Building a Wavefront-Driven Refractive Practice: Optimizing Results, Expanding Indications, and Applying the Latest Technology

Leading clinicians report on exciting advancements in US clinical trials and share their personal experience with recently approved wavefront technologies such as Fourier Analysis and Iris Registration.

Inside:
- The Cosine Effect: Compensating for Unique Corneal Geometry with Peripheral Ablations
- US Presbyopia Clinical Trial: The First Report
- Report from the U.S. Clinical Trials: High Myopia and Mixed Astigmatism
- Can Iris Registration Improve a High Volume Practice?
- The Impact of Iris Registration on Cylinder, Acuity and Visual Quality
- “Optimized” vs. Wavefront-Guided Ablations: Is There a Difference?

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The shape of the anterior cornea has a significant effect on laser-tissue interaction and must be taken into consideration to achieve the desired wavefront-guided LASIK ablation.

The Cosine Effect, which is the loss of laser energy as a result of both reflection and area expansion, occurs as the laser moves from the corneal center to the periphery. To compensate for this energy loss, additional laser energy (pulses) is placed in the corneal periphery.

Using actual patient K values versus the default K value is an important factor in reducing induced spherical aberrations.

By Louis E. Probst, M.D.

As the laser moves from the corneal center to the periphery, laser energy is reflected and the beam becomes ovalized.

Energy Loss

Understanding what happens to laser energy at the center of the cornea versus the periphery is key to achieving the most accurate ablation. Corneal power, reflection, and area expansion are the major factors involved in laser energy loss at corneal periphery.

Corneal power is a measure (in diopters) of the capability of a lens to converge (plus lens) or diverge (minus lens) light rays. Reflection involves the bouncing back of light rays by a mirror-like surface. Area Expansion is the ovalization of the laser beam.

For example, for typical corneas (K = 44 D), at a distance of 3 mm from the vertex, the fluence loss is 2.5% for reflection, and 8.1% for area expansion.

The VISX laser uses algorithms to compensate for reflection and area expansion by increasing the number of pulses fired in the periphery. VISX has compensated for the Cosine Effect since 1986.

However, if no K value is entered into the laser, the system uses a default K value of 44 D. The default K value was determined by analyzing a population of patients.

Using actual patient K values versus the default K value is very important because the amount of the compensation of the cosine effect is dependent on the K values. The Cosine Effect is due to the relative steepness in the cornea. Therefore, a steeper cornea requires more compensation than a flatter cornea. If the patient has a steep cornea and the actual K’s are not entered, the laser will use the default. Therefore, full compensation will not be used and the patient will not get the full benefit of the treatment.

Case Studies

For a -5D myopic treatment case study in which no K’s were compared to actual K’s, the patient had a 6 mm pupil, and a 6mm OZ, 8mm AZ. The actual K was 44D. Figure 2 shows the treatment profile difference if no K values are used. In a case such as this when no K value is used compared to the actual K value, as much as 0.14 microns of spherical aberration can be induced in this -5D myopic treatment.

For a +5D hyperopic treatment case study in which the default K was compared to the actual K, the patient had a 6 mm pupil, a 6mm OZ, and a 9.5mm AZ. The actual K reading was 30D and the default K was 44D. Figure 3 shows the treatment profile difference. In a case such as this one, using the default K value compared to the actual K values as much as 0.38 microns of spherical aberration can be induced in this +5D hyperopic treatment.

By entering the actual K values on this case, versus using the default K values, 0.38 microns of additional spherical aberration is treated in this +5D hyperopic case.
Better Wavefront Results With Fourier

By following key guidelines, surgeons can optimize custom LASIK outcomes

By Eric Mandel, M.D.

Results from a three-month, wavefront-guided LASIK study using the CustomVue procedure with the Fourier algorithm showed superior results, when compared with treatments using CustomVue with the Zernike algorithm. Surgeons can optimize their wavefront-guided results by following several key guidelines culled from my wavefront-guided LASIK clinical experience, as well as from my teaching and consultation with many LASIK surgeons.

The Study
The prospective study included our first 51 eyes that underwent Fourier CustomVue treatment at their first point of stability 10 to 16 weeks post-op. These patients were the first eyes to have Fourier analysis and treatment in our practice. There was no learning or transitional period.

