



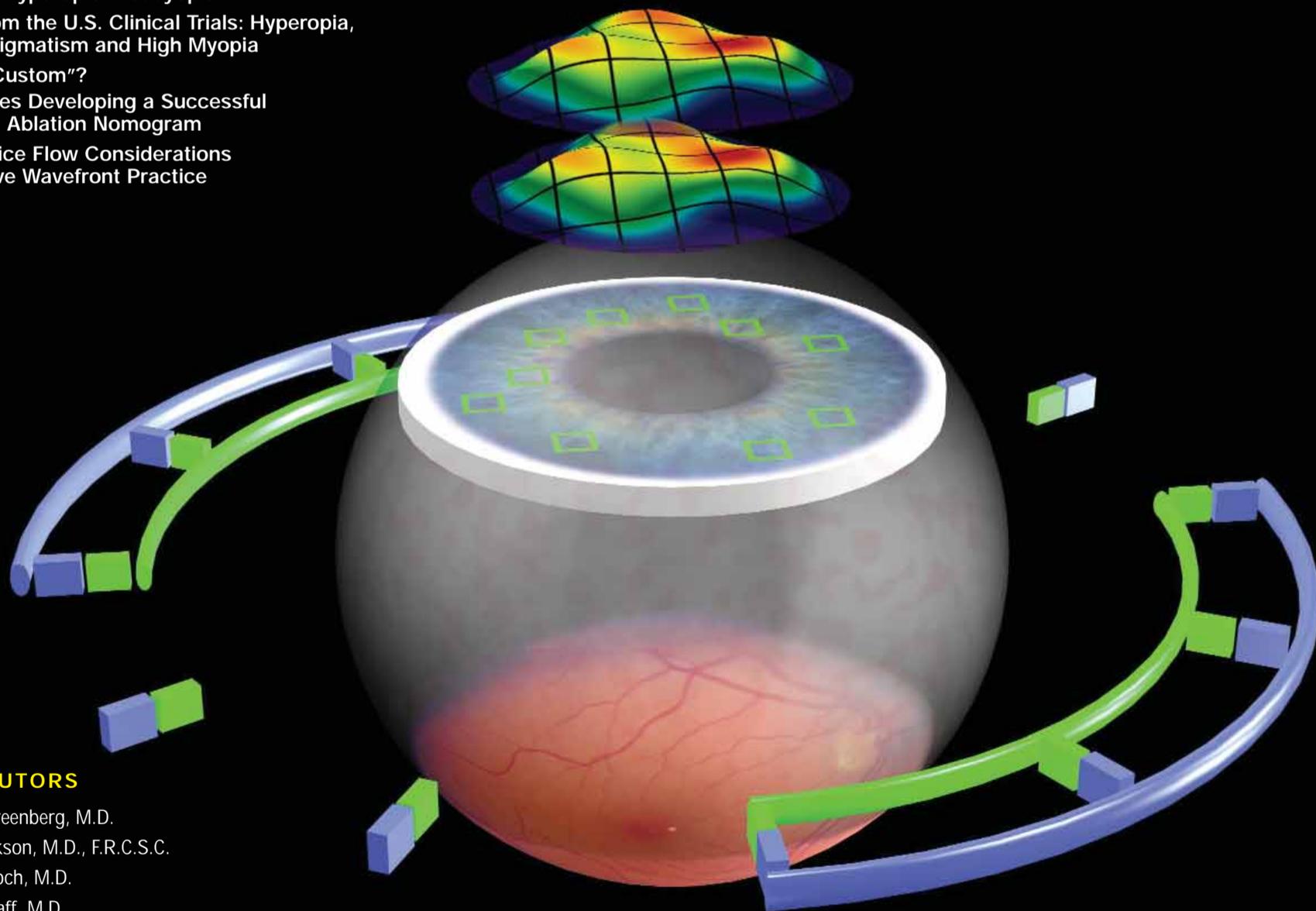
Steven Schallhorn, M.D.

Taking Wavefront to the Next Level: Refining Results, Expanding Indications, and Applying the Latest Technologies

Leading clinicians discuss their experiences with wavefront technology and what the future holds for customized laser vision correction.

INSIDE:

- Fourier Wavefront Reconstruction: How Will this Improve Precision?
- International Clinical Experience with Iris Registration Technology
- Developing the Optimal Multifocal Shape for Hyperopic Presbyopia
- Report from the U.S. Clinical Trials: Hyperopia, Mixed Astigmatism and High Myopia
- What is “Custom”?
- Experiences Developing a Successful Wavefront Ablation Nomogram
- Key Practice Flow Considerations in an Active Wavefront Practice



CONTRIBUTORS

Kenneth A. Greenberg, M.D.
W. Bruce Jackson, M.D., F.R.C.S.C.
Douglas D. Koch, M.D.
Colman R. Kraff, M.D.
Jeffery J. Machat, M.D.
Louis E. Probst, M.D.
Robert E. Smith, II, M.D.
Julian D. Stevens, M.D., F.R.C.S.
John A. Vukich, M.D.
J. Trevor Woodhams, M.D.



“ With Fourier analysis all data points are weighed equally and are incorporated into the derived shape. ”

John A. Vukich, M.D.

Fourier Wavefront Analysis: How will this improve precision?

The Fourier-driven wavefront shapes reveal details of the visual system that cannot be detected with Zernikes.

By John A. Vukich, M.D.

Fourier Analysis is an alternative to Zernike polynomials for describing optical wavefronts and, in turn, providing the basis for designing a custom corneal ablation profile. Although there are potential advantages to either method, the increased resolution of complex shapes with Fourier transformation may prove to be a more useful modality in treating patients.

Wavefront reconstruction

These algorithms are two different mathematical ways by which we can process the same data to achieve the goal of reconstructing the wavefront of the visual system. The Fourier method involves the use of a series of chosen sine waves to reconstruct a complex pattern. Mathematician Jean Baptiste Fourier (1768 to 1830) showed that any discrete waveform could be broken down into a series of sine waves at appropriate amplitudes and phases. It is possible to take an appropriate set of sine

waves and add them together to describe a given shape, such as a square wave.

