Customized Laser Vision Correction

Three surgeons discuss their preferences for customization.

BY ARTHUR CUMMINGS, MB ChB, MMed(Ophth), FCS(SA), FRCS(Ed); DIEGO DE ORTUETA, MD, FEBO; AND STEVEN C. SCHALLHORN, MD

Having access to a variety of custom treatments allows surgeons to enhance quality of life for a broad range of patients.

By Arthur Cummings, MB ChB, MMed(Ophth), FCS(SA), FRCS(Ed)

Customized LASIK can take many forms, as evidenced by opinions from both industry and practitioners. As far as I am concerned, having one profile (standard) with one additional profile (wavefront-guided) hardly constitutes true customization.

The Alcon Laboratories, Inc./WaveLight AG (Fort Worth, Texas/Erlangen, Germany) family of lasers allows one to truly customize a laser procedure. I use the basic profile, which is wavefront-optimized, for approximately 80% to 85% of procedures. When I want to customize the procedure further, I have a host of options depending on where the problem lies. I can do any of the following procedures that, for the correct indication, will give me a better result than the wavefront-optimized procedure:

- Wavefront-guided (based on Tscherning aberrometry data);
- T-CAT (based on Placido-disc data) and Oculink (based on Scheimpflug data) topography-guided;
- Custom-Q (ability to influence target asphericity); or
- *Ray-tracing* profiles (currently under investigation in a multicenter European clinical trial).

DECISION TREE

With so many treatment options, a decision tree is useful to keep things straightforward.

Scenario No. 1. Any patient who is satisfied with his BCVA and experiences no glare or other visual quality issues, especially in scotopic and mesopic conditions, will respond well to the wavefront-optimized profile. The US Food and Drug Administration (FDA) clinical trial showed that wavefront-guided surgeries started outperforming wavefront-optimized cases only when the higher-order root-mean-square (hRMS) error approached 0.40 µm.[1] Higher-order errors less than 0.40 µm did not benefit from wavefront-guided surgery.

Scenario No. 2. If the patient has visual symptoms such as glare, halos, or starbursts or cannot be corrected to 6/6 or better, I consider a customized procedure. In these patients, wavefront data are crucial. Wavefront maps not only identify higher-order errors including spherical aberration, vertical coma, horizontal coma, higher-order astigmatism, trefoil, and quatrefoil, but they also quantify the extent of the higher-order errors.

Errors greater than 0.40 hRMS can benefit from wavefront-guided surgery, especially if C7, C8, and C12 are 0.30 µm or greater. The Tscherning aberrometer allows one to validate the raw data on the retina, to ensure that the software has captured the spots correctly, and to check pupil centration. If the maps are validated and are repeatable, the wavefront-guided procedure can be performed with an expectation of excellent outcomes and a reduction in higher-order errors. This was demonstrated as early as 2004, when the Allegretto (WaveLight AG) received FDA approval for its wavefront-guided mode.[1] The Allegretto demonstrated the ability to reduce higher-order aberrations in FDA clinical trials.[2]

Scenario No. 3. If the wavefront map cannot be validated, and if the main aberration is spherical (C12), I consider using the Custom-Q mode of the WaveLight laser. Here, the target Q value (asphericity) is entered to further refine the ablation profile and to create a more prolate corneal shape postoperatively.

More often than not, I revert to a topography-guided procedure because it too can target a specific Q-value. It also automatically corrects for angle-kappa without having to adjust the laser settings and addresses corneal irregularities. Topography-guided procedures can be based on Placido-disc (Topolyzer; WaveLight) or Scheimpflug technology (Oculyzer; WaveLight); this decision is made by considering data quality (raw data and repeatability) as well as the location of the corneal irregularities (central vs peripheral). Hazy corneas are better mapped by the Topolyzer, as the Oculyzer tends to read an area with haze as steeper than it is. The Oculyzer accurately samples the center of the cornea, whereas the Topolyzer has a central scotoma and interpolates central data. Interestingly, when comparing ablation profiles as graphic presentations on the laser portal software, they typically look similar if not exactly alike. I have not been able to demonstrate that one device delivers better results than the other.[3]

