# Which Ablation Procedure Produces Customized

Wavefront-guided ablations deliver more predictable and better results than standard ablations.

**BY CAPTAIN STEVEN C. SCHALLHORN, MD**

I contend that wavefront-guided ablation for LASIK produces more predictable results and better visual quality than standard (wavefront-optimized) ablation procedures. Based upon numerous wavefront-guided studies[1-3] that have been conducted using multiple laser platforms, wavefront-guided ablations lead to fewer retreatments and happier patients. Currently, colleagues and I are conducting ongoing studies[1,3] to compare the outcomes between standard and wavefront-guided LASIK.

## STANDARD VERSUS WAVEFRONT-GUIDED ABLATIONS

### Study Parameters

In this study, my colleagues and I performed all of the wavefront-guided LASIK procedures using the Star S4 excimer laser with Customvue (Visx Incorporated, Santa Clara, CA) "straight out of the box" (ie, with no nomogram adjustments). We treated 170 consecutive eyes and have followed them for 3 months or longer. We compared these results retrospectively to a matched group of 500 eyes from a previous study of conventional LASIK using optimized nomograms on four commercially available laser systems: Ladarvision4000 (Alcon Laboratories, Inc., Fort Worth, TX); EC-5000 (Nidek Inc., Fremont, CA); Star S4; and Technolas 217z (Bausch & Lomb, Rochester, NY). We followed patients postoperatively for 6 months or more.

The patients in the two groups were carefully matched. The mean age was 36 years in the standard-ablation group and 33 years in the wavefront-guided group. In terms of preoperative spherical equivalent, the mean was slightly more than -3.00D in both groups. The enrollment criteria for both groups was between -1.00 and -6.50D manifest refractive spherical equivalent. In the standard-ablation group, the mean range for sphere was -3.26 ±1.18D and cylinder was -0.61 ±0.53D. In the wavefront-guided group, the mean range for sphere was -3.13 ±1.14D and cylinder was -0.66 ±0.51D. All eyes were targeted for emmetropia.

### Postoperative Results

At 3 months postoperatively, 91% of the standard-ablation eyes could see 20/20 or better, and 84% were within 0.50D of the intended correction. These excellent results truly represent the best of standard LASIK. The customized-ablation results are better, however. In the wavefront-guided group, 93% could see 20/20 or better, and 90% were within 0.50D of the intended correction.

The mean postoperative refraction in the standard-ablation group was +0.01 ±0.42D and -0.16D ±0.33 in the wavefront-guided group. Although the slight myopia in the wavefront-guided group indicates the need for a nomogram adjustment, the standard deviation is

*(Continued on page 36)*

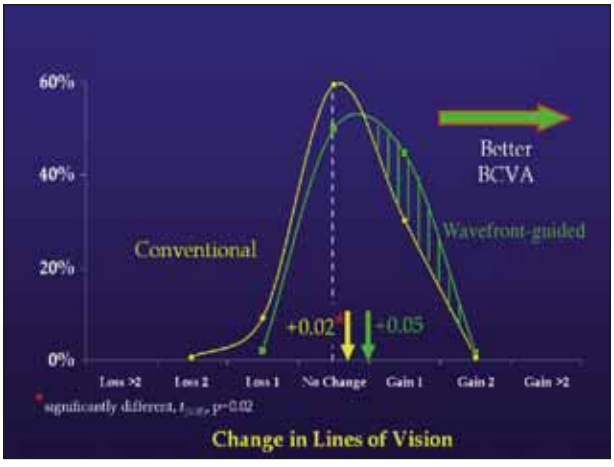


**Figure 1. Patients in the wavefront-guided group were more likely to experience gains in BCVA than patients in the conventional group.**

# Improved Postoperative Vision, or Standard?

The Allegretto Wave's standard ablation program has a number of advantages that enhance quality of vision.