More complex patterns can be described similarly, and this is the basis of the Fourier method in optical wavefront analysis. Fourier transformation analysis uses a mathematic process of harmonic analysis that does not split the visual system into individual terms but, rather, creates a description of the whole wavefront. The breaking-apart of complex waves into components of sine waves is called Fourier Analysis. For the process known as wavefront analysis, a complex pattern is decomposed into sine waves.

Zernike polynomials break down a complex wavefront into specific and discrete shapes. For refractive surgery there are limitations inherent in the use of Zernike polynomials. These are a consequence of using a polar coordinate based system.

Zernikes are mathematically unable to describe a straight line. This has implications in terms of analyzing visual aberrations that result from striae, cap amputations, or any number of other defects that have linear quality.

Another limitation is that an increasing number of terms are necessary to provide resolution of complex wavefronts. Limiting the number of Zernike terms used to describe a shape will result in attenuation of detail. Michael Smolek, Ph.D., and Stephen Klyce, Ph.D., reported that when Zernikes are used to fit a complex surface, such as a keratoconic cornea, there is a substantial amount of fit error. If limited to the 6th order, Zernikes may not be fully adequate to describe complex wavefront patterns in refractive surgery.

Data

With Fourier analysis all data points are weighed equally and are incorporated into the derived shape. The derived wavefront shape depends on the quantity of data used to determine the shape. Fourier analysis incorporates each unique centroid and does not require adjacent data points to be included in the analysis. Data points from the margin of the pupil as well as those points outside of a round pupil are incorporated in the analysis.

However, the mathematics of Zernike polynomial interpretation requires a cluster of points to be

analyzed and totaled. There must be adjacent data to each individual data point to allow interpretation. Therefore, centroids at the pupil margin are not included in the wavefront analysis. This method also eliminates data points in which the adjacent centroids are non-interpretable.

Of the approximately 240 Hartmann-Shack centroids in a 7 mm pupil, an average of 26 data points are generated for use in fitting the Zernike polynomials. The polar-coordinate nature of the Zernike system defines a circular shape for the polynomial. This works well for round pupils but will ignore some data in oval or irregularly shaped pupils.

Therapeutic applications

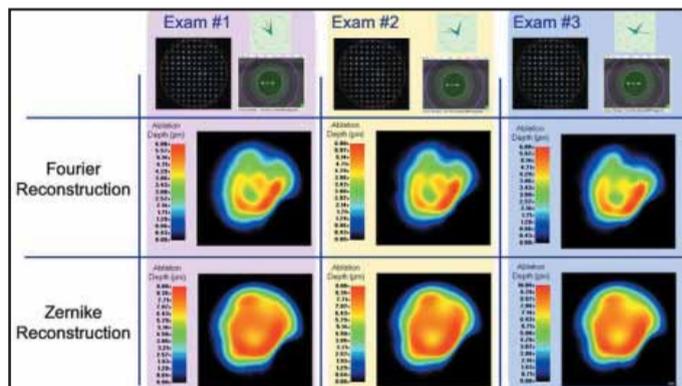
Therapeutic wavefront-guided ablations are not yet available routinely. Using Zernike polynomials, problematic issues with therapeutic applications include the significant degree of smoothing and the translation of complex shapes. As a result, it does not provide the resolution necessary for many therapeutic treatments.

Preliminary data results using the Fourier-based algorithm developed by Julian Stevens, MRCP, FRCS, FRCOphth, M.D., demonstrate there is greater detail and accuracy in the ablation shape when compared to the traditional Zernike method. Fourier analysis improves the reconstruction of the wavefront shape in normal eyes and has shown promise in improving the quality of vision for therapeutic patients.

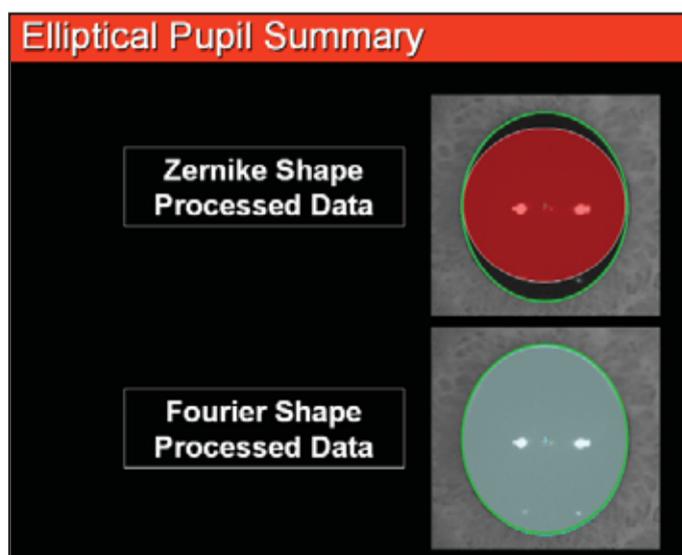
Conclusion

While both Fourier and Zernike generate ablations that are repeatable over time in size, orientation, and aberration shape, with Zernikes a distinct smoothing can be observed. The Fourier-driven wavefront shapes reveal details of the visual system that cannot be detected with Zernikes. Both techniques represent well-validated mathematical models of describing complex wavefronts, and continued use will ultimately validate which method provides superior results in the long run.

John A. Vukich, M.D. is assistant clinical professor at the University of Wisconsin, Madison. He is a consultant for VISX.



For each examination, the target ablation pattern was calculated using Zernike polynomials and Fourier reconstruction.



Because Fourier peripheral information is not constrained by circular patterns, additional information can be processed and utilized for ablation zones greater than or equal to 7 mm.



“IR could have a huge impact on outcomes in eyes with high cylinder or those who have more dramatic cyclotorsion during surgery.”

Jeffery J. Machat, M.D.

In order to maximize custom ablation outcomes, it is important to position the ablation pattern onto the cornea in a manner that corresponds directly to the measurements taken by the wavefront device. In addition to centering the ablation, rotational alignment of the wavefront map is necessary.

Studies have shown that cyclotorsional misalignment as the result of improper registration of the intended ablation shape with the cornea during a wavefront procedure can induce significant RMS error and result in suboptimal outcomes. For example, a 1° rotational shift can have a measurable impact on outcomes, while a 30° shift can result in an induction of nearly 1.0 D of RMS error—and significant degradation of visual quality. (Figure 1) Studies by VISX have shown that patients have an average outward rotation, or excyclotorsion, of 2.2° when moving from an upright to a supine position.