Of the first 51 eyes treated, 100% were 20/20 or better, and 100% of patients did not complain of any significant or problematic glare or halo. The vast majority of patients met or exceeded their expectations. Some surgeons even felt their expectations were improved, but not as high as their expectations. In our CustomVue Zernike study presented several years ago, we first achieved 95% of eyes with 20/20 or better in the same group.

Getting Better Results
Some surgeons have remarked that when they switched from conventional LASIK to wavefront-guided LASIK with Zernike, or from Zernike to Fourier wavefront-guided LASIK, their results were improved, but not as high as their expectations. Some surgeons even felt that conventional surgery achieved more consistent results.

This study proves that using the Fourier algorithms and treatments yield excellent results. Surgeons who follow these guidelines can help optimize their best possible outcomes:

1) Acquire Wavefront Information the Day of Surgery. High volume surgeons often contend that this step takes too much time and hinders patient flow on the day of surgery. Instead, they often use wavefront data that is days or weeks old. However, in my experience, I find that it is best to do the wavefront acquisition the same day as the surgery.

2) Remove Contact Lenses Earlier. Patients who have their contacts out during the procedure the longest period of time prior to surgery have better results. Surgery is then performed on the eyes in their most natural and non-iatrogenic state. This is more important today than ever before because we have learned that not only hard lenses, but also soft and toric lenses can warp the corneal surface.

Therefore, we require patients to remove soft lenses a minimum of two weeks pre-op, and toric and gas permeable lenses a minimum of three weeks.

3) Lubricate, Lubricate, Lubricate. Aggressive pre-operative lubrication is essential. We treat pre-operatively with tears, ointments at night (like Refresh PM, Allergan, Irvine, Calif.), and, often, with silicone or hydrogel plugs. We also use Restasis (Allergan) extensively both pre- and post-operatively.

4) Acquire Wavefront Information Carefully. It is very important to employ an experienced technician with exquisite attention to detail. The technician must make sure patients do not accommodate while acquiring wavefronts. Accommodation can significantly affect lower and higher-order aberrations.

This technician should also ensure that each patient's head is in the correct position while the wavefront data is being acquired. The technician should check to make sure the chin does not tilt up or down, and their eyes do not slightly roll up (Bell's reflex).

Also, it is very important that the surgeon check to make sure that fluid from the tear film does not egress onto the stromal bed creating an irregular ablation.

5) Intra-operative Tips and Technique. During surgery, surgeons can prevent a slightly off-axis ablation (Cosine Effect) and avoid suboptimal results by making sure the patient's actual K values are used; that the chin does not tilt up or down, and their eyes do not slightly roll up. Extra equipment such as backup humidifiers, dehumidifiers, and portable air conditioner units on hand in the OR to make sure the proper conditions can be maintained at all times.

6) Keep Humidity and Temperature Tightly Controlled. Consistent humidity and temperature in the operating room are very important. Keep extra equipment such as backup humidifiers, dehumidifiers, and portable air conditioner units on hand in the OR to make sure the proper conditions can be maintained at all times.

7) Less Illumination, More Dim Lighting. Dim lighting during surgery is better for patient comfort, and it also helps avoid a shifting pupil centroid. With dim lighting on a non-dilated pupil, the laser system will keep the pupil centroid in the best location.

8) Optimize Healing. Adequately preparing the patient's surface pre-operatively and quickly repositioning the flap with minimal handling will minimize the amount of post-operative healing and remodeling.
Early results are promising for wavefront-guided laser vision correction of hyperopic presbyopia

By Colman R. Kraff, M.D.

Results have been very promising from a U.S. study to determine the preliminary safety and effectiveness of CustomVue WaveScan-guided LASIK for the treatment of presbyopic patients with hyperopic refractive errors.

VISSX has developed a patented, multifocal ablation profile designed to give patients good uncorrected near and distance vision in the same eye. Using Variable Spot Scanning, the laser creates a subtle change in the ablation shape derived from the subject's wavefront map.

The goal is to provide near vision in the steepened central zone, and distance vision in the peripheral zone. 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 beyond what monovision can offer.