**BY RAYMOND STEIN, MD, FRCSC**

Customized wavefront procedures have generated much interest and enthusiasm in the refractive surgery arena. However, a true understanding of the benefits of wavefront remains elusive, and its clinical utility has yet to be fully established in primary, non-complex cases.[1-5] At the Bochner Eye Institute in Toronto, a randomized, double-blind clinical study compared standard (wavefront-optimized) ablations using the Allegretto Wave excimer laser (Wavelight Laser Technologie AG, Erlangen, Germany) and customized (wavefront-guided) ablations using the Star S4 excimer laser (Visx Incorporated, Santa Clara, CA). One of the principal purposes of this study was to investigate whether the improved outcomes in primary surgeries with the customized Star S4 platform are due to wavefront-guided treatments or other factors, such as a change in the shot-pattern delivery of the laser beam, larger optical zones, improved nomograms, or the elimination of the prophylactic central-island treatment. All of the aforementioned changes have been incorporated into the standard platform of the Allegretto Wave.

## INVESTIGATION

### Study Design

Twenty myopic eyes of 10 patients underwent bilateral LASIK and were randomized between the standard program of the Allegretto Wave and wavefront-guided ablation with the Star S4. Postoperatively, the average spherocylindrical equivalent refractive error was -4.25D with the Allegretto Wave and -4.40D with the Star S4 (cylinder range, 0 to 2.00D). Average cylinder was -0.55D with the Allegretto Wave and -0.45D with the Star S4.

Pre- and postoperative measurements included (1) UCVA; (2) a manifest refraction with BCVA; (3) contrast sensitivity testing in conditions of low and high luminance as well as glare; (4) computerized videokeratography, (5) wavefront analysis using both the Allegretto and Visx devices, and (6) a detailed patient questionnaire that evaluated symptoms of glare, starbursts, haloes, ghost images, poor contrast, and night-vision problems. An unbiased, masked observer conducted follow-up examinations at 1 day, 1 week, 1 month, 3 months, and 6 months.

## STUDY RESULTS

At 6 months postoperatively, the average UCVAs and BCVAs were 20/16 and 20/15, respectively, with both the Allegretto Wave (n=10 eyes) and Star S4 (n=10 eyes). The average postoperative spherocylindrical equivalent refractive error with both lasers was +0.15D. Standard deviation was ±0.15D with the Allegretto Wave and ±0.23D with the Star S4. A gain of one or more lines of BCVA occurred in seven eyes with the Allegretto Wave and in five eyes with the Star S4. No eyes lost lines of BCVA with either laser. At 6 months, all patients described excellent quality of vision without adverse symptoms. The higher-order aberration RMS values increased postoperatively from baseline, but the increase was less with the Allegretto Wave (average 24%) than with the Star S4 (average 34%) at a pupil size of 6mm. Spherical aberration was reduced in six of 10 Allegretto Wave eyes and in three of 10 Star S4 eyes as measured by the Visx wavefront unit. Using the Allegretto wavefront unit, all eyes showed an increase in spherical aberration as measured with an 8-mm pupil, but this increase was less in the Allegretto Wave eyes. Patients reported no glare, halos, or difficulty with night vision with either treatment (Figures 1-3).

## CONCLUSION

Myopic LASIK results using the standard program of the Allegretto Wave and the customized program of the Star S4 were comparable in terms of UCVA and BCVA. The superior performance of the Allegretto Wave in terms of higher-order aberrations and, specifically, spherical aberration may