Scenario No. 4. The final ablation profile—worth mentioning briefly, as the study has not formally been completed—is what was formerly referred to as *ray-tracing*. This term will be renamed, because it does not accurately convey where the data that drives this treatment come from. The data are derived by adding the patient's accurate optical biometry to all of the measurements and then calculating the ablation profile using this personalized eye model rather than a generic model such as the Gullstrand model. The most accurate description for the profile may be the *IROC Ocular Modeling Profile*, as it was developed at the Institute for Refractive and Ophthalmologic Surgery (IROC) in Zurich, Switzerland. Data are not derived from the iTrace device (Tracey Technologies, Corp., Houston), as many surgeons assume when the terminology ray-tracing is referred to.

STUDYING RAY-TRACING TECHNOLOGY

A European clinical trial involving three surgeons at three centers (Theo Seiler, MD, PhD, at IROC; Matthias Maus, MD, PhD, at the SehKraft Clinic in Cologne, Germany; and myself at the Wellington Eye Clinic in Dublin, Ireland), as well as Michael Mrochen, PhD, an optical engineer at IROC, was performed with full ethical committee approval for each center. Recruitment was completed in March 2010. More than 120 eyes were treated, and 75 have undergone 3-month follow-up visits at the time this article printed. The trial has already demonstrated the full potential of laser vision correction, surpassing any outcomes that I have previously achieved in terms of UCVA, BCVA, safety, predictability, and management of astigmatism. The majority of patients experience improvement in contrast sensitivity, despite the criteria for enrollment being more than 4.00 D of myopia or more than 2.00 D of astigmatism (as long as the spherical equivalent refraction [SE] was more than -4.00).

I compared 3-month outcomes for all five treatment methods, all with preoperative myopia of more than -4.00 or astigmatism of more than -2.00 with a SE greater than -4.00, so that each group matched the ray-tracing group. The best outcomes were achieved with ray tracing, followed by wavefront-guided, Custom-Q, and wavefront-optimized procedures, respectively. The profile that performed poorest in primary eyes absent serious aberrations was the topography-guided profile. This serves as evidence that topography-guided ablation profiles were primarily conceived for aberrated and complicated eyes, for which validated wavefront maps are impossible to capture.

When dealing with difficult eyes that have small optical zones, decentered optical zones, or irregular astigmatism as a result of previous laser surgery, topography-guided procedures are superior to wavefront-optimized procedures. The advanced profile from IROC has the potential to improve results in secondary eyes. Results are significantly better when the patient's biometric data are taken into account.

CONCLUSION

Being armed with this array of tools, which are able to enhance patients' quality of vision and, hence, their lives, is what custom LASIK is all about.

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Topography-guided algorithms offer the potential to treat highly aberrated corneas.

By Diego de Ortueta, MD, FEBO

All surgeons today should be providing customized patient-oriented laser vision correction treatments, planning the optimum ablation pattern for each eye based on the patient's history, diagnosis,