To compensate for cyclotorsion, VISX has recently introduced a new feature for its CustomVue™ system, automated Iris Registration (IR).

Iris Registration

Iris Registration is a method of digitally registering the WaveScan and laser images of the eye based on the natural iris pattern. The iris ring is located in both images and is divided into a set of radial sectors. For each sector, the most prominent iris texture region is detected and stored using an image-processing algorithm.

The VISX system then compares the iris blocks in the reference image obtained from the WaveScan system with the second image obtained from a camera mounted on the laser. Once this step is completed, relative posi-

International Clinical Experience with Iris Registration Technology

Automated iris cyclotorsion compensation is a key upgrade to wavefront-driven outcomes.

By Staff Writer

tional changes in the iris determine the amount of rotation of the eye between the two images and the system automatically adjusts the treatment to compensate for the movement.

According to Jeffery J. Machat, M.D., co-Medical Director of TLC Laser Eye Center in Toronto, Ontario, Canada, automated IR is an important incremental improvement in the VISX system. “IR could have a huge impact on outcomes in eyes with high cylinder or those who have more dramatic cyclotorsion during surgery. It also will eliminate the step of manual torsional marking,” he said.

IR in practice

Machat recently treated his first few cases using automated Iris Registration. Once the new technology is installed, the only extra step is the push of a button. At the WaveScan, the operator sees a confirmation on the screen that the WaveScan capture is acceptable for Iris Registration. Sondra Black, O.D., Clinical Director at TLC-Toronto, said that getting an acceptable image is not difficult, although technicians have taken extra care during the capture process to ensure that the patient's eye is open wide and the image is well-centered.

The treatment is planned as usual, but is transferred to the laser via digital memory stick, rather than floppy disk.

After the flap is created in the laser suite, the laser operator pushes a button to activate the laser camera. At that point the system confirms the pre-operative iris map features, identifies the degree of cyclotorsion, and rotates the treatment accordingly. If the iris features cannot be identified for any reason, the operator can simply override Iris Registration.

“We were initially concerned that IR would not work under IntraLase flaps, which we use in 95% of cases,” Machat said. “However, after just a few cases, there seems to be no problem for the system in matching iris features in eyes with IntraLase flaps.”

Black noted that the patient verification feature of IR may be an added benefit for some practices. “We have always taken great care to verify that we have the correct eye of the correct patient prior to treatment,” she said. “However, it is reassuring that because iris patterns in every eye are unique, the IR technology provides yet another method for verification.” (Figure 2)

One of the first patients treated at TLC-Toronto using IR was a high

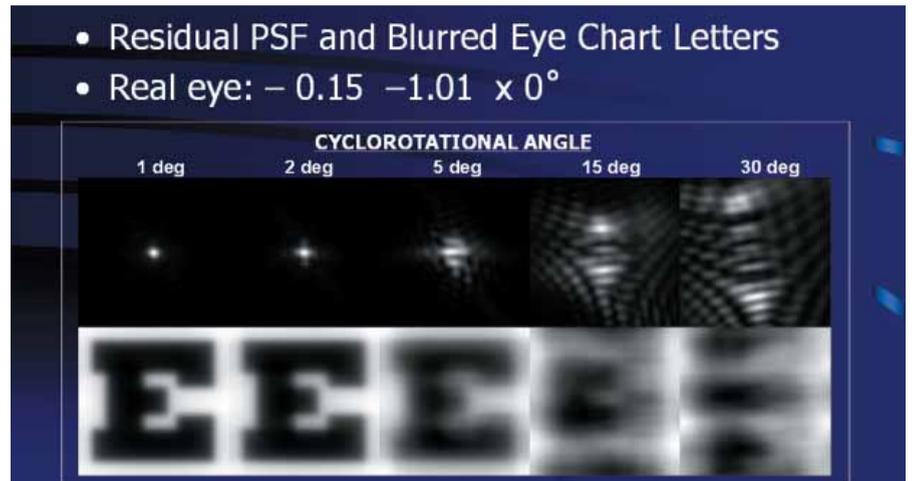


Figure 1: A 1° rotational shift can have a measurable impact on outcomes, while a 30° shift can result in an induction of nearly 1.0 D of RMS error—and significant degradation of visual quality.

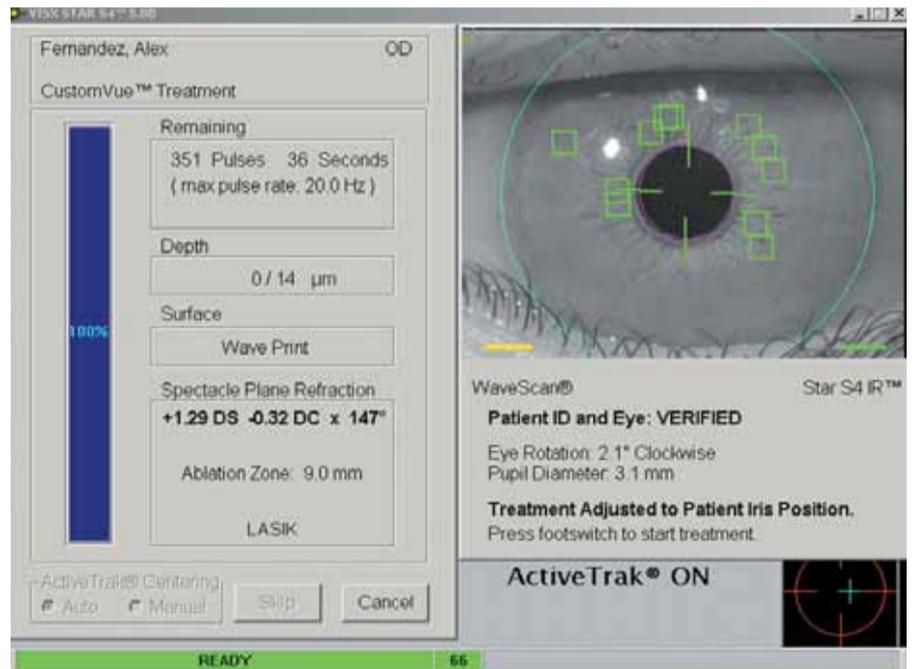


Figure 2: At the laser, the patient's ID and eye are verified during the automated iris registration process.

mixed astigmat with a preoperative refraction of +1.00 D -3.75 D x178 (OD) and +1.25 D -3.50 D x10 (OS). On the first post-operative day, the patient was plano 20/20 UCVA in both eyes. Moreover, the degree of cyclotorsion was recorded as 3.8%. Had IR not been in use, this ablation might have been improperly applied for a less-than-optimal outcome, Machat said.

