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LASIK for $-6.00$ to $-12.00$ D of Myopia With up to $3.00$ D of Cylinder 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 high myopia and cylinder at one center with one surgeon comparing two laser platforms.

METHODS: A total of 206 eyes of 121 patients were treated for $-6.00$ to $-12.00$ diopters (D) of spherical equivalent refractive error with up to 3.00 D of cylinder. All eyes underwent LASIK with the ALLEGRETTO WAVE 200-Hz (n=141) or 400-Hz (n=65) laser (Alcon Laboratories Inc) between 2003 and 2009. Corneal flaps were created with the IntraLase femtosecond laser (Abbott Medical Optics) at an intended thickness of 100 or 110 µm in all cases.

RESULTS: At 3- and 6-month follow-up in the 200-Hz group, 77% (109/141) and 86% (121/141) of eyes, respectively, were within $\pm 0.50$ D of intended correction. In the 400-Hz group, 98.5% (64/65) and 100% (65/65) of eyes were within $\pm 0.50$ D of intended correction at 3 and 6 months postoperatively. At 3- and 6-month follow-up, 84% (119/141) and 77% (109/141) of eyes, respectively, in the 200-Hz group and 80% (52/65) and 92% (60/65) of eyes, respectively, in the 400-Hz group had 20/20 or better uncorrected distance visual acuity. At 6-month follow-up, refractive predictability and visual acuity were statistically superior in eyes in the 400-Hz group (chi square, $P<.01$). No eyes underwent retreatment as a secondary procedure during the time of analysis.

CONCLUSIONS: LASIK with the ALLEGRETTO WAVE 200- and 400-Hz laser is effective and predictable for the treatment of high myopia with astigmatism in appropriately selected patients. The acuity and predictability of refractive results may be slightly better when using the 400-Hz platform. [J Refract Surg. 2010;26(10):S814-S818, doi:10.3928/1081597X-20100921-08]

The ALLEGRETTO Wave excimer laser (Alcon Laboratories Inc, Ft Worth, Texas) is approved for reducing or eliminating myopia of up to $-12.00$ diopters (D) of sphere and up to 3.00 D of astigmatism at the spectacle plane in patients who are 18 years or older. The 200-Hz system was approved in October 2003 and the 400-Hz system was approved in July 2006. The device uses optical zones of 6.0 and 6.5 mm with an ablation zone of up to 9.0 mm.

Literature reports of LASIK to treat high myopia indicate varying degrees of success. Lindbohm et al1 assessed the long-term results of LASIK for the correction of high myopia. Patients underwent LASIK with the VISX STAR S2 excimer laser (Abbott Medical Optics [AMO], Santa Ana, California) to treat myopia of at least $-9.00$ D. The investigators determined that, with careful patient selection and safety precautions, LASIK is safe with moderate stability but limited predictability in the treatment of $-9.00$ to $-17.00$ D of refractive error. Liu et al2 also assessed the long-term results of LASIK for correcting moderate to severe myopia. Patients were followed for 7 years after surgery, and the investigators found that LASIK had predictable and stable results in both refractive and visual outcomes for correcting moderate to high myopia. Refractive stability was maintained over 7 years, and patients had no evidence of late-onset complications. Our study reports a consecutive series of patients treated by one sur-
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gon at a single site for high myopia (≥−6.00 D) with up to 3.00 D of cylinder using the 200- and 400-Hz ALLEGRETTO WAVE lasers. Results at 3 and 6 months postoperative are compared between the two platforms.

The ALLEGRETTO WAVE has both a wavefront-optimized and a wavefront-guided platform. The ALLEGRETTO WAVE wavefront-guided LASIK procedure is approved by the US Food and Drug Administration (FDA) for the reduction or elimination of up to −7.00 D of myopia or myopia with astigmatism up to 3.00 D. The ALLEGRETTO WAVE wavefront-optimized procedure is FDA-approved for the reduction or elimination of up to −12.00 D of myopia or myopia with astigmatism up to 6.00 diopters. Wavefront-optimized LASIK is designed to treat spherocylinder errors without inducing spherical aberration. This study only includes patients treated with the wavefront-optimized platform.