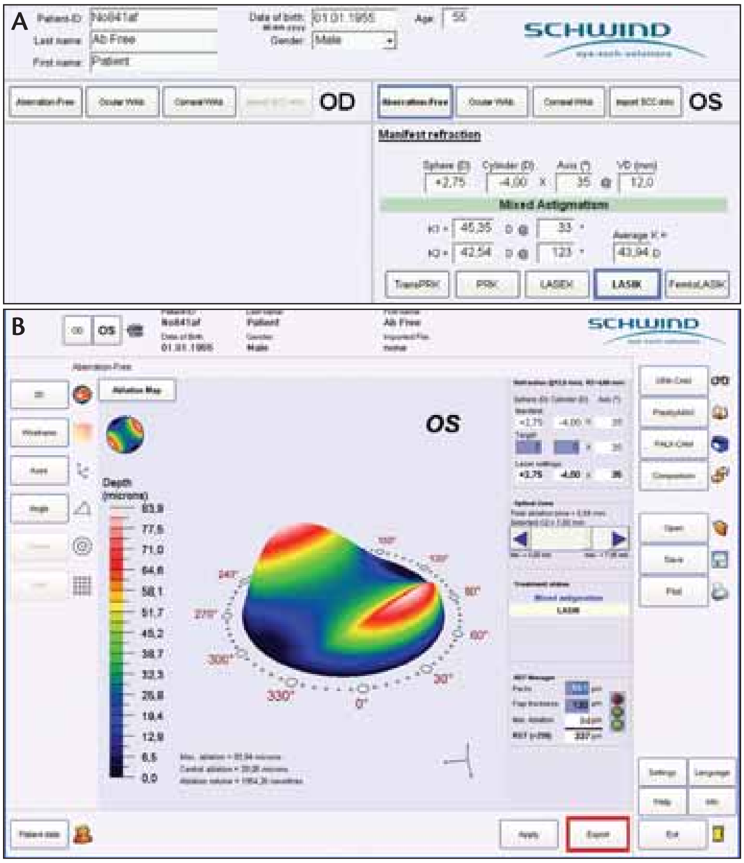

Figure 1. (A) ORK-CAM entry menu. (B) The aberration-free aspheric algorithm available corrects for sphere and cylinder and maintains other existing aberrations as long as they are not symptomatic.

and visual demands. Most surgeons have already transitioned to this type of customized laser vision correction.

The goal of corneal surgery in virgin eyes with good BCVA is to correct the refractive error without inducing aberrations. This means that the ablation profile must consider biomechanics and laser geometry to avoid postoperative increases in aberrations. Aberrated eyes require further customization based on corneal or ocular wavefront measurements.

The aberration-free aspheric algorithm available with the Schwind Amaris excimer laser (Schwind eye-tech-solutions, Kleinostheim, Germany; Figure 1) corrects for sphere and cylinder but maintains other existing aberrations as long as they are not symptomatic. In this way, the ablation profile's effects on existing wavefront aberrations are balanced, providing normal eyes with the best quality of vision.

The aberration-free profile takes into account keratometry data, the corneal vertex position, pupillometry, and dynamic and static cyclotorsion. We use this aberration-free aspheric profile in 90% of patients, selecting those who have good visual acuity and higher-order aberrations less than 0.30 µm under mesopic conditions. We select one of three goals: an aberration-free profile, an aberration-free cornea, or an aberration-free eye. The profile does not induce a significant amount of aberrations.[1,2]

WHY ABERRATION-NEUTRAL TREATMENT?

Studies have shown that eyes with what is called *super-normal vision* (ie, UCVA better than or equal to 20/15) have some optical aberrations,[3] and that individuals with the least aberrations do not necessarily have the greatest visual acuities.[4] Additionally, research in the area of neural adaptation has shown that the plasticity of the neural system allows the brain to correct for distortions in the visual field,[5] but that the brain rejects corrections that are too far removed from its normal experience. Furthermore, moderate levels of wavefront aberration enhance the stability[6] of image quality for wider visual fields. Taken together, these findings suggest that there are at least three visual factors (chromatic blur, depth of focus, and wide field vision) that support the strategy of leaving clinically insignificant amounts of optical aberrations untreated.

The aberration-neutral treatment is optimal for patients whose sight is not affected by existing higher-order aberrations and for those who possess good visual acuity. If higher-order aberrations impair a patient's visual performance, they should be corrected; if that is the case, we recommend wavefront-guided treatments that include corneal and/or ocular wavefront data.

According to some studies,[9,10] wavefront-guided treatments induce fewer aberrations than conventional profiles; however, they do not reduce preoperative aberrations but rather create new ones. Higher-order aberrations seem to be induced in wavefront-driven ablations if the eye has 0.30 µm or less of preoperative higher-order aberrations.[9,10]

Measurement of ocular wavefront entails a degree of artificial noise; it is not always reliable because the wavefront measurement changes with accommodation and pupil shift. The spread of this measurement indicates that there is variability in wavefront measured values, which may be why only patients with higher-order aberrations of more than 0.30 µm benefit from this kind of treatment.