*(Continued on page 37)*

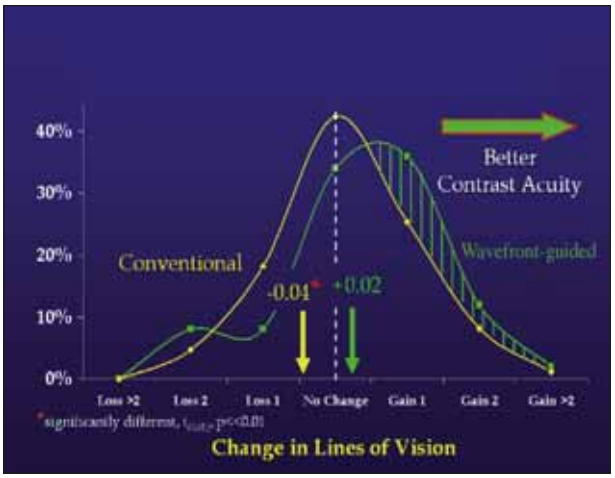


**Figure 2. Significantly more patients in the wavefront group achieved a gain in contrast acuity than a loss.**

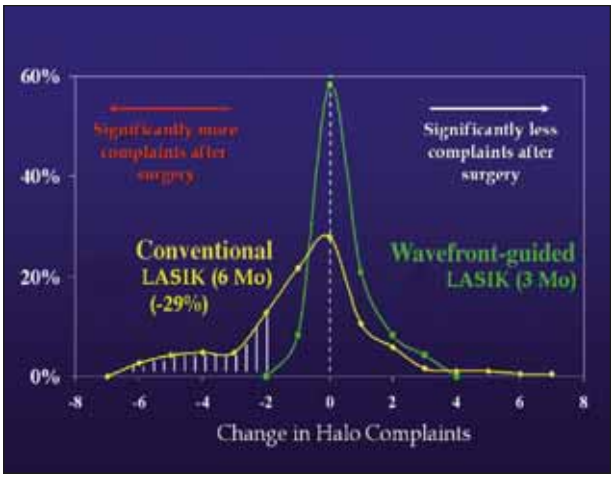


**Figure 3. By the 3-month wavefront-guided and six-month (standard) follow-up examinations, more than 14% of the standard patients still had increased halo complaints, compared to 4% of the wavefront-guided patients.**

*(Continued from page 34)*

not be much higher than the error of repeated refractions. In my opinion, standard ablation is setting new standards for refractive predictability.

Patients in the wavefront-guided group were more likely to experience gains in BCVA (Figure 1). This group had a small but statistically significant gain in 5% contrast acuity when compared with the loss of contrast acuity after standard LASIK (Figure 2). Significantly more patients achieved a gain in contrast acuity than a loss. These results are the opposite of what is routinely seen after standard LASIK.

We measured subjective quality-of-vision symptoms with a psychometric questionnaire. There were significantly more symptomatic patients with standard LASIK than with wavefront-guided LASIK. Six months after conventional surgery, 14% of patients had a measurable increase in symptoms compared with 4% of patients 3 months after wavefront-guided LASIK (Figure 3). The reason for the increase in symptoms, in my opinion, relates to the reduced induction of higher-order aberrations.

Although customized LASIK induced some higher-order aberrations postoperatively, standard LASIK induced more. Almost none of the standard eyes experienced a decrease in higher-order aberrations following treatment, although approximately 15% of the wavefront-guided group experienced a measurable decrease. Those with greater preoperative higher-order aberrations were most likely to achieve a postoperative decrease in higher-order aberrations.

## CONCLUSION

Wavefront-guided LASIK resulted in a more predictable postoperative refraction, a greater percentage of eyes with 20/20 UCVA, and a greater gain in BCVA. A nomogram adjustment should improve upon these already impressive results. With this procedure, we saw a lesser induction of higher-order aberrations that resulted in better night vision and contrast acuity when compared with standard surgery. I believe these quality-of-vision improvements demonstrate the greatest difference between standard and customized ablations. This difference should translate into happier patients who are less likely to need a retreatment. Our results with wavefront-guided LASIK are some of the best ever obtained at our laser center.

The results of the wavefront-guided LASIK studies presented to the FDA bear out our experience. Regardless of laser platform, all of the studies have found better quality of vision with wavefront-guided surgery when compared with conventional procedures with the same laser. ■

*Captain Steven C. Schallhorn, MD, is Director of Cornea Services at the Naval Medical Center in San Diego. He states that he holds no financial interest in any of the products or companies mentioned herein. Dr. Schallhorn may be reached at (619) 532-6702; scschallhorn@nmcsd.med.navy.mil.*

1. Kim TI, Yang SJ, Tchah H. Bilateral comparison of wavefront-guided versus conventional laser in situ keratomileusis with Bausch & Lomb Zyoptix. *J Refract Surg.* 2004;20:432-438..

