

Wavefront-guided Enhancements Using the WaveLight Excimer Laser in Symptomatic Eyes Previously Treated With LASIK

A. John Kanellopoulos, MD; Lawrence H. Pe, MD

ABSTRACT

PURPOSE: To describe our clinical experience in wavefront-guided LASIK enhancements using the WaveLight ALLEGRETTO system (WaveLight Technologie AG, Erlangen, Germany) for symptomatic eyes previously treated with standard LASIK.

METHODS: Twenty-six eyes of 20 patients with residual myopia, hyperopia, or mixed astigmatism and/or night vision symptoms after primary standard LASIK were considered for wavefront-guided customized retreatment using the WaveLight ALLEGRETTO WAVE 200 Hz excimer laser system (model 106). Preoperative best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity, topography with the ALLEGRETTO Topolyzer, wavefront analysis using the ALLEGRETTO WAVE Tscherring Analyzer, and contrast sensitivity were compared to postoperative (enhancement) measurements.

RESULTS: Twenty-two of the original 26 eyes underwent wavefront-guided enhancement, 4 were excluded because they did not meet wavefront-guided treatment inclusion guidelines of this study. Mean follow-up was 8 months (range: 6 to 13 months). All patients were within ± 0.50 diopters (manifest refraction) of intended postoperative refraction. The mean preoperative BSCVA improved from 20/25 to 20/18 postoperatively. All patients gained at least one line of BSCVA, and a maximum of three lines. There was no loss of BSCVA in any patient. The total amount of high order aberrations (RMSH) decreased from an average of 1.04 to 0.46 μm . Patients also had a mean improvement in low contrast sensitivity of 59%.

CONCLUSIONS: Based on this small series, customized wavefront-guided enhancements using the WaveLight ALLEGRETTO system in patients who underwent previous LASIK appear to be safe and effective in correcting residual refractive error, reducing high order aberrations, and improving visual symptoms when reliable and reproducible measurements are achieved. [*J Refract Surg.* 2006;22:xxx-xxx.]

Several wavefront-guided excimer laser platforms are available today, and some have been shown to provide good results in enhancement in patients with residual problems after refractive surgery.^{1,2} This study is designed to evaluate the safety and efficacy of wavefront-guided LASIK enhancements using the ALLEGRETTO system (Wavefront analyzer and ALLEGRETTO WAVE 200Hz excimer laser; WaveLight Technologie AG, Erlangen, Germany) for symptomatic eyes after LASIK.

PATIENTS AND METHODS

Twenty-six symptomatic eyes that underwent LASIK were evaluated for possible wavefront-guided enhancement with the WaveLight ALLEGRETTO system. Inclusion criteria were previous LASIK surgery with residual myopia, hyperopia, or mixed astigmatism with a refractive error within ± 1.50 diopters (D) (spherical equivalent). The diameter of the planned wavefront-guided laser treatment had to be ≥ 6 mm and ≤ 7 mm. The root-mean-square higher order aberration (RMSH) value had to be ≥ 0.4 μm when measured by the ALLEGRETTO WAVE Analyzer at a 6.5-mm pupil diameter. Indications included: 1) small original optical zone, 2) decentered ablation, 3) irregular astigmatism, 4) night vision problems, and 5) under- and overcorrection. An additional criterion for study inclusion was our ability to obtain highly reproducible, higher aberration maps that had a diameter of at least 6 mm after the eye had been dilated with a single drop of tropi-

From the LaserVision.gr Eye Institute, Athens, Greece; Department of Ophthalmology, Manhattan Eye, Ear and Throat Hospital, New York, NY; and Department of Ophthalmology, New York University Medical School, New York, NY.

The authors have no financial or proprietary interests in the materials presented herein.

Presented at: American Academy of Ophthalmology Annual Meeting; October 23-26, 2004; New Orleans, La.

Correspondence: A. John Kanellopoulos, MD, LaserVision.gr Eye Institute, Pyrgos Athinon, Mesogeion 2 & Vasilissis Sofias, Ampelokipoi, 11527, Athens, Greece. Tel: 30 210 7472 777; Fax 30 210 7472 789; E-mail: laservision@internet.gr

Received: July 16, 2004

Accepted: June 12, 2005

camide 1%. The wavefront measurements were taken in a dark room 20 to 30 minutes following the single 1% tropicamide drop administration.

Preoperative evaluation of each patient included refraction (manifest, cycloplegic, and wavefront), uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), measurement of scotopic pupil size (Colvard Pupillometer; Oasis Medical, Glendora, Calif), topography and simulated K with the Orbscan II (Bausch & Lomb, Rochester, NY), and wavefront measurements using the ALLEGRETTO WAVE Topolyzer (WaveLight Technologie).

