Peer-Reviewed Literature:

LASIK Options in the Era of Wavefront

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One complex decision faced by ophthalmic surgeons considering the adoption of wavefront-guided refractive surgery involves selecting a proprietary treatment platform. During the decision-making process, the most useful comparison would be a randomized, prospective, side-by-side trial of all available wavefront-guided or wavefront-optimized systems. However, no such trial exists, and surgeons are left without direct comparative data for determining which system may best serve their patients.

The goal of this literature review is to briefly summarize FDA or recent postmarket data from myopic clinical trials of four wavefront systems in use in the US. It will also compare two emerging platforms. In addition to the FDA data (available at: http://www.fda.gov/cdrh/LASIK/lasers.htm), the following articles were reviewed:

1. *Gulani AC, Probst L, Cox I, Veith R. Zyoptix: the Bausch & Lomb wavefront platform.* Ophthalmol Clin North Am. *2004;17:173-181.*
2. *Lawless MA, Hodge C, Rogers CM, Sutton GL. Laser in situ keratomileusis with Alcon CustomCornea.* J Refract Surg. *2003;19(suppl):691-696.*
3. *Kaiserman I, Hazarbassanov R, Varssano D, Grinbaum A. Contrast sensitivity after wavefront-guided LASIK.* Ophthalmology. *2004;111:454-457.*
4. *Gimbel HV, Sofinski SJ, Mahler OS, et al. Wavefront-guided multipoint (segmental) custom ablation enhancement using the Nidek NAVEX platform.* J Refract Surg. *2003;19(suppl):209-216.*
5. *Reinstein DZ, Neal DR, Vogelsang H, et al. Optimized and wavefront guided corneal refractive surgery using the Carl Zeiss Meditec platform: the WASCA aberrometer, CRS-Master, and MEL80 excimer laser.* Ophthalmol Clin North Am. *2004;17:191-210.*

SYSTEMS AND APPROVALS

The Technolas 217z Zyoptix customized ablation system (Bausch & Lomb, Rochester, NY) is approved for the correction of up to -7.00 D of myopia with up to -3.00 D of astigmatism and a total myopic spherical equivalent of less than -7.50 D.[1] The CustomVue wavefront excimer laser system (Visx, Inc., Santa Clara, CA) was approved for the treatment of myopia of up to -6.00 D and astigmatism of up to -3.00 D. The CustomCornea wavefront-guided system (Alcon Laboratories, Inc., Fort Worth, TX) was the first to receive FDA approval for wavefront-guided laser surgery. Its initial approval for myopia of up to -7.00 D with less than -0.50 D of astigmatism was recently (June 2004) expanded to treatments of myopia of up to -8.00 D and cylinder as high as -4.00 D. The NAVEX (Nidek Advanced Vision Excimer Laser system; Nidek Inc., Fremont, CA) customized ablation platform for refractive surgery is not FDA-approved. Wavelight Laser Technologie AG (Erlangen, Germany) has not yet sought approval for true customized ablations (eg, wavefront-guided treatment derived from wavefront maps of individual patients) with the Allegretto Wave platform. However, the Allegretto Wave laser is approved to treat myopia of up to -12.00 D of sphere and -6.00 D of cylinder using a wavefront-optimized ablation profile designed to minimize the induction of spherical aberration. The MEL 80 excimer laser and the MEL 80's CRS-Master software (both from Carl Zeiss Meditec Inc., Dublin, CA) are not yet approved for use in the US.

RESULTS

Zyoptix

The FDA released phase III 6-month follow-up results for 340 patients in October 2003. Enrolled patients were required to have 20/40 or better BCVA with myopia and/or astigmatism not exceeding the range described earlier. As with other FDA studies, efficacy was determined on the basis of UCVA and the predictability of the postoperative manifest refraction. Preoperative myopia ranged from -0.46 to -7.13 D (-3.17 ±1.60 D) (mean ± stand deviation), and astigmatism ranged from 0.02 to 3.12 D (0.71 ±0.56 D). Attempted corrections targeted the full refractive error as determined by Zywave aberrometry (Bausch & Lomb). At 6 months, 70% of the eyes achieved 20/16 visual acuity or better without correction, and 92% achieved 20/20 or better. Seventy-six percent of the eyes were within ±0.50 D of the targeted MRSE, and 94% were within ±1.00 D. BCVA was unchanged or improved in 94% of the eyes, and contrast sensitivity remained stable or improved in 98% (mesopic) and 97% (photopic) of the eyes. A fellow-eye series (n = 40) within the FDA study comparing aberrations between Zyoptix and conventional Technolas 217 LASIK for spherical myopia revealed a similar total wavefront root mean square in both groups. Higher-order aberrations were reduced in more Zyoptix patients (38%) than conventional patients (13%), but no difference in subjective visual symptoms was present.