He cautioned that lighting must be taken into consideration when using IR, especially for patients with large pupils. “If the lighting in the laser room is bright and the pupil constricts significantly smaller than it was during WaveScan capture, the system may not be able to recognize the iris features,” he said. Adjusting the lighting in the laser room should resolve this problem.

Optimizing outcomes

Certainly, manual registration based on ink marking of the sclera at the slit lamp, and alignment with the reticle has provided excellent clinical results, both in the U.S. FDA CustomVue clinical trials and in commercial use since approval. However, there are several advantages to an automated cyclotorsional registration method. The iris-based method uses natural, unchanging features of the eye and is precisely automated. Because it does not rely on manual ink markings, there is less chance for human error. In addition, iris data captured at the time of WaveScan measurement can be recalled at a future date, unlike manual marks that disappear in a matter of minutes or hours.



“ Patients reported high satisfaction with the treatment. All patients indicated they would have the procedure done again. ”

W. Bruce Jackson, M.D., F.R.C.S.C.

Developing the Optimal Multifocal Shape for Hyperopic Presbyopia

The multifocal corneal ablation shape for the treatment of presbyopia works well and offers flexibility in treatments.

By W. Bruce Jackson, M.D., F.R.C.S.C.

Recent data on the multicenter studies using a multifocal corneal ablation for the treatment of presbyopia are very promising with patients reporting high satisfaction.

Correcting presbyopia

Using the excimer laser for the correction of presbyopia is less invasive than other treatments, and it is being performed with an established and improving laser vision technology. Surgeons also can correct the present refractive error as well as customize the ablation using wavefront.

A disadvantage of treatment includes the risk of inducing visual symptoms such as glare and double vision. In addition, myopes and emmetropes can be difficult to please because they want excellent distance as well as excellent near vision. They may experience some loss of quality of vision, and there also is a dependence on pupil size.

Treatment design

The VISX multifocal treatment design uses a patented VISX multifocal ablation profile. The VSS ablation technology is used to create subtle ablation shape changes to the subject's wavefront map. The central zone is steeped to provide near vision, and the peripheral zone is targeted for distance vision.

The combination of the pupil size-dependent central zone, the peripheral zone, and the LASIK flap produces an aspheric curve that expands the depth of focus. (Figure 1)

The shape for the hyperopic patients has worked extremely well, with the longest follow-up now to one year. Distance vision has not

been compromised and patients are able to read.

In addition, the ablation shape is very flexible. Although we have not retreated any patients in this group, it should be possible. With time, patients may become more hyperopic, so the hyperopia could be corrected with additional central treatment for near. As yet, we have not done this.

The study results

Thirty-two eyes of 16 hyperopic, presbyopic patients were treated in the hyperopic cohort of the multicenter trial, as reported at the 2004 ESCRS meeting. Follow-up is available to 12 months. Pre-op refractions included mean manifest sphere of 1.48 D and cylinder of 0.31 D. The mean patient age was 56 years old.

At six months, 71% of the eyes were 20/20 or better for uncorrected visual acuity (UCVA) for distance. (Figure 2) At 12 months 90% were 20/20 or better, and 100% were 20/40 or better.

Results for near vision took from one to six months to improve. However, at six months, 57% of eyes were J1 or better in this group. At 12 months 60% were 20/20 or better.

For patients who were corrected for the distance vision and then evaluated for near visual acuity, 60% were J1, and 90% were J2 or better at 12 months.

Simultaneous uncorrected distance and near vision was achieved in the majority of eyes. For uncorrected distance vision, 86% achieved 20/25 and J3. (Figure 3)

Patients reported high satisfaction with the treatment. All patients indicated they would have the procedure

done again. Some indicated that they would like to gain a little more reading.

Approximately 20% of patients need glasses some of the time for reading very small print. However, most manage well without glasses.

For distance vision, there have been some reports of ghosting, but no double images. There have not been two lines or more loss of high contrast BSCVA acuity for distance under bright or dim illumination at six months or greater. At near, there was no significant loss of visual acuity with correction because the mean MRSE was slightly plus. Patients also experienced a small gain in distance corrected near acuity.

Future applications

The results thus far from Canadian-approved multicenter trials using a multifocal corneal ablation for the treatment of presbyopia are extremely promising. The shape for the hyperopic patients has worked well and enables patients to read without compromising their distance vision. The multifocal corneal ablation shape design also offers the flexibility for future retreatments if necessary or desired by the patient.

W. Bruce Jackson, M.D., F.R.C.S.C. is director general, University of Ottawa Eye Institute, Ottawa Hospital, and chairman, Department of Ophthalmology, University of Ottawa.

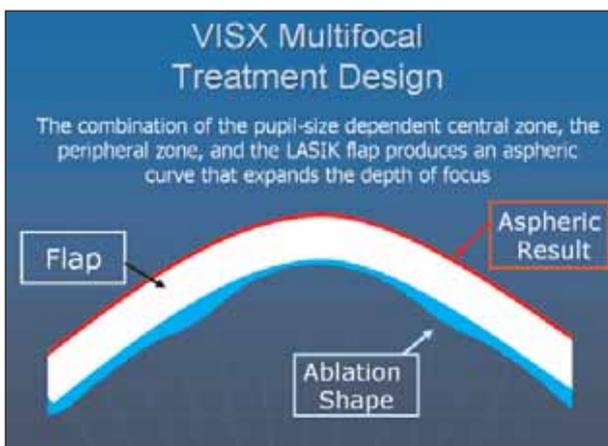


Figure 1: VISX proprietary multifocal treatment design.



Figure 2: At six months, 71% of the eyes were 20/20 or better for uncorrected visual acuity (UCVA) for distance.

