evolve over the past decade. We all look to find the technology that can provide our patients with the best outcomes. Two such promising approaches that we have tried in our practice are the wavefront-guided technique, with the VISX Star S4 (AMO, Santa Ana, California) and the wavefront-optimized approach, with the Allegretto Wave (WaveLight Laser Technologie AG, Erlangen, Germany).

These approaches augment conventional LASIK very differently. The wavefront-guided technique allows surgeons to measure and treat lower- and higher-order aberrations in the eye with the aid of an aberrometer. With this method each patient receives a unique custom treatment.

On the other hand, the WaveLight-optimized approach does not measure aberrations. Instead, with this approach a standardized spherical aberration coefficient is utilized on all patients to compensate for induced spherical aberration. This is accomplished through placement of additional laser pulses in the corneal periphery. We all understand that conventional LASIK is able to effectively deal with lower order terms. The problem has been that conventional LASIK induces higher order aberrations, most importantly spherical aberration, and secondarily coma.

Therefore, it stands to reason that an ablation profile which compensates for spherical aberration would be better than a standard ablation profile. But how does a wavefront-optimized approach compare to a customized approach in the real world?

**A real world view**

In our office we’ve done thousands of wavefront optimized and wavefront-guided procedures. For a time, we used to market conventional LASIK, wavefront-optimized, and wavefront-guided LASIK to our patients in a three-tiered approach. Our standard program was the Planoscan with the Bausch & Lomb 217 (Rochester, New York). The intermediate-priced approach, which we called “Prolate,” was the WaveLight-optimized technique. CustomVue was our premier approach.

Our clinical results mirrored our pricing system both in terms of safety (loss of BCVA, night glare) and visual and refractive results. The Prolate approach worked for most patients. It was easy and less time consuming than our Custom approach, with substantially better outcomes than the conventional approach, but the Prolate clinical results paled in comparison to our CustomVue outcomes.

While 20-30% of our Prolate eyes improved BCVA, versus only 2-3% of our conventional Planoscan eyes, over 50% of our CustomVue patients gained BCVA. Since the WaveLight Prolate program does not compensate for induced spherical aberration above -6.00 diopters, we suspected that it would be only these patients who would complain of night glare. But such was not the case.

Even at low levels of myopia we were surprised to find the occasional patient complaining of difficulty driving at night after optimized ablations. We attributed this to increases in other higher order aberrations, and we certainly tried to avoid the wavefront-optimized program for all severe myopes (>6.00D). Similarly, the surprises with loss of best corrected vision with Prolate occurred only sporadically. This was a finding we never observed with CustomVue.

**The enhancement issue**

Another point of comparison was that our enhancement rate with the WaveLight-optimized approach was more than double what it was with the CustomVue wavefront-guided approach. Furthermore, we found that the only way to make our WaveLight-optimized patients truly happy was to perform a CustomVue enhancement on top of their Prolate ablation.

A good example of wavefront-guided fixing a Prolate treatment problem involves a patient with induced coma. Both eyes received primary Prolate treatment that resulted in induced coma, trefoil, and spherical aberration, as well as residual refractive error.

In the right eye, the Prolate treatment increased the patient’s coma value from .30 to .44. After retreatment with CustomVue, it was reduced to .23. BCVA in the right eye had dropped to 20/25+1 from 20/20 pre-op with Prolate, but was restored back to 20/20 after retreatment. Similarly, in the left eye coma increased from .19 with Prolate to .40, and was then reduced to .23 after CustomVue retreatment. (See figure below)

Trefoil increased from .04 to .34 with Prolate and decreased with CustomVue retreatment to .19. Even spherical aberration increased in this patient from treatment with the WaveLight — despite a pre-op myopia level less than -6.00 diopters — from .04 OD and .07 OS to .16 OD and .31 OS.

Ultimately, my partners and I decided to switch exclusively to the CustomVue wavefront-guided approach. We found that we had more referrals from those patients who had undergone the CustomVue procedure, and that over time other doctors disproportionately started to refer their patients specifically for our custom approach as well.

Overall, after more than a decade of evolution in laser vision correction it is apparent from our results that the WaveLight-optimized approach, while a significant step forward compared to conventional ablation profiles, still is not comparable to custom ablation profiles. Without question, customized ablations are the best means to not only avoid problems but also obtain superior outcomes.