The ALLEGRETTO WAVE Analyzer, prior to generating customized treatment information for the laser apparatus, took the average of four surgeon-selected highly reproducible maps of each patient's higher and lower order aberrations. The reproducibility of the individual wavefront measurements was determined by the surgeon both qualitatively by comparing the topographic distribution of high order aberrations as well as quantitatively by comparing total and individual RMS deviation and individual Zernike polynomials. On the final treatment planned by the laser software, the surgeon could only modify the amount of sphere corrected when the clinical measurements were significantly different than the default sphere calculated by the wavefront measurements and the wavefront treatment diameter, which had to be 6, 6.5, or 7 mm, according to our study design.

The system's software does not currently allow manual changes in the amount and axis of astigmatism, because the average of the high order aberration maps predetermines this information. All cases involved lifting, but never cutting, of the original LASIK flap. The flap diameter and hinge length were measured intraoperatively. Ultrasonic pachymetry measurements were obtained preoperatively and following lifting of the flap, and the data were used to calculate the residual stromal bed thickness using the subtraction method.

Patient contrast sensitivity was measured pre- and postoperatively under mesopic conditions, using low contrast materials, and glare was measured preoperatively by means of the CSV-1000 (VectorVision, Arcanum, Ohio). Intraoperative complications were recorded in the patient's chart.

Patients' subjective responses to their visual function postoperatively were also recorded. On a scale of -1 to 3, -1 represented worsening, 0 represented no improvement, and 1-3 represented improvement.

Postoperative follow-up intervals were 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year, at which time all of the above parameters were remeasured. At these follow-up intervals, adverse effects

and/or complications were also evaluated. The measurements were performed by the surgeon (A.J.K.) and his associate optometric staff.

RESULTS

This study included 22 of the 26 eyes considered, all of whom were symptomatic with night vision problems or mesopic and scotopic ghosting. We excluded four patients: one did not possess the calculated amount of residual corneal thickness necessary for retreatment (we generally require a stromal bed reserve of at least 260 μm under the flap following the enhancement and a total corneal reserve of 400 μm). The three remaining patients were excluded because of our inability to obtain reproducible wavefront maps. They were all initial corrections of >7.0 D of myopia and the specific wavefront measurements on these eyes were found to be variable both qualitatively when evaluating topographic representation of high order aberrations as well as quantitatively when comparing specific RMS deviations of various Zernike polynomials.

Follow-up ranged from 6 to 13 months (mean: 8 months). Of the 22 eyes treated, the average preoperative amount of sphere was -0.92 D (range: plano to -1.50 D). The mean amount of cylinder was -0.85 D (range: 0 to -1.75 D). The mean preoperative BSCVA was 20/25, and this improved to a mean of 20/18 postoperatively. No patient lost lines of BSCVA. All patients gained at least one line of BSCVA, and a maximum of three lines. The total amount of high order aberrations, as measured by the parameter RMSH, decreased from an average of 1.04 to 0.46 μm . In addition, patients experienced a mean improvement in low contrast sensitivity of 59% (Figs 1 and 2). No significant flap complications were encountered with the flap lifting maneuvers.

Regarding quality of vision, according to the patients' subjective responses, 21 of the 22 eyes corrected had significant improvement (rated 2-3) and one had mild improvement (rated 1). The mean postoperative visual function score, as rated by the patients, was $+2.5$.

DISCUSSION

With the popularity and volume of refractive surgery, surgeons inevitably run into some problems that result in less than satisfactory vision for the patient after the procedure. Among these problems are under- or overcorrections, decentered ablations, and small optical zone ablations that may result in "ghosting" symptoms and night vision problems.²⁻¹¹ In these cases, the refractive surgeon is left with the difficult task of improving these visual complaints and the possibility of offering an enhancement procedure. Modern