EYES WITH SIGNIFICANT HIGHER-ORDER ABERRATIONS

The eye's internal aberrations are calculated by subtracting the corneal wavefront from the ocular wavefront. If the ocular and corneal aberrations are similar, I default to the corneal wavefront because it encompasses a larger area of information without the influence of pupil size. If the global optical difference between the corneal and ocular wavefront aberrations is more than 0.50 D of defocus equivalent for any eye, the internal wave aberration is considered relevant; in this case, the best treatment is ocular- wavefront–guided if the patient is not age appropriate or does not meet the ophthalmic indications for IOL exchange. If the patient meets the criteria for IOL exchange, laser corneal refractive treatment is not recommended.

Topography-guided or corneal-wavefront–guided algorithms allow the surgeon to treat highly aberrated corneas, such as those with decentered ablations, or corneal pathologies such as scars. The software system incorporates the impact of higher-order aberrations into the refraction so that the expected theoretical objective impact of the higher-order aberrations is balanced by the manifest refraction as measured by the surgeon.

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The future of LASIK is moving beyond 20/20.

By Steven C. Schallhorn, MD

Significant advances have been made in laser vision correction since the first human eye was treated using an excimer laser in 1989,[1] with surgeons and patients alike driving its progress by demanding better results. Aberrometry is one of the most important advances, allowing us to measure and then understand how higher-order aberrations influence vision. The coupling of aberrometers to excimer lasers has led directly to the most sophisticated treatment available today, wavefront-guided LASIK.

QUALITY MATTERS

There is no question that custom laser vision correction is a growing sector of the refractive surgery market. Studies have shown that the worldwide volume of conventional LASIK has dropped by almost 40%, but custom LASIK has grown from approximately 11% of all procedures in 2004 to more than 45% in 2010.[2] At Optical Express, wavefront-guided treatments combined with femtosecond flap creation are mainstay procedures.

Many surgeons believe that cost is the single most important consideration for patients; however, this is not the case. Among 40,000 consecutive patients recently treated at Optical Express centers, approximately 70% paid a premium for all-laser LASIK. Procedure cost is important, but patients are willing to pay a higher price for a procedure that can improve safety and obtain better visual results.

Are the results better with modern technology? Yes. In one published example, which was a comparison of 2,000 treatments, 96% of eyes that underwent wavefront-guided LASIK with a femtosecond laser achieved a UCVA of 20/20 or better at 3 months postoperative, whereas 93% that underwent the procedure with a mechanical microkeratome achieved the same result (P=.01; Figure 2).[3] The group that received the all-laser procedure also had less loss of BCVA in the early postoperative period, with 2.8% of the microkeratome cohort lost 2 or more lines at 1 week postoperative compared with 0.9% in the all-laser group.

HIGHER-ORDER ABERRATIONS AND ADVANCED TECHNOLOGY

Spherical aberration is among the most common higher-order aberrations present after laser vision correction and a potential cause of disturbing visual phenomena. Patients describe these phenomena as glare, halos, starbursts, and doubling or ghosting of images. Unlike defocus and astigmatism, higher-order aberrations cannot be corrected with standard prescription lenses. In contrast to conventional LASIK, which may induce significant higher-order aberrations, especially spherical aberration, wavefront-guided procedures induce less and, depending on the level before surgery, can reduce or eliminate them.

Technology improves as more experience is gained and refinements are incorporated. Laser vision correction has followed this path, with innovations such as iris registration, improved ablation profiles, and pupil centration compensa-

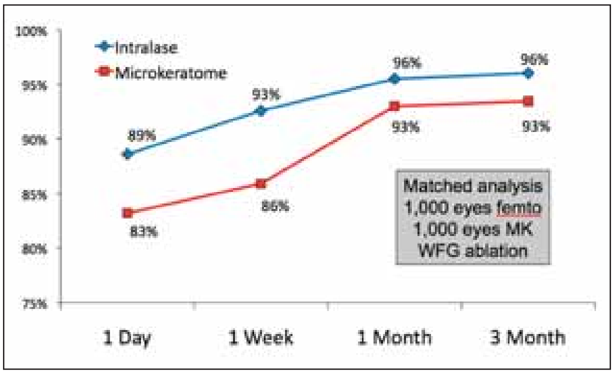

Figure 2. Femtosecond versus mechanical microkeratome: Percentage of eyes achieving 20/20 UCVA.

