

# LASIK Laser Platforms

FDA comparisons and one surgeon's experience.

BY MICHAEL GORDON, MD

I have performed refractive surgery since 1980 and began using excimer lasers in 1989 as one of the original investigators for Summit Technology. With platforms from Summit, Visx, Incorporated (now Advanced Medical Optics, Inc., Santa Ana, CA), Alcon Laboratories, Inc. (Fort Worth, TX), and Bausch & Lomb (Rochester, NY), I have performed more than 30,000 refractive procedures. As one of the original investigators for the Allegretto Wave (Wavelight AG, Erlangen, Germany) in the US, I have performed more than 3,000 refractive procedures.

## COMPARING APPLES TO APPLES

Unlike company-sponsored marketing studies, the FDA studies are unbiased clinical trials that must conform to the agency's rigorous requirements and supervision. Figures 1 through 4 present the FDA clinical trial results of the Allegretto Wave's standard (wavefront-optimized) platform compared with the customized (wavefront-guided) platforms of the Visx Star S4 excimer laser with Customvue (Advanced Medical Optics, Inc.) and Alcon's Ladarvision platform with Ladarwave Customcornea Wavefront System.<sup>1</sup> In a comparison of patients' postoperative UCVA's versus their preoperative BSCVA's, the Allegretto Wave standardized program provided the same or better visual acuity than the Visx or Alcon wavefront-guided programs (Figure 1).

Regarding UCVA at 3 months in the group of patients with spherical corrections, the Allegretto Wave's patients achieved better vision with the standardized program than those who received treatment with the Visx or Alcon wavefront-guided programs (Figure 2). Also, based on the

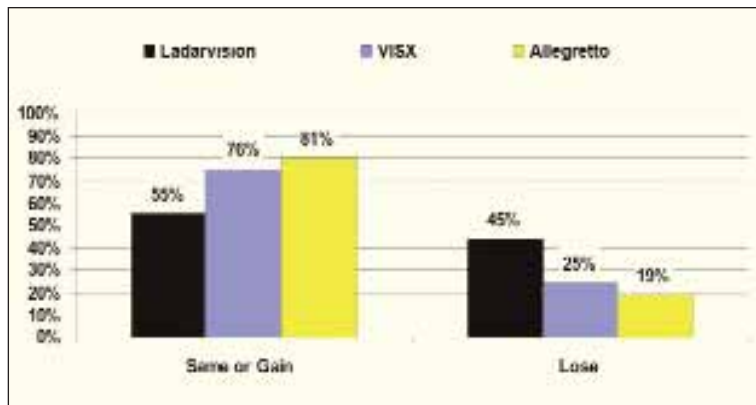


Figure 1. The FDA clinical trial results compared patients' UCVA's 3 months postoperatively with patients' preoperative BSCVA's.

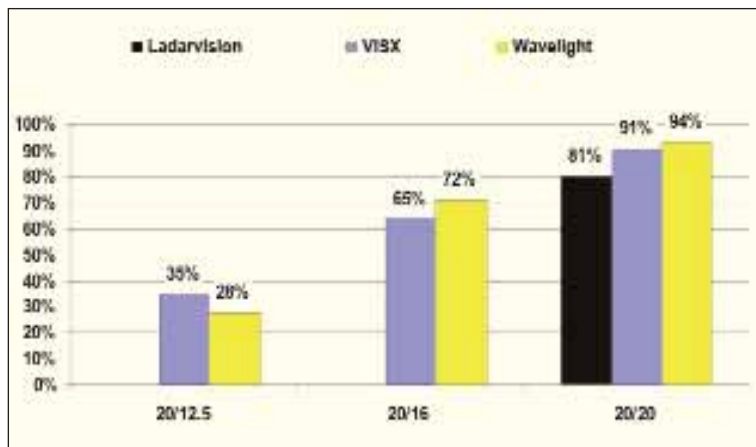


Figure 2. The FDA clinical trial results compared the UCVA's 3 months postoperatively among three different lasers in the spherical correction treatment group.

postoperative manifest spherocylindrical equivalent refractions, eyes treated with the Allegretto Wave were closer to their target prescription (within  $\pm 0.50D$ ) than any of the eyes treated with the other platforms (Figure 3).