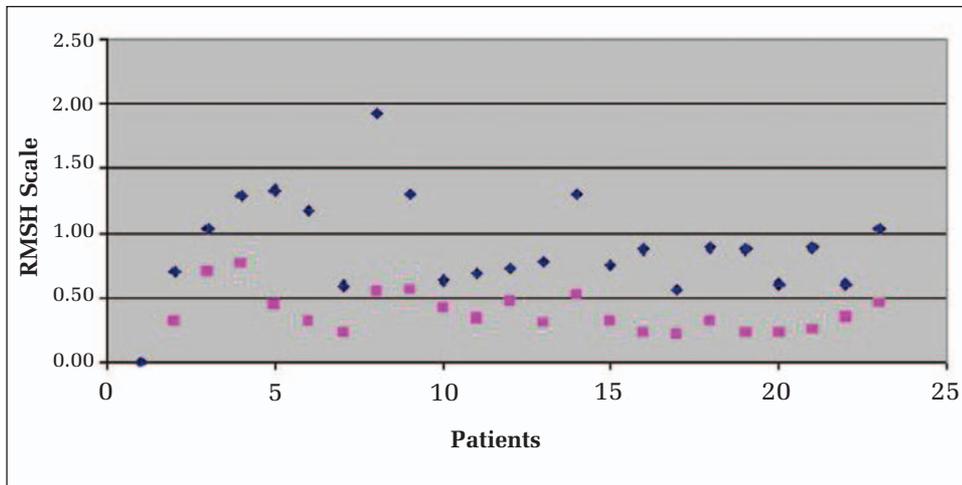


Figure 1. Root-mean-square higher order aberration (RMSH) values at 6.5-mm optical zone before (blue dots) and 6 months after (pink dots) wavefront-guided enhancement.

wavefront capture systems and the possibility of wavefront-guided systems have enhanced the refractive surgeon's armamentarium in this regard. The strength of these systems lies in the ability to diagnose more specific deviations present in the patient's wavefront map and the ability to potentially improve these deviations with customized treatments.^{12,13} This is in contrast to traditional forms of refractive correction (spectacles and "standard" ablations), which basically treat only the spherocylindrical error. This may well be the best route to take in managing patients with symptoms after LASIK given the knowledge that the previous refractive procedure may have interfered with wavefront norms and the complex nature of the refractive error.

Regarding the quality of vision in the present study, which was measured by the patients' subjective responses, the majority reported significant improvement.

Wavefront measurements and our measurements of these patients' low contrast sensitivity indicated a significant clinical improvement in all eyes, justifying the above subjective responses. No patient demonstrated a need for further enhancement during the study's brief follow-up period. Although the size of the study was limited, these results suggest that wavefront-guided LASIK retreatments with this laser are safe and effective for the correction of residual refractive error. We attribute the enhancement of visual function to the significant improvement of the patients' high order aberrations and low contrast sensitivity. The ALLEGRETTO WAVE wavefront analyzer and excimer laser allowed us to measure and treat most symptomatic patients, with predictable outcomes.

This treatment, however, cannot be offered to all post LASIK symptomatic eyes, as several limitations are present. These limitations, as noted in our study design, are the actual objective measurements of such a deviation from normal. This means that although the patients are symptomatic, the clinical device could

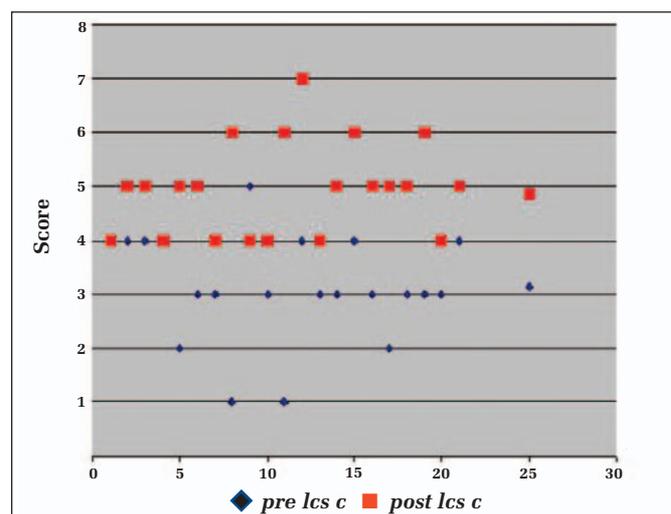


Figure 2. Low contrast sensitivity scores (12 cycles/degree) before (blue diamonds) and 6 months after (red squares) wavefront-guided enhancement. The last column represents the average.

not measure significant high order aberrations and/or deviation from low contrast sensitivity and because the clinical indices could not be altered, the treatment could not be offered.

