LASIK for Mixed Astigmatism Using the ALLEGRETTO WAVE: 3- and 6-month Results With the 200- and 400-Hz Platforms

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ABSTRACT

PURPOSE: To report the refractive results after LASIK for mixed astigmatism at one center with one surgeon comparing two laser platforms.

METHODS: A total of 137 eyes of 69 patients were treated with LASIK for mixed astigmatism up to 3.33 diopters (D) using either the ALLEGRETTO WAVE 200- or 400-Hz laser (Alcon Laboratories Inc) between April 2006 and December 2009. The degree of astigmatism was higher in the 400-Hz group. Corneal flaps were created with the IntraLase femtosecond laser (Abbott Medical Optics) in all cases.

RESULTS: The refractive outcomes with both laser systems were statistically similar. At 6 months, 78% of eyes had 20/20 or better uncorrected distance visual acuity (UDVA) with all but one eye achieving 20/30 or better UDVA. At 6 months, 10% of eyes treated with the 200-Hz system lost one line of corrected distance visual acuity (CDVA) whereas no eyes treated with the 400-Hz system lost any lines of CDVA. Residual astigmatism was <0.50 D for all eyes treated with both platforms.

CONCLUSIONS: Both laser platforms provided predictable and effective treatment of mixed astigmatism in the patient populations treated, with over 90% of eyes achieving UDVA of 20/25 or better 6 months after surgery. [J Refract Surg. 2010;26(10):S819-S823.] doi:10.3928/1081597X-20100921-09

The calculation of ablation profiles for laser refractive surgery for hyperopia and/or myopia with astigmatism is relatively straightforward; in both meridians the nature of the ablation will be similar, either myopic or hyperopic, with only the degree of treatment being different. Mixed astigmatism, on the other hand, involves the correction of myopia in one meridian and hyperopia in another. By its nature, the ablation profile will be more complex. The objective is to appropriately treat the degree of mixed astigmatism while removing a minimum amount of tissue. Because of the more complex ablation profiles involved, it is useful to evaluate mixed astigmatism results for an excimer laser system separately from myopic or hyperopic results.

The question of appropriate ablation profiles used to treat mixed astigmatism has been debated in the literature. There is a minimum volume solution if the keratometry of the eye is known; however, most solutions that are more general, but bitoric in nature (hyperopic correction in one meridian, myopic in the other), will be close to this optimum. The ALLEGRETTO WAVE excimer laser (Alcon Laboratories Inc, Ft Worth, Texas) has such a bitoric ablation profile.

Albarrán-Diego et al reported 6-month results for a series of patients treated for mixed astigmatism using the Technolas 217 laser (Bausch & Lomb, Rochester, New York). Of 28 eyes, 78% had uncorrected distance visual acuity (UDVA) better...
than 20/40, with 21% better than 20/20. Three (11%) eyes lost one line of corrected distance visual acuity (CDVA). Mean residual cylinder changed from −4.04 diopters (D) preoperatively to −0.67 D postoperatively. Khalifa et al6 reported 60 eyes treated with conventional LASIK and wavefront-guided LASIK with and without iris registration using the VISX Star S4 excimer laser system (Abbott Medical Optics [AMO], Santa Ana, California). Residual refractive astigmatism was <±0.50 D in 60% to 80% of eyes, depending on treatment modality. With conventional treatment, 25% of eyes lost one or more lines of CDVA at 3 months, whereas 10% of eyes in the wavefront-guided group lost 1 line of CDVA and no eyes lost any lines of CDVA in the wavefront-guided group with iris registration. De Ortueta and Haecker7 reported similar results with the SCHWIND ESIRIS system (SCHWIND eye-tech-solutions, Kleinostheim, Germany) and a modified Chayet ablation algorithm. With 19 eyes treated for mixed astigmatism, the mean residual cylinder at 3 months was −0.45 D and 59% of eyes had UDVA of 20/25 or better postoperatively. Rueda et al8 reported the postoperative results of 40 eyes treated with the NIDEK EC-5000 excimer laser system (NIDEK Co Ltd, Gamagori, Japan) for mixed astigmatism up to 6.00 D; 50% of eyes at 6 months had ≤0.50 D of astigmatism, although they noted a general moderate undercorrection in this patient population. This latter study points to the value of being able to adjust the cylinder nomogram in an astigmatic treatment.