Ultimately, I would expect that the patients who respond best to this treatment will be low hyperopes in the presbyopic age group.

Case results

The preliminary results have been outstanding. Corrections have been accurate and predictable, and patient satisfaction with both near and distance uncorrected acuity has been high.

Colman R. Kraff, M.D.

Three months after treatment, his manifest refraction in that eye was -0.25 +0.50 x 125. He has 20/20 uncorrected distance vision and 20/32 intermediate vision. Uncorrected near vision improved six lines from 20/160 to 20/40, compared to a two-line gain in the monofocal eye.

Binocular near acuity increased five lines to 20/32. Both eyes achieved 20/20 distance UCVA. There was no significant loss of best-corrected acuity although the multifocal eye lost one line of distance BCVA, from 20/16 to 20/20.

The distance vision obtained by patients in this trial is at least as good, and possibly better than we would expect from hyperopic CustomVue. The use of Iris Registration in this trial may be a factor in the outcomes due to better cyclotorsional alignment.

If the results continue in this vein, a multifocal wavefront-guided treatment could become my treatment of choice for presbyopic patients.

Case Study

54 year old female

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Wavefront-guided laser vision correction offers excellent quantity as well as quality of vision
By Terrence P. O’Brien, M.D.

L
ike others who participated in the VISX CustomVue high myopia clinical trial, I was excit-
ed about the opportunity to provide customized laser vision correction to patients with, arguably, the most to gain from the treatment. However, we also had some very specific concerns going into this trial. In patients with high refractive error, one must already remove a lot of tissue. A custom treatment removes slightly more tissue than a conventional one, so there were concerns about the potential for creation of iatrogenic kerat-ectasia. Because of this, we were very careful with pre-operative and intra-
operative monitoring to leave at least 250 microns of tissue remaining in the stromal bed after the ablation.

Study design
Ninety-two patients were treated in the clinical trial. All were treated bilaterally (184 eyes), and all of the eyes were targeted for emmetropia. We were able to make use of the new Fourier wave-
front reconstruction algorithm for more precise wavefront maps, and Variable Repetition Rate for faster treatment times. Both of these are now standard for all CustomVue procedures.

Pre-operative refractive error was quite high, with average sphere of -8.0 (±1.4 D, range -5.5 to -11.3 D). Average cylinder was -1.0 D (±1.0, range 0.0 to -5.3 D). Manifest refraction spherical equivalent was -8.5 D (±1.3, range -6.4 to -11.8 D).

Results
At six months, 98% of the eyes were seeing 20/40 or better uncorrected, 84% were 20/20 or better, and 65% were 20/16 or better. Three-quarters had the same or better post-op UCVA compared to their pre-op BSCVA. Among the spherical myopes, 99% were 20/20 or better uncorrected, with 84% 20/16 or better at six months.

Not surprisingly, these patients - many of whom had been wearing glasses since kindergarten or earlier - are ecstatic with the dramatic change in their visual performance."

Terrence P. O’Brien, M.D.

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VISX CustomVue mixed astigmatism receives FDA approval

By Stephen Coleman, MD

The CustomVue treatment for mixed astigmatism is demonstrating positive results at nine months, with 74% of eyes achieving 20/20 or better uncorrected visual acuity (UCVA), and 99% achieving 20/40 or better UCVA.

The FDA recently approved the VISX CustomVue LASIK procedure for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1 D to 5 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs.

The VISX CustomVue mixed astigmatism procedure is proving to be the treatment of choice for high myopes. However, that has certainly not proven to be the case.

Visatracor Mixed Astigmatism

At nine months, UCVA was excellent, with 74% of eyes 20/20 or better, 87% 20/25 or bet-

ter, and 99% 20/40 or better. Stability was achieved at three months post-op. One hundred per-
cent of eyes maintained 20/16 at all visits.

The accuracy of the sphere was also impressive. At nine months, 77% of eyes were within ± 0.5 D of intended MRSE. In a survey of patients regarding vision at night, 63% said they were satisfied or very satisfied pre-op (with glasses), and this improved to 89% post-op (without glasses). For vision at night with glare, 38% of patients were unsatisfied pre-op, and this number decreased to 8% post-op. Patients also reported that their frequency of halos around lights decreased, as did their post-op frequency of glare.