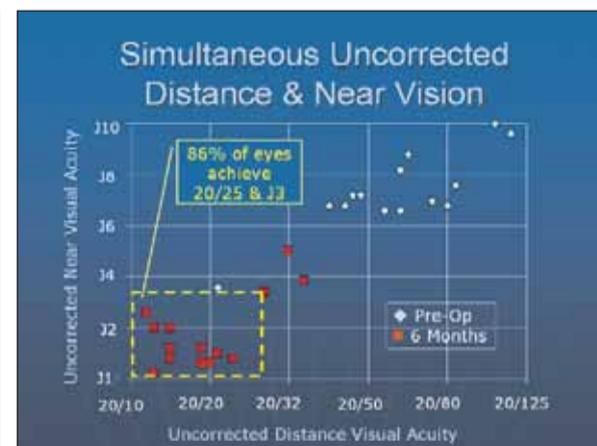


Figure 3: Simultaneous uncorrected distance and near vision was achieved in the majority of eyes. For uncorrected distance vision, 86% achieved 20/25 and J3.



“There is a superior shape to standard ablation, the variable spot scanning is more precise, and the variable repetition rate results in a faster ablation.”

Douglas D. Koch, M.D.

Patients treated with CustomVue for hyperopia have excellent results, with high patient satisfaction and a low rate of complications, according to Douglas D. Koch, M.D.

Baylor College in Houston is one of six centers participating in the U.S. clinical trials for WaveScan-guided LASIK for hyperopic and mixed astigmatism. “For the hyperopia cohort, at nine months 72% of eyes were 20/20,” he said. “For the mixed astigmatism cohort, at six months, 62% of eyes were 20/20 or better and 96% were 20/40 or better.”

Wavefront advantages

Dr. Koch explained that the VISX CustomVue procedure, from VISX USA Inc., of Santa Clara, California, provides several technical advantages regarding LASIK for hyperopic and mixed astigmatism patients.

“There is a superior shape to standard ablation, the variable spot scanning is more precise, and the variable repetition rate results in a faster ablation,” he said.

First, the system builds a virtual physics-based model of the cornea. It “ablates” the cornea with the treatment table and studies the resulting temperatures. Then the timing between a few pulses is modified and simulation is repeated. This process is repeated until the treatment is as quick as can be safely done within proprietary parameters.

Study results

For the U.S. clinical trial, all patients received bilateral LASIK treatment using The VISX Star S4 Active Trak with Variable Repetition Rate (up to 20 Hz). A Hansatome or Amadeus microkeratome was used. (The Moria was used for mixed astigmatism

Report from the U.S. clinical trials: Hyperopia and Mixed Astigmatism

The treatment produces positive results and high patient satisfaction.

By Staff Writer

treatment.) No nomogram adjustments were made. All eyes were targeted for emmetropia, and follow-up is available to nine months. The hyperopia cohort includes 144 eyes of 74 subjects. Mean patient age was 53 ± 7 years.

“For uncorrected visual acuity, 62% were 20/20 or better at six months, and 72% were 20/20 at nine months. These results are superior to conventional LASIK treatments for this patient population, Dr. Koch said. (Figure 1)

At six months, 98% of eyes were with ± 1.0 D intended versus achieved MRSE. “Ninety-eight percent of eyes changed less than or equal to 1.0 D between three and six months. Stability was achieved by six months and confirmed at nine months,” Dr. Koch reported.

At six months, patients also reported improved satisfaction with their vision following surgery. (Figure 2) Seventy five percent had the same or better best spectacle corrected visual acuity (BSCVA) at six months. One eye lost more than one line of BSCVA and no eye lost more than two lines of BSCVA. “There were no ongoing

adverse events reported at six months or later,” he added.

Mixed astigmatism

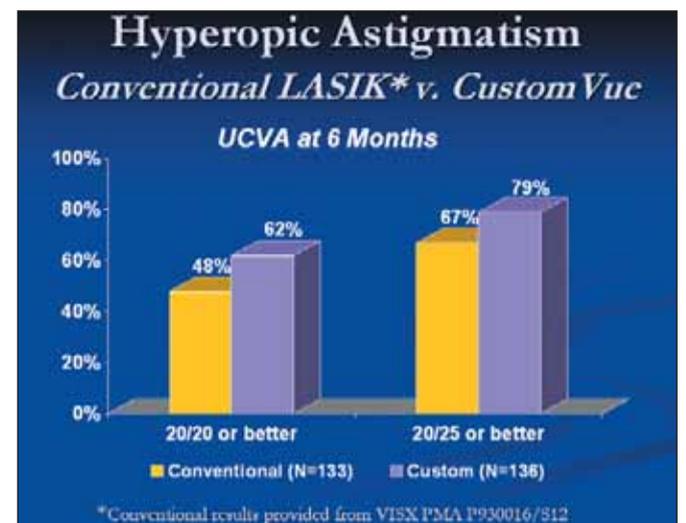
For the mixed astigmatism cohort, 86 eyes of 44 subjects were treated. The mean patient age was 41 ± 11 years. For preoperative manifest refractive error, sphere was -1.68 ± 1.12 D, cylinder was $+2.98 \pm 1.20$ D, and the MRSE was -0.19 ± 0.89 D.

For uncorrected visual acuity, 62% were 20/20 or better, and 86% were 20/25 or better at six months.

Post-op refractive reduction and accuracy were excellent. At six months, for sphere 77% were with 0.5 D, and 97% were within 1D. For cylinder, 56% were within 0.5 D, and 92% were within 1D. For MRSE, 66% were within 0.5 D, and 86% were within 1D.

At six months, patients reported improved satisfaction with their vision following surgery. (Figure 3)

“At six months, 85% of eyes had the same or better BSCVA. One eye (1.4%) lost two lines of BSCVA, and no eyes lost greater than two lines. These results confirm the high quality of vision achieved by these patients,” Dr. Koch noted.



At six months wavefront-guided LASIK results demonstrate improved outcomes compared to conventional LASIK.

Report from the U.S. clinical trial: High Myopia

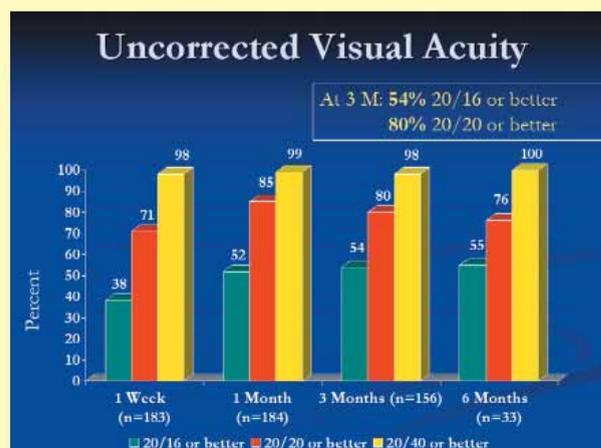
By Colman R. Kraff, M.D.