2. Gulani AC, Probst L, Cox I, Veith R. Zyoptix: the Bausch & Lomb wavefront platform. *Ophthalmol Clin North Am.* 2004;17:173-181.

3. Kanjani N, Jacob S, Agarwal A, et al. Wavefront- and topography-guided ablation in myopic eyes using Zyoptix. *J Cataract Refract Surg.* 2004;30:398-402.

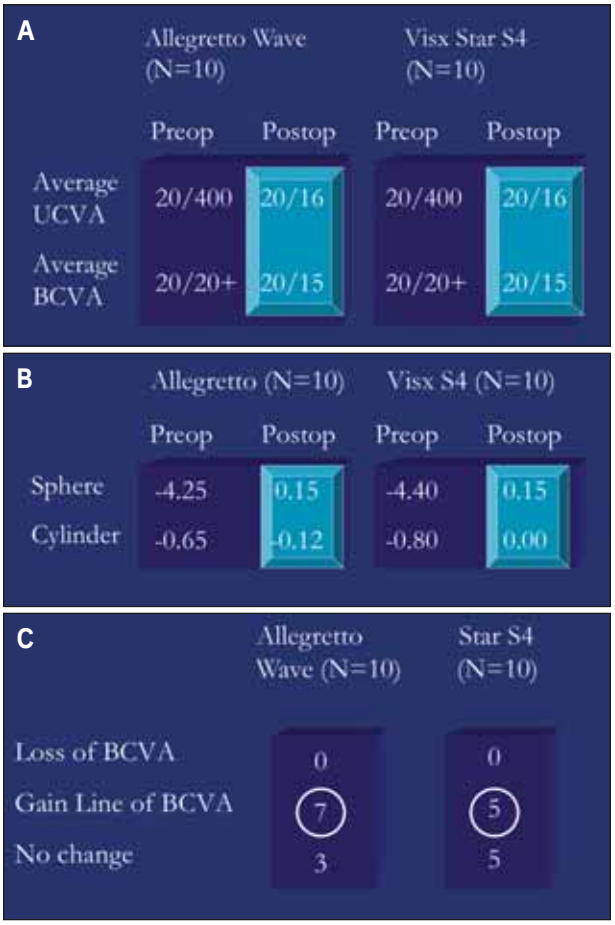


**Figure 1. Six-month postoperative results show the average UCVAs and BCVAs using the standard program of the Allegretto Wave and the customized program of the Star S4 (A), as well as sphere and cylinder outcomes using the standard program of the Allegretto Wave and the customized program of the Star S4 (B), and loss or gain of BCVA using the standard program of the Allegretto Wave and the customized program of the Star S4 (C).**

*(Continued from page 35)*

be related to the laser's ability to adjust corneal asphericity. The reported improvement in outcomes using the customized program of the Star S4 in the primary cases may not be attributable to the wavefront-guided platform, because other factors such as enlarged optical zones, a change in shot-pattern delivery, and the elimination of prophylactic central island treatment may be involved.

## STANDARD VERSUS CUSTOMIZED ABLATION

To determine whether improved outcomes with customized ablations are primarily related to wavefront-guided treatments, the Star S4 laser system should be examined and a comparison of its standard and customized ablations performed. For standard ablations, the Star S4 uses a broad-beam laser, performs a prophylactic central-island treatment, and has a maximum optical zone size of 6.5mm. With a case of pure astigmatism (eg, plano = -2.00D x 90), the short meridian is only 5mm. However, with a customized ablation, the system uses variable-spot scanning, with which there is a change in shot-pattern delivery. Consequently, no prophylactic-island treatment is required, the optical zones are enlarged, and wavefront-guided ablations have been added. The Star S4 produces superior results with wavefront-guided treatments compared with standard ablations. In the majority of primary surgeries that have a low incidence of preoperative higher-order aberrations, I believe these improved outcomes are related not to wavefront technology, but to other changes made to the laser program. These aforesaid changes are included in the Allegretto Wave's standard treatment. Noteably, engineers who added wavefront technology their own laser systems without making other changes to the platforms did not find any difference in surgical outcomes by adding wavefront alone.[7]