Finally, of the patients undergoing spherical treatment, more treated with the Allegretto Wave standardized program patients achieved UCVA's of 20/20 or better when

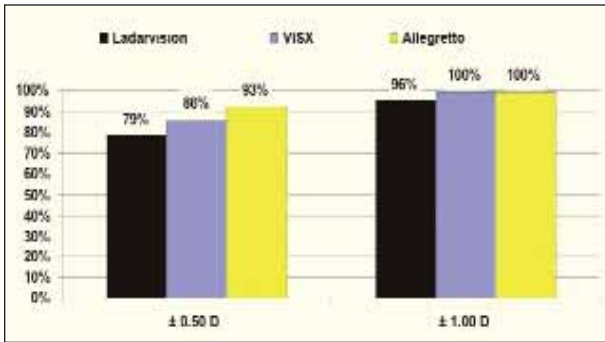


Figure 3. The FDA clinical trial compared the spheroequivalent manifest refraction results of three lasers.

compared with the Visx and Alcon laser wavefront-guided treatment groups (Figure 4).

According to these FDA comparisons, the Allegretto Wave provides equivalent or better outcomes compared with the Visx and Alcon systems. Although, in some cases, resultant higher-order aberrations may measure lower with wavefront-guided systems, this does not directly correlate to postoperative visual acuity, patients' satisfaction, or a gain or loss of BSCVA.

**OUTCOMES IN MY PRACTICE**

Although I currently have three lasers (the Star S4, Ladarvision, and Allegretto Wave) in my practice, I perform more than 95% of my LASIK procedures with the Allegretto Wave, because I have found that it achieves the best outcomes and greatly reduces the need for en-

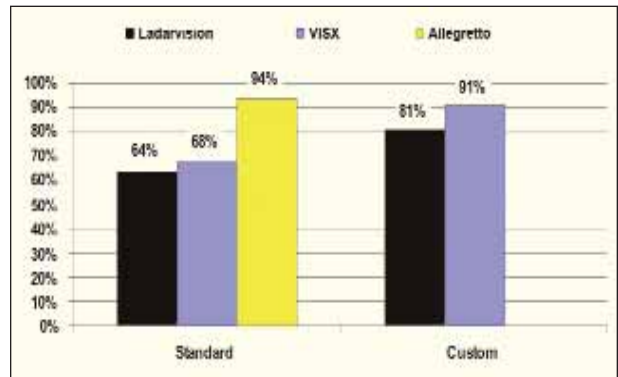


Figure 4. According to the FDA clinical trial's results, the Allegretto standard program compares favorably to the wavefront-guided platforms of the Visx and Alcon lasers.

“The speed of the Allegretto Wave contributes to the increased accuracy of the procedure in addition to decreasing the enhancement rate.”

hancements. In my hands, the retreatment rate with the Allegretto Wave is only 2% versus higher than 8% with the Star S4 and Ladarvision. Beyond the direct effect a decreased enhancement rate has on office overhead, a surgeon will see benefits through increased satisfaction among patients, stronger word-of-mouth referrals, and a reduction in liability exposure.

What was attractive about this laser that made me changeover to use it was that, although the initial investment was higher, the Allegretto was significantly more cost effective to operate. I was paying \$100 more per eye for customized treatments, with no added advantage in the outcomes of the procedures. Moreover, the speed of the Allegretto Wave contributes to the increased accuracy of the procedure in addition to decreasing the enhancement rate. Performing customized treatments with the Visx, Alcon, or Bausch & Lomb lasers was more time consuming. ■

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**WHEN IS WAVEFRONT-GUIDED TREATMENT NECESSARY?**

I think that wavefront-guided treatments are the most appropriate choice for individuals with prominent preexisting higher-order aberrations (greater than 0.3 to 0.4µm). This group stands to benefit from a wavefront-guided treatment because there seems statistically to be less induction of higher-order aberrations. However, in patients with preexisting higher-order aberrations less of than 0.3µm, there is no statistical difference. Looking at treatments with the Allegretto laser internationally, where surgeons have access to any software program of their choice, wavefront-guided treatments constitute only about 5% of all treatments.<sup>1,2</sup> Likewise, in my practice, I have found that only about 5% of patients necessitate wavefront-guided treatment, although the remaining 95% are excellent candidates for the Allegretto Wave.

1. Cummings A. Allegretto visual results good with both customized, conventional treatments. *Ocular Surgery News*. 2003;21:23:32-34.  
 2. Stein R. Which ablation procedure produces improved postoperative vision: customized or standard? *Cataract & Refractive Surgery Today*. 2005;5:2:35-38.

1. Holladay JT, Dudeja DR, Chang J. Functional vision and corneal changes after laser in situ keratomileusis determined by contrast sensitivity, glare testing, and corneal topography. *J Cataract Refract Surg*. 1999;25:663-669.