Another limitation is obtaining several reproducible wavefront maps to maintain a high index of certainty that these results are reproducible. The specific wavefront technology in this study uses the Tscherning principle of calculating wavefront deviations from the image of a series of simultaneously projected laser spots onto the retina. Invariably, eyes that had undergone LASIK for spherical equivalents >7.0 D of myopia did not offer a well-defined image of these diagnostic laser spots and therefore the wavefront calculation on part of this technology was variable both qualitatively (site and specific Zernike polynomial deviation) as well as quantitatively (amount of specific Zernike polynomial deviation). Therefore, as noted in the study, a certain

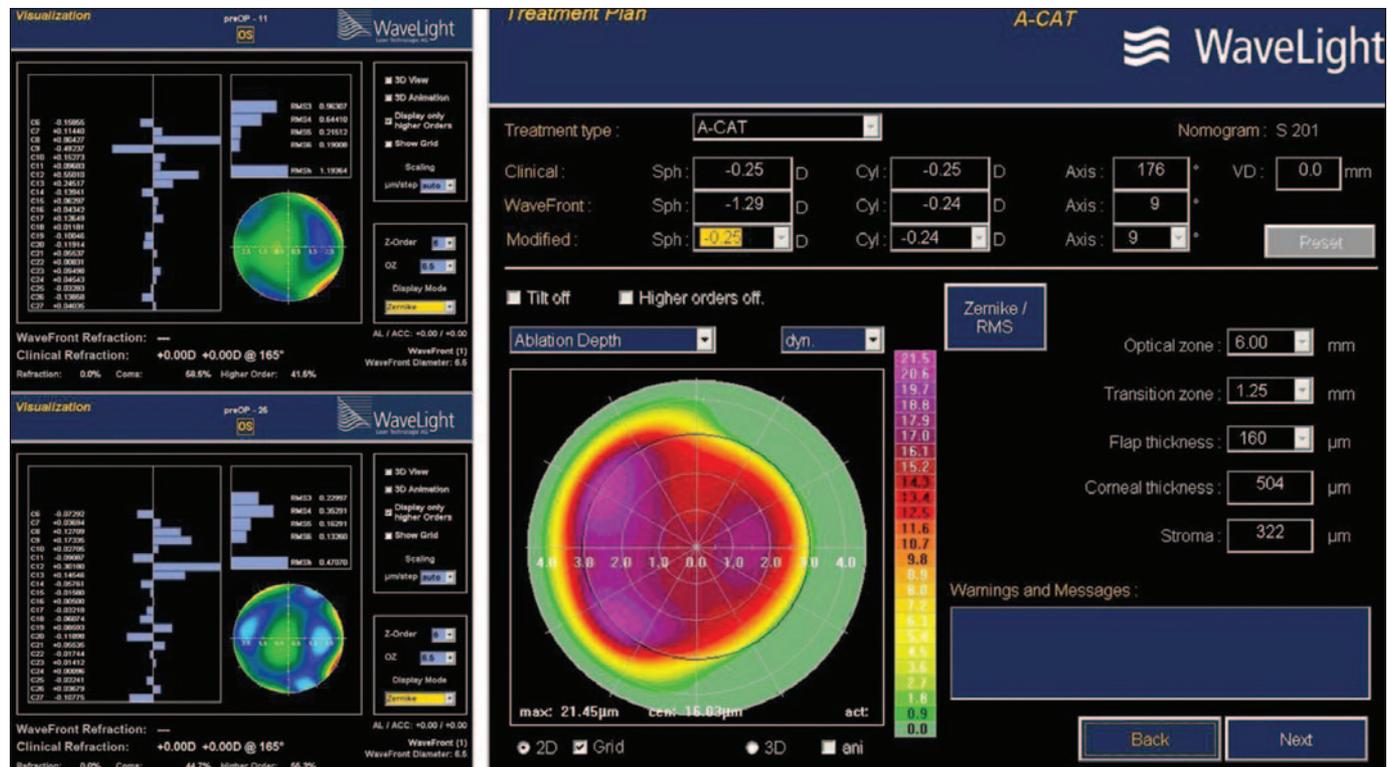


Figure 3. The upper left image illustrates the pre-enhancement wavefront analysis of one of the cases in this study. The refraction was -0.25 , UCVA and BSCVA were 20/20. The wavefront analysis shows multiple significant deviations when evaluating each Zernike polynomial individually, and a total high order aberration (RMSH) index of 1.2; the color map section demonstrates the topographic wavefront analysis depicting significant vertical coma. The lower left image demonstrates the post-enhancement wavefront analysis. The direct comparison of each Zernike polynomial, the RMSH that has been reduced to 0.4, and the topographic wavefront map improvement post-enhancement are illustrated. This improvement correlated well with the clinical improvement in night vision problems and contrast sensitivity experienced by the patient postoperatively. The color map on the right demonstrates the actual treatment plan for this wavefront-guided procedure as averaged by the software by four reproducible examinations. This picture illustrates the planned ablation pattern and the tissue demanded for removal and is amenable to adjustment by the surgeon as far as the sphere for refraction (not the cylinder and/or axis) and the zone diameter of the planned ablation.