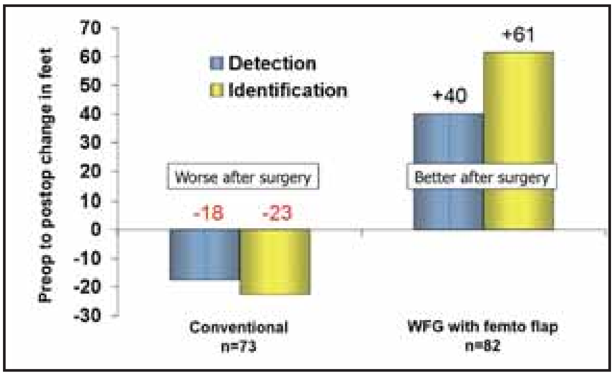

Figure 3. Difference in night-driving performance.

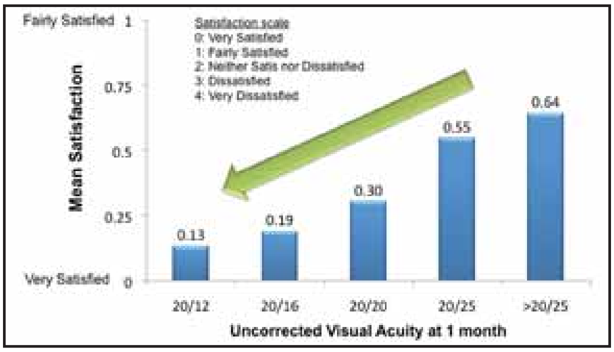

Figure 4. Mean satisfaction as a function of UCVA.

tion. As a testament to the impact these advances have on outcomes, patients' abilities to detect and identify targets were significantly better with custom wavefront-guided LASIK compared with conventional surgery in a study of night-driving performance (Figure 3).[4]

Wavefront-optimized ablation profiles also represent an improvement over conventional treatments. However, the basis for optimized treatment is the manifest refraction, whereas custom wavefront-guided surgery is based on a measurement of all ocular aberrations using an aberrometer. Because of this and other technologic features, such as iris registration, my preference remains wavefront-guided LASIK.

PATIENT EXPECTATIONS BEYOND 20/20

Patient expectations have risen steadily over the past decade. As more patients experience good results, they share their excitement with family and friends. Expectations naturally increase, suggesting that we are victims of our own success. Fortunately, across the spectrum of treatments and around the world, LASIK results have been excellent and are getting better. In more than 90,000 consecutive laser vision correction procedures recently performed with the Visx Excimer Laser (Abbott Medical Optics Inc., Santa Ana, California), more than 60% of eyes achieved 20/16 or better UCVA. The demographics of this group were diverse: The age ranged from 18 to 70 years, preoperative sphere from -12.00 to 5.00 D, and preoperative cylinder from 0.00 to -6.00 D. These remarkable results show that we can now achieve better than 20/20 UCVA in the majority of patients we treat.

It was not long ago that 20/40 UCVA was an acceptable outcome. More recently, we considered 20/20 a good result. Many clinics still do not refract patients or even measure vision beyond that. But the bar has been raised again. In a patient satisfaction study including more than 15,000 LASIK patients, those who had emmetropia as the goal of surgery and achieved 20/16 UCVA had a higher mean satisfaction score than those who achieved 20/20 (Figure 4).[5] Additionally, patients who obtained 20/12 had a higher mean satisfaction than those who achieved 20/16.

The bottom line is that, in order to further improve patient satisfaction, we must think beyond 20/20 and strive to achieve the best possible UCVA. Surgeons can do this by measuring patients beyond 20/20, analyzing outcomes, applying proper nomograms, and using the latest technology, including custom LASIK. Remember that happy patients are the best way to drive referrals and grow business. ■

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