For best spectacle corrected visual acuity (BSCVA), no eye lost more than two lines of BSCVA.

High Myopia Uncorrected Visual Acuity

At 6 months, 65% of patients were 20/16 or better, while 84% are 20/20 or better uncorrected.

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ter, and 99% 20/40 or better.
Iris Registration a Far Greater Advance than Anticipated

This new technology is able to identify and compensate for small amounts of cyclorotation that can have a large impact on post-op results

By 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 the past, some surgeons have marked the cornea while others have relied on careful positioning and observation to ensure that the cornea was properly aligned and the treatment well centered.

VISX has recently introduced automated Iris Registration (IR) for its CustomVue system. IR relies on matching reference points in the natural iris pattern to compensate for cyclotorsion and pupil centroid shift between the time of wavefront capture and the ablation.

I expected this new process to be of incremental value and, to be honest, doubted that I actually needed it. But now that I’ve used IR for several months, I find myself increasingly reliant on it. Moreover, I’ve been humbled to realize how flawed my own judgment of centration and alignment really is. Whereas I was once quite confident that I could recognize significant cyclotorsion when it happened, I now know that it is entirely possible for an eye to be 4-5 degrees cyclotorted without my being aware of it in the least.

A couple of my recent cases illustrate what might have happened had I not been using Iris Registration. In one, a 55-year-old male with high cylinder preop (+0.25 - 4.50 x 164 OS) cyclotorted 5.8 degrees. Without IR, this patient would have had induced sphere and cylinder, and poor quality of vision.

IR Pearls

Iris Registration compares iris markings in two images—one taken at the WaveScan during surgery. With IR, he had an excellent outcome and maintained his preop BCVA of 20/20. Without it, he would have had induced sphere and cylinder and poor quality of vision.

Case Study

Without IR, this patient would have had induced sphere and cylinder, and poor quality of vision.

IR Results in Less Cylinder, Better UCVA Postop

A multi-center study finds significant differences between treatments with and without IR

In a retrospective analysis of data from four international centers, Iris Registration has made a significant difference in outcomes. In 270 primary laser vision correction patients with preop BCVA of 20/20 or better, the mean cyclo torisional movement was 2.4 ± 2.0 degrees.

A comparative analysis was conducted on a subgroup of eyes with 1.5 D or greater preoperative cylinder. Cohort A (n=57) was treated without IR. Cohort B (n=59) was treated with IR. The two groups had similar levels of cylinder preop. Postop, the IR cohort had 50% less cylinder (0.2 D, compared to 0.4 D for the non-IR cohort).

Additionally, there was a statistically significant difference between the two groups in the percentage of eyes achieving 20/20 or better UCVA postop. Ninety-two percent of the IR cohort, versus 82% of the non-IR cohort, was 20/20 or better at the last postop visit.

At one of the centers, Dr. David Chao Kai Chang, of Taipei, Taiwan, performed a contralateral eye study in which 26 patients received CustomVue with IR in one eye and CustomVue without IR in the other. At one week postop, nearly half the patients (46%) had better uncorrected vision in the eye treated with IR. Not a single patient had better UCVA in the non-IR eye.

The IR cohort has 50% less post-op cylinder than the Non-IR cohort.

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The Impact of Iris Registration on Cylinder, Acuity, and Visual Quality

Proper alignment of wavefront-guided ablations is key to reducing post-operative visual complaints

By Julian Stevens, F.R.C.S.

A recent study of 69 eyes that received wavefront-guided LASIK using VISX Iris Registration demonstrated that the technology had more precise alignment, prevented angle errors, and helped improve outcomes, according to Julian Stevens, of Moorfields Eye Hospital, London.

Angle and Rotation

Dr. Stevens notes that Iris Registration is an important advancement in wavefront-guided LASIK, according to Dr. Stevens.

The iris registration technique is flexible for both PRK and LASIK. In addition to compensating for cyclo-torsional error, this upgrade also compensates for any pupil centroid shift from the WaveScan pupil to the pupil image under the laser.

Future Outcomes

The Iris Registration technology is an important advancement in wavefront-guided LASIK, according to Dr. Stevens.