PATIENTS AND METHODS

STUDY DESIGN

This retrospective review of a consecutive series of patients was conducted at The Laser Center, Greensboro, North Carolina and included 206 eyes of 121 patients treated for −6.00 to −12.00 D of spherical equivalent refractive error with up to 3.00 D of cylinder by one surgeon (K.G.S.). All eyes underwent LASIK with the 200- or 400-Hz ALLEGRETTO WAVE laser between October 2003 and May 2009. Corneal flaps were created with the IntraLase femtosecond laser (AMO) in all cases. Flap thickness was targeted between 100 and 110 µm based on preoperative corneal pachymetry. Informed consent was obtained from all patients. No patient had prior eye surgery.

CLINICAL OUTCOME MEASURES

Pre-, intra-, and postoperative data were collected retrospectively from the patient files. Corrected distance visual acuity (CDVA), uncorrected 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 at 3- and 6-month follow-up (when available).

SURGICAL TECHNIQUE AND INSTRUMENTATION

The ALLEGRETTO WAVE is a scanning spot excimer laser system that includes delivery of a high pulse repetition rate (200 and 400 Hz) using two galvanometer scanners for positioning the laser pulses. The system has a 400-Hz eye-tracker that tracks fast eye movements or interrupts treatment if the eye moves out of a predetermined range. The tracker uses an infrared high-speed camera with a capture rate of 200-Hz to photograph the eye. These images are used to determine the position and size of the pupil. This information about the pupil position is used to determine the placement of the next laser pulse on the eye. This entire process takes less than 10 milliseconds. The desired contour of the treated surface is achieved by ablating the calculated profile of the ablation area (6.0- or 6.5-mm optical zone with a 9.0-mm ablation zone) with a small-spot diameter (0.95±0.1 mm) Gaussian laser pulse. The small-spot diameter allows for lower pulse energy with fluence averages of 200 mJ/cm² and 400 mJ/cm². All LASIK flaps were created using the IntraLase femtosecond laser at either a 100- or 110-µm desired thickness.

With high myopia, corneal thickness can be a limiting factor because a sufficiently thick residual stromal bed is important. The ablation zone is limited to 6.5 mm for patients with myopia of ≤−11.75 D. The maximum ablation depth would be 183 µm in this case. Smaller ablation zones can be used to treat higher amounts of astigmatism. Treating 13.50 D of myopia with a 6.0-mm zone would require an ablation depth of 176 µm. Thin flaps can be helpful in permitting larger ablation zones in these patients.

RESULTS

In the study cohort of 206 eyes, 126 (61%) were in female patients and 80 (39%) were in male patients. Patient race was not recorded. Mean patient age was 33.8 years (range: 20 to 60 years).

Mean sphere for eyes in the 200-Hz group was −6.76±1.01 D (range: −6.08 to −11.25 D) whereas eyes in the 400-Hz group had mean sphere of −7.07±0.89 D (range: −6.86 to −12.63 D), a statistically but not clinically significant difference (t test, P=0.035). Mean cylinder treated in the eyes in the 200-Hz group was 0.72±0.76 D (range: 0 to 1.25 D) and 0.56±0.56 D (range: 0 to 2.34 D) in the 400-Hz group; these were not significantly different (t test, P=0.13). The maximum cylinder treated was 2.54 D with the 200-Hz system and 2.32 D with the 400-Hz system.

At both 3- and 6-month follow-up, 100% (141/141) of eyes treated with the 200-Hz platform had UDVA of 20/30 or better. At 3 months, 98.5% (64/65) of eyes treated with the 400-Hz platform had UDVA of 20/30 or better, which improved to 100% at 6 months. At 3-month follow-up, the 200- and 400-Hz system treatments resulted in UDVA of 20/20 or better in 84% (119/141) and 80% (52/65) of eyes, respectively. At 6-month follow-up, the 200- and 400-Hz system treatments resulted in UDVA of 20/20 or better in 77%
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(109/141) and 92% (60/65) of eyes, respectively. At 6 months, the percentage of eyes achieving 20/20 or better UDVA was statistically significantly greater using the 400-Hz system (chi square, \( P < .01 \)).