The only difference between the Allegretto's standard and customized ablations is the addition of a wavefront-guided treatment. At the Bochner Eye Institute, the treatment results for myopia and astigmatism (-1.00 to -10.00D) in more than 5,000 consecutive eyes using standard ablation with the Allegretto Wave achieved an average UCVA of 20/15 in 60% of eyes and 20/20 or better in 91%. Breaking down this large group into those with -6.00D or less of myopia and -3.00D or less of astigmatism revealed that 98% were 20/20 or better. In my opinion, these standard-ablation results with the Allegretto Wave can compete with or surpass any wavefront-guided system's currently on the market.

## CLINICAL APPLICATIONS

During the past 14 years, I have treated thousands of eyes using multiple laser systems, including those made by Nidek Inc. (Freemont, CA), Lasersight Technologies (Winter Park, FL), and all of the Visx lasers, including the 20/20 B and the Star S4. I began a trial using the Allegretto Wave in June

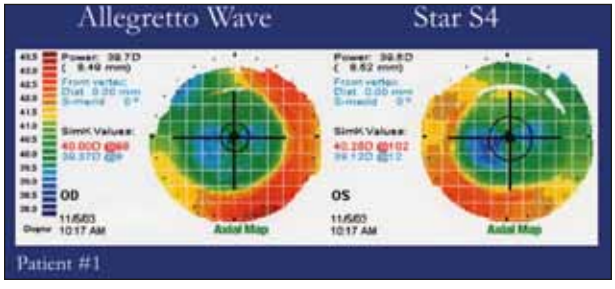


**Figure 2. Computerized videokeratography shows comparable corneal maps of a study patient after undergoing surgery with the Allegretto Wave and the Star S4. Note the similar optical and transition zones.**

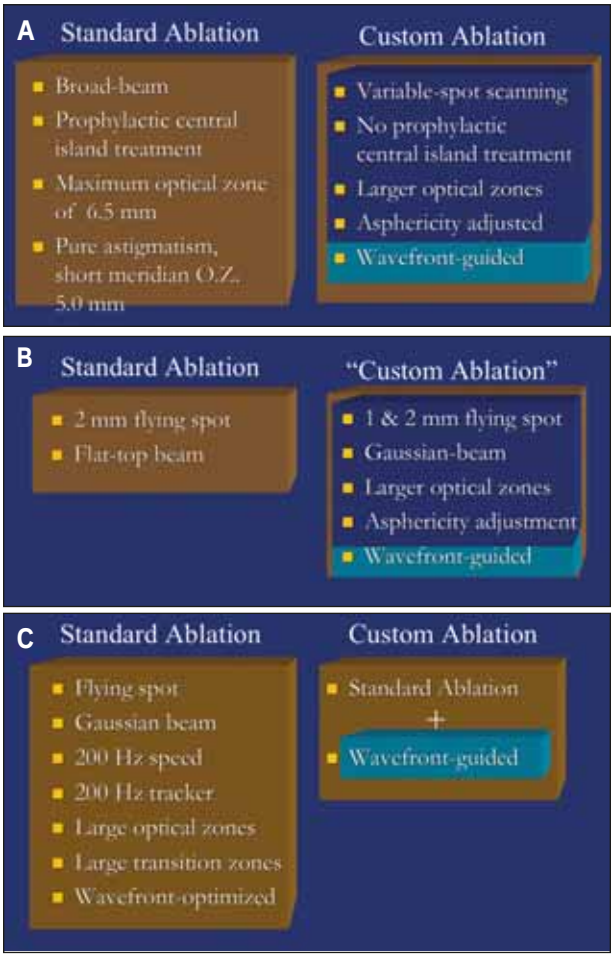


**Figure 3. Pictured is a comparison of the features of the Star S4 (A), the Technolas 217z (Bausch & Lomb, Rochester, NY) (B), and the Allegretto Wave (C) wavefront-guided platforms. Superior outcomes with the Star S4 and the Technolas 217z may be due to changes to the lasers' wavefront-guided platforms.**

2002, and 2 months later, I purchased the laser. Ninety-nine percent of the procedures my colleagues and I perform at the Bochner Eye Institute are with the Allegretto Wave. During the past 2 years, I have performed more than 5,000 procedures using this innovative technology.