This technology provides instant feedback. For the first time, surgeons and staff receive feedback as to how well we’re aligning our patients."

By Julian Stevens, F.R.C.S.
“Optimized” vs. Wavefront-Guided Ablations: Is There a Difference?

Regardless of pre-operative aberration structure, wavefront-guided ablations provide a better result than both conventional and wavefront-optimized ablation

By Steven C. Schallhorn, M.D.

Wavefront-optimized refractive surgery is a technique in which extra laser pulses are added in the periphery of the cornea in an attempt to reduce the induction of spherical aberration commonly associated with conventional LASIK. The correction is not customized in the sense that we typically think of a “wavefront” procedure being customized. Rather, it is based on the patient’s sphere and cylinder prescription, just as in conventional LASIK.

And as with conventional LASIK, a wavefront-optimized procedure aims to correct only lower-order aberrations; namely, sphere and cylinder. To the extent that it can do this without inducing as much spherical aberration as LASIK typically induces, wavefront-optimized surgery is certainly better than conventional surgery. But that doesn’t necessarily make it as good as wavefront-guided surgery.

A “Wavefront-Guided” (WFG) refractive surgery procedure enables the surgeon to measure all of the eye’s aberrations—both lower- and higher-order aberrations—and then designs a customized treatment profile based on those aberrations.

The visual improvement from a WFG treatment would be very apparent in a patient with significant pre-op, higher-order aberrations (HOA). The greater the pre-op HOA, the greater is the benefit from a wavefront-guided procedure in addressing those aberrations. Offering wavefront-optimized surgery only to those with very low HOA would require wavefront aberrometry on all patients, and then selection criteria based on the aberrations.

However, the visual advantages of WFG over optimized should also be evident in patients without significant pre-operative higher aberrations. An optimized procedure is designed to reduce the induction of spherical aberration. However, other higher-order aberrations, such as coma and trefoil, are also induced by conventional LASIK.

The optimized procedure will likely induce these same aberrations. Of note, WFG surgery also reduces the induction of these other aberrations. The net effect is an improved quality of vision with a WFG procedure.

We tested this theory by creating a model of the visual effect of aberrations induced by the procedures. Three real patients were analyzed. The first had a “normal” level of HOA, the second had an elevated level of HOA (representing a therapeutic treatment of a post-conventional LASIK patient), and the third had negative spherical aberration.

Each patient was theoretically “treated” with three LASIK ablations: conventional, optimized, and WFG. All three treatments were assumed to perfectly correct sphere and cylinder. The induction of higher-order aberrations was patterned after our large population studies of both conventional and WFG LASIK. The mean and standard deviation of each higher-order term was calculated. Using these standard deviations, a random wavefront map was created for each treatment modality, which had the appropriate RMS value for the induced HOA.

For the optimized procedure, no post-op change in spherical aberration was assumed, while other higher-order terms were induced similar to a conventional procedure. Comparison was done with maps, point-spread functions, and a convolved letter E.

In the first two patients, the optimized procedure resulted in improved visual quality over conventional. However, the WFG procedure was superior to both conventional and optimized, primarily due to less induction of higher-order aberrations, not just the spherical term. In the third patient, who had negative spherical aberration, the visual result of conventional was actually better than optimized. This is significant as 5-10% of the population has negative spherical aberration.

This is because conventional LASIK induces positive spherical aberration, hence reducing the amount of this aberration in this patient. Even in this patient, the WFG procedure was still superior to both other treatments because it was able to measure and treat the negative spherical aberration.

No wavefront-guided platform has fully achieved the goal of induceing zero aberrations and/or completely eliminating all pre-existing aberrations. But as we learn more about higher-order aberrations, how to correct them, and what they mean for vision, the value of platforms that can adjust corrections based on this information will become greater and greater.

Wavefront-optimized treatments may be better than conventional for most patients because they induce less spherical aberration. However, the future lies not in simply optimizing corrections for a population mean, but in further perfecting individually customized corrections.

Treatment Outcome Comparison

Modeling of 3 real patients with 3 different LASIK ablations. All 3 treatments were assumed to perfectly correct sphere and cylinder. Using induced HOA standard deviations from our large data sets, a random wavefront map was created for each treatment modality.