Customvue

Three hundred fifty-one eyes of 189 patients were studied in the FDA trial of the Customvue platform, and results were based on the 6-month follow-up interval. Enrollment required a BSCVA of at least 20/20+3 through a customized Prevue lens (Visx, Inc.). The mean preoperative sphere and cylinder were -3.60 ±1.40 D (range, -0.75 to -7.00 D) and +0.70 ±0.70 D (range, 0 to +3.00 D), respectively. In 80% of the eyes, the preoperative BCVA was achieved or surpassed at the 6-month mark. For spherical myopia (n = 71), 96% of eyes were corrected to 20/20 or better; the corresponding statistic in myopic astigmatism was 93% (n = 206). Eighty-six percent of the eyes reached within ±0.50 D of the intended MRSE, and 100% achieved within ±1.00 D. Seventy-six percent of eyes maintained or gained lines of BSCVA, and 24% lost at least one line. Ninety-one percent of the eyes with spherical preoperative myopia achieved a UCVA of 20/20 or better.

Customcornea

The FDA data for the Customcornea trial included 139 eyes with a mean preoperative spherical equivalent refraction of -3.23 ±1.31 D. At 6 months, 79.9% of the eyes had a UCVA of 20/20 or better. Additionally, 74.8% of the eyes maintained the MRSE within ±0.50 D of the intended correction, and 95.7% had a MRSE within ±1.00 D. At the same postoperative interval, 91% of the eyes with spherical myopia maintained or gained lines of BSCVA, and 8.6% lost one line. Lawless et al[2] also published results in 31 eyes of 17 patients, with 92.7% of the eyes' demonstrating 20/20 or better UCVA 3 months after undergoing Customcornea LASIK.

> "For any surgeon who is already offering conventional treatments, the question remains: will patients be better served by one of the newer platforms?"

Allegretto Wave

One hundred eighty patients were enrolled in the Wavelight Allegretto Wave wavefront-optimized system's FDA study. Six months after surgery, 93% of the eyes were within ±0.50 D of the intended MRSE, and 100% were within ±1.00 D. Additionally, 81% of the eyes maintained or gained lines of BSCVA, and 19% lost at least one line. Ninety-three percent of eyes with spherical preoperative myopia achieved a UCVA of 20/20 or better.

Kaiserman et al[3] recently published a consecutive case series comparing early contrast sensitivity results in wavefront-guided LASIK using the WaveLight Allegretto Wave with noncustomized Gaussian ablations using the same system. The wavefront-guided group included 24 eyes of 13 patients with a mean spherical refraction of -1.70 ±1.20 D (mean ± standard error) and a mean cylinder -1.10 ±0.90 D. The Gaussian ablation group included 22 eyes of 12 patients with comparable preoperative refractive statistics. At 1 month, the contrast sensitivity measurements improved from preoperative values in 88% of eyes in the customized-LASIK group compared with 40% in the standard LASIK group.

NAVEX

Initial outcomes have been described by investigators from Italy, Brazil, and Canada,[4] but no peer-reviewed outcome reports are available. In an unpublished study involving 132 primary eyes (range, up to -8.25 D of sphere and up to -3.00 D of cylinder), Arturo Chayet, MD, of Tijuana, Mexico, and Mihai Pop, MD, of Montreal reported that 87% of the eyes were within ±0.50 D and 98% were within ±1.00 D of the intended spherical equivalent correction at 6 months. Additionally, 93% of the eyes achieved a BSCVA of 20/20 or better, and 95% maintained

or gained lines of BSCVA.

MEL 80

At this time, no outcome data have been presented in the peer-reviewed literature for the MEL 80 system. A small contralateral eye study in 17 patients evaluated UCVA, accuracy of treatment, and BSCVA at 3 months when simple MEL 80 prolate-optimized profiles (not wavefront-derived) were compared with corneal refractive surgery-derived, wavefront-guided treatments.[5] Although the induction of higher-order aberrations was reduced in the wavefront-guided eyes, no differences in the visual outcome measures were found.

Given the limitations of any direct comparison of these six promising technologies, what is the surgeon to make of the clinical evidence?

First, the FDA data are compelling in their demonstration of the safety and general efficacy of the four tested systems. These data are certainly the most critical issues for any surgeon who is considering offering wavefront-guided or wavefront-optimized treatments to his patients. However, for any surgeon who is already offering conventional treatments, the question remains: will patients be better served by one of the newer wavefront platforms?

Strong evidence that the incorporation of wavefront technology improves visual outcomes is pending peer-reviewed reporting. The studies reviewed in this article show excellent visual acuity results that markedly surpass those of the older FDA PRK and LASIK trials. The correlation between the reduction of specific higher-order aberrations and improved visual acuity is not clearly established, however. An improvement in outcomes with subsequent laser systems over time is complicated by the fact that wavefront was not added as an independent variable; concurrent advances have included improvements in beam homogeneity, a transition from broad-beam to small-spot lasers, increases in pulse frequencies with faster treatments, decreases in variability from stromal desiccation, and the incorporation of highly sophisticated tracking systems. All of these changes have had a significant positive impact on treatment accuracy. Although visual acuity outcomes are often similar between customized and conventional treatments, a better characterization of the quality of vision between the two groups and its correlation to higher-order aberrations may reveal benefits that extend well beyond Snellen acuity. One of the most promising potential applications of wavefront technology will be in the treatment of highly aberrated eyes (eg, postkeratoplasty), a subset of patients that has not yet been systematically studied but that stands to benefit the most.

Clearly, the prospects for good vision after laser vision correction surgery have never been better, and each platform provides an impressive forward-looking approach to continuing this trend. ■

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