The clinical outcomes reported herein were collected at a single center and represent a consecutive series of eyes with mixed astigmatism that one surgeon treated using the ALLEGRETTO WAVE excimer laser 200- and 400-Hz systems. These systems were approved in April 2006 and April 2007, respectively, for the reduction and elimination of mixed astigmatism up to 6.00 D at the spectacle plane in patients who are 21 years of age or older. An ablation zone of 9.0 mm is used for the treatment of mixed astigmatism. The 3- and 6-month data are reported. The ALLEGRETTO Wave has the potential to provide wavefront-optimized and wavefront-guided treatments. The former is designed to treat spherocylindrical refractive errors without affecting higher order aberrations. The latter is designed to treat the minority of patients with high preoperative higher order aberrations. This study only includes patients treated with the wavefront-optimized platform. No eyes included in the study had previous eye surgery or underwent retreatment.

**PATIENTS AND METHODS**

**Patient Population**

This retrospective review of mixed astigmatism results on a consecutive series of patients was conducted at The Laser Center, Greensboro, North Carolina and included 137 eyes of 69 patients. A total of 111 eyes of 56 patients were treated for mixed astigmatism with the 200-Hz ALLEGRETTO WAVE laser whereas an additional 26 eyes of 13 patients were treated with the 400-Hz system by a single surgeon (K.G.S.). Appropriate informed consent was obtained from all patients.

Mean patient age was 37 years (range: 20 to 58 years). The population was 53% female. The mean degree of cylinder treated was 1.06±0.90 D (maximum 3.33 D) with the 200-Hz system and 2.55±0.15 D (maximum 2.66 D) with the 400-Hz system. A statistically significantly higher level of astigmatism was noted in eyes treated with the 400-Hz system (P<.05). Mean spherical equivalent refraction was 0.78±0.52 D (range: +0.99 to −1.01 D) in the 200-Hz group and 0.20±0.31 D (range: +0.99 to −1.01 D) in the 400-Hz group.

All patients who underwent primary LASIK treatment for mixed astigmatism using either the 200- or 400-Hz ALLEGRETTO WAVE laser between April 2006 and December 2009 were included in these results. Any patients who had prior eye surgery were excluded from the data set.

**Clinical Outcome Measures**

Pre-, intra-, and postoperative data were collected retrospectively from the patient files. Corrected distance visual acuity, UDVA, manifest and cycloplegic refraction, intraocular pressure, computed corneal topography, corneal pachymetry, and slit-lamp and funduscopic examination were performed and recorded for 3- and 6-month follow-up. Results reported are the refractive and visual acuity results at 3 and 6 months for both the 200- and 400-Hz systems. Cylinder is reported by magnitude only; vector analysis was not performed.

**Surgical Technique and Instrumentation**

The ALLEGRETTO WAVE is a scanning spot excimer laser system that includes an excimer laser with a high pulse repetition rate (200 and 400 Hz), beam delivery optics, and two galvanometric scanners for positioning the laser pulses. The beam is a small-spot Gaussian beam <0.95 mm in diameter. The system has a 400-Hz eye-tracker to track patient eye movements and either compensate for changing eye position or interrupt treatment if the eye moves out of a predetermined range.

The treatment of mixed astigmatism was applied using a bitoric ablation profile designed to minimize tissue removal to achieve the desired correction. The treatment was delivered using a 9-mm ablation zone with a 6.0- to 6.5-mm optical zone. The calculation of the bitoric ablation profile is performed internally by...
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the ALLEGRETTO software and applied with a single ablation.

All LASIK flaps were created using the IntraLase femtosecond laser (AMO) specifying either a 100- or 110-µm desired thickness.

RESULTS

Three months postoperatively, 24% of eyes (27/111) in the 200-Hz group and 27% of eyes (7/26) in the 400-Hz group had UDVA of 20/16 or better, with 79% (88/111) and 81% (21/26), respectively, having UDVA of 20/20 or better. No statistically significant difference was noted in the distribution of UDVA between the 200- and 400-Hz groups (chi-square, \( P = .84 \)) at 3 months. All eyes in both groups had a mean spherical equivalent refraction within ±0.50 D of the intended correction at 3 months. The magnitude of residual astigmatism was ≤0.50 D in all eyes treated on both platforms, with 81% of eyes (90/111) treated on the 200-Hz system and 92% of eyes (24/26) treated on the 400-Hz system having <0.25 D. In the 200-Hz group, 3 (2.7%) eyes lost 1 line of CDVA whereas 44 (40%) eyes gained 1 line. At 3 months, no eyes lost CDVA in the 400-Hz group whereas 3 (12%) eyes gained 1 line.