The percentages of eyes with a mean spherical equivalent refractive error within \( \pm 0.50 \) D of intended correction for the 200- and 400-Hz platforms were 86% (121/141) and 100% (65/65), respectively, at 6-month follow-up (Fig 1). This percentage was statistically significantly greater using the 400-Hz system (chi square, \( P < .01 \)). Figure 1 also shows UDVA at 20/16, 20/20, and 20/30 as well as corrections within \( \pm 0.50 \) and \( \pm 1.00 \) D of intended in the 200- and 400-Hz platform groups.

The scattergram series for the 3- and 6-month data on the 200-Hz platform is shown in Figure 2. The \( R^2 \) value for the 3-month data is 0.99 and 0.95 for sphere and cylinder, respectively. The \( R^2 \) value for the 6-month data is 0.99 and 0.86 for sphere and cylinder, respectively.

Figure 3 shows the scattergram series for the 3- and 6-month data on the 400-Hz platform. The \( R^2 \) value for the 3-month data is 0.99 and 0.94 for sphere and cylinder, respectively. The \( R^2 \) value for the 6-month data is 0.99 for both sphere and cylinder.

Corrected distance visual acuity at 6 months was also compared between platforms. A gain of one line of CDVA occurred in 32% (45/141) of eyes treated with the 200-Hz platform and in 26% (17/65) of eyes treated with the 400-Hz platform. No patient lost more than one line of CDVA with either system. No intraoperative complications were encountered, and no perioperative complications were reported. No eyes developed iatrogenic keratectasia. Only eyes without retreatment were included in the analysis.

Figure 1. Uncorrected distance visual acuity and targeted refractive results at 6 months in eyes that underwent LASIK with the ALLEGRETTO WAVE 200- or 400-Hz platform.

Figure 2. Attempted vs achieved sphere and cylinder in eyes that underwent LASIK with the 200-Hz ALLEGRETTO WAVE platform.
DISCUSSION

LASIK is utilized for a wide range of both spherical and cylindrical refractive error; however, in recent years, arguments with respect to predictability and stability have been presented. With both intraocular and corneal treatments available, the question remains at what level should patients be referred for an intraocular rather than a corneal procedure? In a 2002 report by the American Academy of Ophthalmology, investigators concluded that LASIK is effective and predictable and provides very good to excellent uncorrected visual acuity in the treatment of low to moderate myopia. However, for moderate to high myopia (>6.00 D), results are not as predictable. In 2006, Sanders and Vukich compared the results of LASIK and the Implantable Collamer Lens (ICL; STAAR Surgical, Monrovia, California) for the correction of 4.00 to 7.88 D of refractive error. They found that the ICL was safer and more effective than LASIK in these patients. Obviously, with an intraocular option, the risk of posterior segment complications increases. However, with corneal procedures at this level of refractive error there have been concerns regarding the quality of vision that can be obtained.

In our series, both laser platforms performed well; however, the 400-Hz platform had improved predictability and outcomes when compared to its 200-Hz predecessor (see Fig 1). At approximately 2 seconds per dioptre of treatment for the 400-Hz laser and 4 seconds per dioptre of treatment for the 200-Hz laser, we believe the improved outcomes relate to the overall speed of delivery related to the treatment profile. The reduced exposure to dehydration and potential loss of patient fixation are plausible explanations for the overall improvement of the final patient outcomes and predictability.

Additional variables, such as the sequential time of treatment of each group (patients undergoing LASIK with the 200-Hz platform were treated earlier in the series, and those undergoing LASIK with the 400-Hz were treated later, as the technology became available) as well as individual differences in the preoperative values between groups (not included) could contribute to the differences noted. However, these are likely to be small among this cohort.

This study indicates that LASIK with the ALLEGRETTO WAVE laser for the treatment of up to 12.00 D of myopia with up to 3.00 D of cylinder is effective. Uncorrected distance visual acuity was 20/30 or better in 97.5% of all eyes and 30% of eyes treated on both platforms gained one line of CDVA. Results with the 400-Hz system showed marginal improvement relative to the 200-Hz system.

AUTHOR CONTRIBUTIONS

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

REFERENCES