Dr. Machat is co-medical director of TLC Laser Eye Center in Toronto, Ontario, Canada.

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**Case Example: KB**

<table>
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<th>Pre-op</th>
<th>Post-Optimized Treatment</th>
<th>Post-CustomVue Retreatment</th>
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<th>Post-Optimized Treatment</th>
<th>Post-CustomVue Retreatment</th>
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<tr>
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After a poor initial correction with optimized, this patient was retreated with a CustomVue wavefront-guided ablation.
For presbyopia correction, combining refractive intraocular lenses yields better results, especially for intermediate vision. By Rick Milne, M.D.

The combined use of refractive intraocular lenses is often the solution to best meet the patients’ refractive needs. By using a complementary approach, surgeons can offer patients a larger range of useful vision in the near range by implanting one ReSTOR and one ReZoom lens.

I now have 55 patients who have bilateral ReSTOR implants. During that time period I learned a good deal about the lens and how it performed in my patients. I also learned that a significant amount of my bilateral ReSTOR patients were not happy with their vision in the intermediate range. Often their near vision correction was closer than they desired, and they also were having difficulty when it came to working on their computers, playing music, doing painting and other activity work, and other intermediate tasks.

**Combination benefits**

For this reason I began combining technologies to create a complementary visual system. I have 35 patients in whom I have placed the ReSTOR in one eye and the ReZoom in the other eye. The most valuable thing we can do for ourselves and for our patients prior to entering into one of these procedures is to listen closely to them about their observations of their vision.

This means taking the time to ask detailed questions. I ask the patient to explain to me their near frustration. What tasks do they perform? What does their near world look like? How much time do they spend in front of a computer? Are they an avid reader? Do they do a lot of desk work?

When a patient describes a demand for intermediate vision tasks, such as hours in front of a computer or heavy deskwork, I no longer feel comfortable with a bilateral ReSTOR procedure in these patients. Instead, I will choose the complementary lens implantation of ReSTOR in one eye and ReZoom in the other. The 35 patients who have had this combination, report that they are very pleased with how their eyes are behaving.

I have also begun to decide on which lens to place in the patient’s dominant eye by listening to their most prevalent near need. If they are an avid reader then they get the ReSTOR in their dominant eye. If they spend eight hours a day in front of a computer they get the ReZoom in their dominant eye.

Initially, I was concerned that the different lenses might be confusing to the patient. Largely, this is not the case. Some patients do prefer one lens over the other, but I stress to them that they should not compare the eyes. Instead, the brain should be allowed to learn to work with them together. As such, this procedure allows for the IOL systems to complement each other and provide a broader range of near vision.

**Results**

The majority of my ReSTOR patients reach 20/30 or better at distance and J2 or better at near, and many are 20/20 distance and J1 near. However, their intermediate vision in often inadequate, and they require reading classes for intermediate tasks.

The ReZoom seems to provide better intermediate vision than the ReSTOR. I have had excellent results with the ReZoom at near vision as well as at distance from 14 inches to 30 inches. The patients are often achieving J2, if not J1 vision, and they are doing so in brighter light than they were able to do with the Array lens of which I implanted more than 900.

I have tested some patients (10) with the near bar. For bilateral ReSTOR patients their sweet spot is close. They can read the J3 on a near bar at 10 inches, and they can continue to read it out to 20 inches. However, the ReZoom eye patients seem to pick up the J3 at 15 inches, and can continue to read it out to 24 to 30 inches. These distances seem to be the averages for these lenses, and are consistent with the add that each manufacturer claims to be in their near component. Some patients exceed these results while others do not perform this well. Age and pupil size may be contributing factors.

The combination refractive IOL implantation has been a nice answer for patients who tell me they have both near and intermediate needs. For example, one patient, a car dealer, was successfully implanted with both lenses. He told me that his vision is excellent for all his near and intermediate needs. With his ReSTOR eye he can read the fine print in the Blue Book that he refers to often, and with his ReZoom eye he can also perform his intermediate visual tasks such as computer work.

Both the ReSTOR and the ReZoom result in equivalent night time halos. Pre-operatively, I inform all patients that there is a good chance that they will have halos around light. Yet, the majority of patients who see halos will adjust within a month to six weeks.

Rick Milne, M.D., is with the Eye Center, P.A., in Columbia, S.C.