percentage of patients did fulfill our inclusion criteria, but we were not able to attain reproducible measurements and they were excluded from the study. This group of cases may be better addressed with the use of topography-guided enhancements as reported by the authors previously.¹⁴ In this group of patients, visual rehabilitation remains problematic. Further studies and a better understanding of this technology and how it alters the physiology of vision may help better manage these patients. In addition, recent data from Applegate et al¹² indicate that actual human vision may improve with the modulation of certain Zernike modes, and not necessarily all modes as defined by the RMSH value. Therefore, in a theoretical setting, where we can manipulate specific Zernike polynomials in our wavefront-guided treatments, a more effective improvement in functional human visual acuity could result. We did not study the specific correction of each Zernike polynomial in these wavefront-guided enhancements, but the total high order deviation through

the value of RMSH was evaluated. One may theorize that applying wavefront-guided treatments as an initial treatment may provide better results. The problem with this approach is that most wavefront aberrations were induced by surgery and are not present preoperatively. The major wavefront index change appears to be the flap creation process. We concentrated on using the initial flap to avoid further changes, theorizing that re-lifting the initial LASIK flap would not induce any additional high order aberration changes. Again, this is an area where further studies, preferably controlled randomized studies, could offer a more conclusive approach.

REFERENCES

- Gimbel HV, Sofinski SJ, Mahler OS, van Westenbrugge JA, Ferenowicz MI, Triebwasser RWJ. Wavefront-guided multipoint (segmental) custom ablation enhancement using the Nidek NAVEX platform. *J Refract Surg.* 2003;19:S209-S216.
- Febbraro JL, Buzard KA, Friedlander MH. Reoperations after myopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2000;26:41-48.

3. Schallhorn SC, Kaupp SE, Tanzer DJ, Tidwell J, Laurent J, Bourque LB. Pupil size and quality of vision after LASIK. *Ophthalmology*. 2003;110:1606-1614.
4. Pop M, Payette Y. Risk factors for night vision complaints after LASIK for myopia. *Ophthalmology*. 2004;111:3-9.
5. Perez-Santonja JJ, Ayala MJ, Sakla HF, Ruiz-Moreno JM, Alio JL. Retreatment after laser in situ keratomileusis. *Ophthalmology*. 1999;106:21-28.
6. Zadok D, Maskaleris G, Garcia V, Shah S, Montes M, Chayet A. Outcomes of retreatment after laser in situ keratomileusis. *Ophthalmology*. 1999;106:2391-2394.
7. Hersh PS, Fry KL, Bishop DS. Incidence and associations of retreatment after LASIK. *Ophthalmology*. 2003;110:748-754.
8. Yavitz E. PRK retreatments after regressed myopic LASIK. *Ophthalmology*. 2002;109:1953-1954.
9. Carones F, Vigo L, Carones AV, Brancato R. Evaluation of photorefractive keratectomy retreatments after regressed myopic laser in situ keratomileusis. *Ophthalmology*. 2001;108:1732-1737.
10. Qi H, Xia Y, Chen Y, Zhu X. Excimer retreatment for undercorrection or regression after laser in situ keratomileusis [Chinese]. *Zhonghua Yan Ke Za Zhi*. 2002;38:72-75.
11. Lyle WA, Jin GJ. Retreatment after initial laser in situ keratomileusis. *J Cataract Refract Surg*. 2000;26:650-659.
12. Applegate RA, Hilmantel G, Thibos LN. Visual performance assessment in customized corneal ablation. In: MacRae SM, Krueger RR, Applegate RA. *Wavefront Customized Visual Correction: The Quest for Supervision*. Thorofare, NJ: SLACK Inc; 2001:81-92.
13. Applegate RA, Marsack JD, Ramos R, Sarver EJ. Interaction between aberrations to improve or reduce visual performance. *J Cataract Refract Surg*. 2003;29:1487-1495.
14. Kanellopoulos AJ. Topography-guided custom retreatments in 27 symptomatic eyes. *J Refract Surg*. 2005;21:S513-S518.

AUTHOR QUERIES

Please place a callout for Figure 3 in the text.

ADDITIONAL QUERIES PER DR WARING

The title has been changed. Okay as edited?

Please include standard deviations for all means.

Should the x axis in Figure 1 be eyes, not patients?

Regarding Figure 2, what is the "last column?"