Early results of the clinical trial for Wavefront-guided LASIK treatments for high myopia in my practice are excellent and patients are reporting a high level of satisfaction.

The results appear to be very accurate and predictable in this high myopic group. Once approved, surgeons will be able to offer a new group of patients the CustomVue process and give them better results than we have been achieving with conventional LASIK in highly myopic patients.

The Trial

In the US clinical trial for high myopia at the Kraff Eye Institute, all patients received bilateral LASIK treatment using The VISX Star S4 Active Trak with Variable Repetition Rate (up to 20 Hz). A Hansatome, Amadeus, or Intralase microkeratome was used. Nomogram adjustments were applied and all eyes were targeted for emmetropia.



At 3 months post-op 80% of patients achieved 20/20 or better and 54% of patients achieved 20/16 or better.



For the procedure, Fourier-based algorithms are used to develop the ablation shapes for all treatments. Variable repetition rate technology was used and provided short treatment times (less than one minute). The Percentage Nomogram Adjustment is applied to the entire WaveScan ablation and there is an expanded wavefront capture to 7mm.

The trial includes 184 eyes of 92 patients, with a mean age of 36 ± 7 years. At 3 months post-op 80% of patients achieved 20/20 or better and 54% of patients achieved 20/16 or better. Compared to pre-op BCVA, 68% had same or better post-op UCVA. Ninety-five percent of patients were within 1.0D of emmetropia. To date enrollment is complete and follow-up is ongoing.



“ The word ‘custom’ can be confusing because other laser platforms also use the term to describe their wavefront-driven product. ”

J. Trevor Woodhams, M.D.

Today in the field of ophthalmology the issue of nomenclature is an important one, and should not be dismissed as semantics. The use of precise language helps deliver the correct message to patients and is not misleading in any way.

Unfortunately there is a great deal of misrepresentation occurring in ophthalmology today with regard to advertising for advances in LASIK surgery. One of the prime ways marketers mislead consumers is to use an elastic term (such as “custom” or “wavefront”) and then try to include their company in it when the term is not an accurate description of the situation.

Wavefront Terms

Wavefront-driven LASIK clearly is an advance that has had tremendous success both on the public and in terms of peer review documentation. It is to a doctor’s advantage to be able to use words such as “custom”, “customize” or “wavefront” in describing a treatment.

The term wavefront-driven or wavefront-guided refers to a new laser diagnostic system that captures a map or “fingerprint” of the eye which is 25 times more precise than what was previously measurable by standard methods. Wavefront-guided LASIK represents technology, such as the CustomVue procedure, and to use that terminology to describe other conventional laser technologies is misleading.

The term “wavefront-optimized” refers to a conventional laser vision correction procedure with a more prolate shape based on a manifest refraction. This system is an advance over conventional LASIK surgery, but it is not “wavefront-driven LASIK,” nor is it “custom LASIK” nor is it “wavefront-guided LASIK.” Using the term “wavefront-optimized” is misleading.

What is “Custom”?

Precise language delivers the correct message to patients.

By J. Trevor Woodhams, M.D.

The unfortunate issue is that numerous websites use incorrect nomenclature when referring to the Wavelight procedure. For example, one website states, the system “incorporates wavefront principles into a standard platform.” Another reads, “integrating an important wavefront-guided treatment feature in standard laser vision correction.” While such language may not be deliberately misleading, I am not sure it would meet the criteria of ethical advertising.

Several other sites refer to the Allegretto laser procedure as “customized refractive surgery.” This statement goes off from a gray area into false and misleading advertising.

Marketing

Such statements confuse patients who do not understand the technology, as well as those in the field of ophthalmology. At my practice we do not use the word “custom”, which can be defined in different ways by different people, in our patient education materials. Instead, we use the more precise words such as wavefront-guided LASIK and then we explain the procedure to patients in a language that they can easily understand.

The word “custom” can be confusing because other laser platforms also use the term to describe their wavefront-driven product. While this is understandable, it tends to lead the public to believe that one wavefront-guided laser system is the same as another. For instance, patients sometimes think various technologies are from just one company or “custom” is the name of the laser.

However, the VISX laser, especially with the Fourier-based algorithm, represents new and advanced technology that I believe is better.

Defining Terms

Ophthalmology organizations such as The American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery should convene a joint committee of nomenclature to clarify terminology.

Today, technology changes far faster than doctors can keep up with sometimes. A central clearing house of definitions and nomenclature in the eye care field would help doctors and the public sort out claims and representations.

J. Trevor Woodhams M.D. is in private practice at Woodhams Eye Clinic in Atlanta, GA



US Air Force Aims for “Weapons Grade Vision” USAF Approves Custom LASIK for Certain Aviators

By Col. Robert E. Smith II, M.D.

In June 2004, the Vice Chief of Staff and the US Air Force Surgeon General approved wavefront-guided LASIK (WFG-LASIK) for aviators in aircraft with cabin altitudes of less than 14,000 feet.

At this time, WFG-LASIK is not approved for those aviators in high performance aircraft (such as fighters and trainers) or those whose aircraft have cabin altitudes potentially above 14,000 feet. Conventional LASIK was not approved for any aviator.

The advantages of LASIK are quicker visual recovery, no long-term use of topical steroids, and decreased incidence of visually significant haze. WFG-LASIK is a major Warfighter readiness issue and these advantages allow for less down time and quicker return to the cockpit for the Air Force’s aviation population. This is critical in today’s expeditionary forces environment. WFG-LASIK is a “performance enhancement procedure” and AF pilots feel as if this surgical procedure gives them a competitive or combat edge in the fight.

I performed the first aviator WFG-LASIK treatment in September 2004 using the VISX S4 platform. That aviator now has 20/12 UCVA (better than his BCVA preop) and states that his night vision performance has been tremendously improved.

This is the typical result that I call an “improvement to the human weapon system” which gives our pilots the competitive edge in their work environment.