Results at 6 months were similar. All but 1 eye (in the 200-Hz group) had UDVA of 20/30 or better. All eyes in the 400-Hz group had UDVA of 20/25. No statistically significant difference was noted in the distribution of UDVA between the 200- and 400-Hz groups (chi-square,
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**TABLE**

<table>
<thead>
<tr>
<th>Study</th>
<th>Device</th>
<th>N</th>
<th>Follow-up (mo)</th>
<th>UDVA 20/20 or Better</th>
<th>UDVA 20/30 or Better</th>
<th>Astigmatism Within ≤ 0.50 D of Intended</th>
<th>Loss of 1 or More Lines of CDVA</th>
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</table>

UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; IR = iris registration.

*Studies vary by inclusion/exclusion criteria, patient characteristics, and refractive errors treated. Comparative data are for general information only.

Technolas 217 (Bausch & Lomb, Rochester, New York); VISX CustomVue (Abbott Medical Optics, Santa Ana, California); SCHWIND ESIRIS (SCHWIND eye-tech-solutions, Kleinostheim, Germany); NIDEK EC-5000 (NIDEK Co Ltd, Gamagori, Japan); ALLEGRETTO WAVE (Alcon Laboratories Inc, Ft Worth, Texas).

P=0.10) at 6 months. The mean spherical equivalent refraction was within ≤0.50 D of the intended correction for 95% of eyes (105/111) in the 200-Hz group and 100% of eyes (26/26) in the 400-Hz group. A gain of one line of CDVA was observed in 40% of eyes (44/111) in the 200-Hz group whereas 10% (11/111) lost one line. In the 400-Hz group, 12% of eyes (3/26) gained one line and no eyes lost CDVA. Figure 1 illustrates the cumulative UDVA distribution for both groups. No statistically significant differences were noted between eyes treated on the 200- or 400-Hz systems with respect to residual refractive error or UDVA (P>0.05 in all cases).

Figures 2 and 3 show the scattergram series for 3-month follow-up on the 200- and 400-Hz platforms, respectively, treating plano to 3.25 D.

Nomogram adjustments for sphere and cylinder were present on both systems and differed slightly. The adjustment for spherical correction was 0.98 and the cylinder correction adjustment was 0.97 with the 200-Hz system, with an R² value of 0.95 for the spherical factor and 0.986 for the cylinder factor. With the 400-Hz system, the corrections for sphere and cylinder were 1.06 and 1.07, respectively, with corresponding R² values of 0.91 and 0.995.

All surgeries were completed without adverse events. No intraoperative complications were encountered, and no perioperative complications were reported. None of the eyes developed iatrogenic keratectasia.

**DISCUSSION**

More than 75% of eyes treated on either system had UDVA of 20/20 or better postoperatively and all eyes but one were 20/30 or better at 6 months. This compares favorably to the approval data submitted to the FDA by WaveLight, in which 68% of eyes had UDVA of 20/20 or better and 96% were 20/40 or better. The Table summarizes results for a number of additional excimer laser systems used to treat mixed astigmatism, as reported in the literature. The data reported herein for the ALLEGRETTO WAVE appear equal or superior to those reported for these other systems, including those based on wavefront-guided treatment. Uncorrected distance visual acuity achieved in this population was high with minimal loss of CDVA. Inclusion and exclusion criteria, range of treatment, and patient selection affect the results of any study, therefore, these figures should be considered as a general comparison only.

As noted in the introduction, nomogram adjustment of the cylinder correction is important to achieve good results, particularly in the case of mixed astigmatism where the primary concern is the reduction or elimination of said astigmatism. The attempted versus achieved correction of cylinder with the ALLEGRETTO WAVE showed an R² value >0.98 for both laser systems (0.986 for the 200-Hz, 0.995 for the 400-Hz). All eyes treated on both systems had ≤0.50 D residual cylinder postoperatively. This result demonstrates
excellent predictability in the correction, particularly noteworthy for the 400-Hz system where the average cylinder treated was >2.50 D.

The results reported herein indicate that LASIK with the ALLEGRETTO WAVE excimer laser system is an effective and predictable method for treating eyes with mixed astigmatism.

**AUTHOR CONTRIBUTIONS**

Study concept and design (K.G.S.); data collection (K.G.S., G.M.K., K.S.); analysis and interpretation of results (K.G.S., G.M.K.); drafting of the manuscript (K.G.S., K.S.); critical revision of the manuscript (K.G.S., G.M.K., K.S.); statistical expertise (K.G.S., G.M.K.); obtained funding (K.G.S.); supervision (K.G.S., K.S.)

**REFERENCES**