My current clinical indications for wavefront-guided ablations using the Allegretto Wave include patients with a high amount of higher-order aberrations and/or a high RMS value, most of which are secondary cases (previous oblate ablations and other types of refractive surgery, such as refractive lens exchange and phakic implants). Other candidates for wavefront-guided ablations are patients with a loss of BCVA from irregular astigmatism, most of whom have forme fruste keratoconus or keratoconus, for which I perform customized surface ablation. In my own clinical practice, I treat 98% of the patients with a standard ablation using the Allegretto Wave and 2% using a wavefront-guided ablation. With this laser, it is not necessary for surgeons to always use the wavefront-guided technology, which is more complex and time-consuming.

In my opinion, correcting preoperative higher-order aberrations is not critical to achieving excellent quality of vision. For routine primary procedures, inducing a minimal increase or decrease in the amount of higher-order aberrations is essential. Most wavefront-guided laser systems show an improvement when compared with conventional treatments, but the technologies tend to increase the amount of higher-order aberrations from baseline. I also believe that wavefront-guided ablation is not needed to decrease higher-order aberrations; they can be reduced by using a better laser beam, larger optical and transition zones, and by improving the postoperative corneal curvature. Maintaining a more aspheric corneal curvature postsurgically can dramatically reduce the induction of spherical aberration.

Encouraging results have been achieved with a new customized ablation system with the Allegretto Wave based on topography. As opposed to wavefront imaging, almost all eyes can be successfully captured with topography. Also, thousands of data points can be collected with topography, compared with approximately 150 to 250 data points with wavefront. This topo-link approach may offer the best quality of vision for complex eyes, such as primary cases with abnormal topography and/or those that have undergone previous corneal surgery.

In my hands, the results of standard aspheric ablations with the Allegretto Wave often surpass wavefront-guided outcomes with other laser systems. This laser is easy to use, reliable, delivers extremely rapid treatments, and allows surgeons to customize optical zones. It also features tissue-saving nomograms that decrease ablation depth and produce aspheric ablations that provide excellent quality of vision. ■

*Raymond Stein, MD, FRCSC, is Medical Director of the Bochner Eye Institute in Toronto and Assistant Professor of Ophthalmology at the University of Toronto. He states that he holds no financial interest in any of the products or companies mentioned herein. Dr. Stein may be reached at (416) 960-2020; rstein@bochner.com.*

1. Rudy MMA, Nabar VA, Hament W, et al. Wavefront-guided versus standard laser in situ keratomileusis to correct low to moderate myopia. *J Cataract Refract Surg.* 2002:28;1907-1913.
2. Hilton L. Technology's ripple effect. *Review of Refractive Surgery.* 2003; 4; 3: 9-11.
3. Henahan S. Experts debate value of customized ablation. *EuroTimes.* 2003; 8; 9: 42-43.
4. Guttman C. Customized ablation research produces some answers but raises even more questions. *EuroTimes.* 2003; 8; 8: 24-25.
5. Bond W, Holladay J, Dell S, et al. The demise of conventional LASIK? *Cataract & Refractive Surgery Today.* 2003; 3; 2: 36-39.
6. Cummings, A. Allegretto visual results good with both customized, conventional treatments. *Ocular Surgery News.* 2003; 21; 23: 32-34.
7. Marshall J. Charles D. Kelman Innovator's Lecture: developments, debate, and dilemma: wavefronts and biomechanics. Paper presented at: The ASCRS/ASOA Symposium on Cataract, IOL, and Refractive Surgery; May 3, 2004; San Diego, CA.