The Air Force now has five Warfighter Refractive Surgery Centers. Since Aug 2000 when it was approved by the AF Surgeon General and the Chief of Staff, the Air Force has done more than 25,000 treatments on its Warfighters with approximately 25% of those being conventional and custom LASIK using the VISX S4 platform.

The Air Force is currently involved with Dr. Steve Schallhorn and the US Navy in a collaborative WFG-PRK study to obtain FDA approval for WFG-PRK using the new VISX Fourier Custom treatment algorithms. Initial results are very promising with quality vision (contrast sensitivity) results better than the original Zernike-based custom treatment profiles.

Col. Robert E. Smith II, M.D., Chief of Cornea/Refractive Surgery at the USAF Wilford Hall Medical Center Dept of Ophthalmology in San Antonio, TX, leads USAF Refractive Surgery as the USAF Surgeon General Refractive Surgery Chief Consultant and the Program Manager of the USAF Warfighter Refractive Surgery Program.





“ In order to develop an individualized nomogram, a careful retrospective analysis of your refractive results at various stages is required. ”

Kenneth A. Greenberg, M.D.

A number of very important changes in the VISX Fourier Wavefront Upgrade will have an impact on your clinical results. Here is a brief review of these changes and a discussion of how to integrate the upgrade with your current CustomVue nomogram.

Fourier wavefront upgrade

A 4.5% boost in the entire WaveScan-defined ablation has been made to compensate for the small mean undercorrection (-0.2 D) experienced in the U.S. FDA Multi-center Clinical Trials. This boost will affect the entire wavefront ablation including sphere, cylinder and higher order terms (See table 1). A careful analysis of the effect this 4.5% boost will have on your results is required.

Percentage nomogram adjustment

The Percentage Nomogram Adjustment allows the surgeon to make a percentage adjustment to the entire WaveScan®-defined ablation. A maximum adjustment of $\pm 10\%$ is allowed. The Percentage Nomogram Adjustment is in addition to the 4.5% boost.

The Percentage Nomogram Adjustment does not change the shape of the ablation. A greater or lesser number of pulses are used to achieve the WaveScan-defined target shape (including higher and lower order terms). As a result, the Percentage Nomogram Adjustment does not affect the calculated depth (Maximum Ablation Depth).

The Percentage Nomogram Adjustment should be used to compensate for results based on individual differences in environmental conditions and surgical techniques after a critical review of refractive results. These variables include but are not limited to surgical technique, environ-

Experiences Developing a Successful Wavefront Ablation Nomogram

Implementing a precise nomogram with the VISX Fourier Wavefront Upgrade is key to optimizing CustomVue outcomes.

By Kenneth A. Greenberg, M.D.

mental conditions (temperature, humidity, elevation,) patient age, refractive error, and microkeratome type. The Percentage Nomogram Adjustment is preferred for nomogram adjustment purposes because it adjusts the entire wavefront treatment (not only the sphere). The Percentage Nomogram Adjustment is different than the Physician Adjustment.

Physician adjustment

The Physician Adjustment allows the surgeon to adjust the spherical component of the WaveScan refraction only by $\pm 0.75D$. The Physician Adjustment option is still available on VISX® Fourier Wavefront Upgrade and it should be used as an endpoint adjustment to deviate from emmetropia (e.g., planned Post-Operative target of -0.25 in a 55 year old patient).

If both the Physician Adjustment and the Percentage Nomogram Adjustment are selected simultaneously, then the following warning will be displayed on the screen: WARNING!

The simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment has not been studied in controlled investigations, and should not be attempted until the accuracy of the nomogram setting has been verified for the same laser, treatment conditions, and type of treatment.

CustomVue™ Nomogram Development

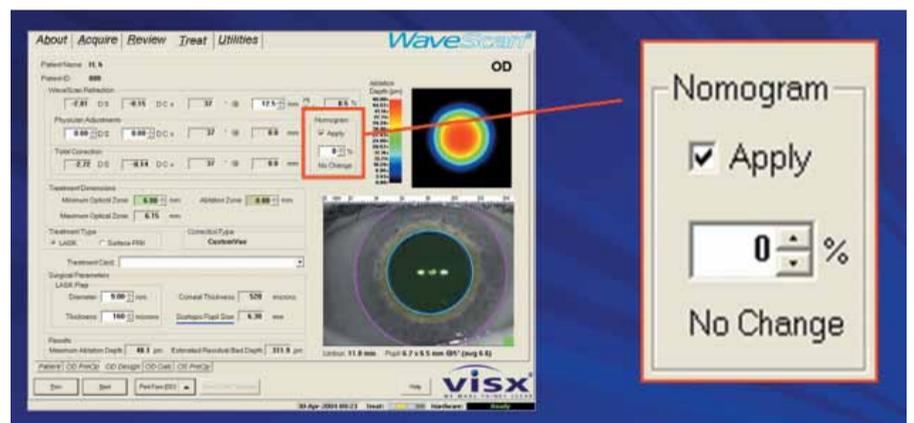
Although nomograms were not used in the CustomVue™ FDA Multi-center Clinical Trial, environmental conditions and surgical techniques were standardized. Post-FDA approval, environmental conditions and surgical techniques may vary from site to site and surgeon to surgeon. VISX anticipated this variability and has provided the flexibility to customize the CustomVue Procedure.

Nomograms for CustomVue™ Myopic LASIK typically involve an increase in the WaveScan®-defined ablation. Due to individual variations in environmental conditions and surgical techniques, a cautious use of a nomogram adjustment can be considered.

In order to develop an individualized nomogram, a careful retrospective analysis of your refractive results at various stages is required (30 days, 60 days, etc). At least 50 eyes with at least one and preferably three months of follow up data should be evaluated to develop a meaningful CustomVue™ nomogram. Start out slowly with

Pre-operative WaveScan Spherical Equivalent	Magnitude of 4.5% Boost
-1.00 D	0.045 D
-2.00 D	0.090 D
-3.00 D	0.135 D
-4.00 D	0.180 D
-5.00 D	0.225 D
-6.00 D	0.270 D

This table lists the approximate magnitude a 4.5% boost will have based on Pre-Operative WaveScan Spherical Equivalent.



The VISX CustomVue system allows the clinician to apply a nomogram adjustment to the entire wavefront correction.

nomogram modifications, changing one variable at a time. CustomVue™ nomograms should be based on alterations to entire wavefront utilizing the Percentage Nomogram Adjustment.

Calculating a PNA

One method that may be used to produce a Percent Nomogram Adjustment is based on the following calculation:

Step 1: For each CustomVue™ patient, perform the following calculation Post-Operatively (Post-Op MRSE / Pre-Op WaveScan® Spherical Equivalent) x 100

Step 2: Calculate the mean percent for all CustomVue™ patients

Integration

There are several options for Integration of current CustomVue™ Nomograms with VISX® Fourier Wavefront Upgrade:

1. Do not initially use the Percentage Nomogram Adjustment or Physician Adjustment

2. Continue to use your current Physician Adjustment by using a Percentage Nomogram Adjustment to account for the 4.5% Boost
3. Continue to Use Physician Adjustment by modifying current Physician Adjustment to account for 4.5% boost
4. Conversion of current Physician Adjustment to Percentage Nomogram Adjustment

Conclusions

Regardless of the method you select for the use of a CustomVue™ Nomogram, a careful ongoing retrospective analysis of your results is required. The Percentage Nomogram Adjustment is the preferred option for CustomVue™ nomograms because it affects the entire WaveScan-defined ablation.

Kenneth A. Greenberg, M.D. is the Medical Monitor for VISX, Incorporated



“ Given that clinical results with all three lasers are comparable in my experience, these practical differences in timing become more relevant to the decision-making process. ”

Louis E. Probst, M.D.

Key Practice Flow Considerations in an Active Wavefront Practice

When clinical outcomes are comparable, consider the time added to the surgical procedure for each wavefront system.

By Louis E. Probst, M.D.

laptop computer at home or from another office.

The Alcon system requires dilation for both acquisition and treatment, so it is highly recommended that both be done on the same day.

Because the Bausch & Lomb system requires a dilated pupil for wavefront acquisition but an undilated pupil for treatment, it is practically impossible to capture and treat on the same day. This can be a barrier to treatment for a patients who must travel a considerable distance. It also presents logistical challenges for surgeons who do consultations in multiple offices that don't all have an aberrometer, those who use open-access centers, or those with a strong O.D. comanagement network.

Ablation

The surgical procedure time is very similar for the VISX and B&L platforms, at seven and eight minutes, respectively.

Much of this timing difference is due to the lasers' spot sizes and speed. The VISX Star S4, for example, operates at 10-20 Hz with a variable spot size from < 1 mm to 6 mm, for an extremely fast ablation. A typical -4 or -5 custom myopic treatment might require 45 seconds of ablation time.

The Zyoptix treatment card adjusts the Technolas' 2 mm beam to 1 mm for about half the treatment, but it is a cumbersome mechanical process that really slows down the ablation time to two minutes or more for the above example. This is true only for U.S. laser systems, which operate at 50 Hz. Internationally Zyoptix ablation times are comparable to the other platforms.

The Alcon LadarVision laser operates at 60-70 Hz with a small spot of less than 1 mm. There are advantages to the precision of the small spot, but because the LadarVision system can't use a larger spot for the gross corrections, the average treatment might take closer to 3 minutes.

Conclusion

As you can see from the chart, the VISX CustomVue™ system adds the least time to a LASIK case—about 13 minutes. Bausch & Lomb Zyoptix takes only a bit longer, at 38 minutes, but there is a significant inconvenience in that measurement and treatment cannot take place on the same day. The additional time required for a CustomCornea procedure is up to four times that required for the other two systems, largely due to dilation.

Company	Wavefront Measurement	Wavefront Ablation
VISX, Inc. CustomVue	Natural Physiologic Pupil	Natural Physiologic Pupil
Bausch & Lomb Zyoptix	Pharmacologically Dilated Pupil	Natural Physiologic Pupil
Alcon CustomCornea	Pharmacologically Dilated Pupil	Pharmacologically Dilated Pupil

Dilation requirements for U.S. wavefront systems.

	VISX CustomVue	Alcon CustomCornea	B&L Zyoptix
• Acquire centration images	-	2 minutes	-
• Pharmacological dilation	-	26 minutes	20 minutes
• Torsional eye marking	-	2 minutes	-
• Wavefront exam acquisition	2 minutes	10 minutes	8 minutes
• Surgeon planning of WF ablation*	4 minutes	2 minutes	2 minutes
• Average WF LASIK procedure time	7 minutes	11 minutes	8 minutes
• Total time for WF procedure	13 minutes	53 minutes	38 minutes*
• When can WF data be acquired for driving procedure?	Surgical Day or Before	Surgical Day Only	Before Surg Day Only
* VISX only platform with ability for laptop programming of wavefront ablation parameters. * Wavefront acquisition and LASIK procedure must be performed on separate days.			

Almost an hour can be saved by choosing the most efficient platform.

Given that clinical results with all three lasers are comparable in my experience, these practical differences in timing become more relevant to the decision-making process.

Louis E. Probst M.D. is Regional Medical Director of TLC Vision laser eye centers in Chicago, IL, Madison, WI, and Greenville, SC. He is a paid consultant to VISX.

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The advent of wavefront technology has brought better outcomes across the board, but it has also added additional steps and time to the conventional LASIK procedure. I have had experience with three different platforms for wavefront-guided surgery (Alcon CustomCornea, Bausch & Lomb Zyoptix, and VISX CustomVue™) and believe that all three are capable of producing excellent results. I timed how long it took me personally to perform each step of the wavefront acquisition, treatment planning, and ablation process for 10 cases on each of the laser systems.

Acquisition

The Alcon system definitely requires more steps in the acquisition process than either of the other platforms, and the requirement for full pharmacological dilation adds tremendous time. The Bausch & Lomb system also requires pharmacological dilation, but only to 6.5 mm, so in this case the dilation only adds about 20 minutes to the total procedure time, rather than 26 minutes with the Alcon system.

Planning and data transfer

With any of the systems, the surgeon needs under 5 minutes to plan the treatment based on the wavefront maps. There are some differences, however, in when and how quickly one can move from measuring to treating.

The VISX system allows for wavefront images to be acquired the day of treatment or at an earlier visit. A new feature, which I like, is the ability for the surgeon to plan treatments on a

