

Reporting Acuity Outcomes and Refractive Accuracy After LASIK

To the Editor:

In their article, “Longitudinal Postoperative LASIK Epithelial Thickness Profile Changes in Correlation With Degree of Myopia Correction,”¹ Kanellopoulos and Asimellis describe the importance of epithelial thickness mapping after LASIK and confirm that epithelial thickness profile changes can be lenticular in shape after myopic LASIK, as measured by spectral-domain ocular coherence tomography. This confirms the results of previous reports using high-frequency ultrasound² and other methods.

These findings are helpful in understanding epithelial change and the contribution of the epithelium to overall refractive change after myopic and myopic-astigmatic LASIK. Almost as an incidental finding, Kanellopoulos and Asimellis cited statistics for refractive accuracy in their patients, reporting that “1 year postoperatively, all patients had a corrected distance visual acuity of 20/20, and 57 of 61 cases were within ± 0.25 D of the intended correction.”¹ This suggests that they obtained a visual acuity of 20/20 in 100% of patients and that the outcome accuracy of 93.4% (57 of 61) can be within ± 0.25 diopters (D) at 1 year postoperatively. This seems like an unprecedented predictability outcome for LASIK up to -8.50 D with any excimer laser, including the Wavelight platform (Alcon Laboratories, Inc., Fort Worth, TX) with which I have extensive experience.

The dynamics of curvature-corrected (ie, “wavefront-optimized”), spherocylindrical shape subtraction as performed by modern excimer lasers, including the Wavelight, dictate that accuracy of correction is proportional to the magnitude of the targeted correction and is influenced by other factors, including temperature, humidity, stromal hydration, ablation speed, plume effects, fluence consistency, beam stability, laser optics, and more. Refractive stability is generally achieved by 12 weeks postoperatively. After that, there can be small amounts of refractive drift related to lens growth (layer formation) and possibly epithelial change for a period of time. In my experience, 20/20 visual acuities are obtained at 90 to 120 days postoperatively in approximately 89% of patients and at 240 to 430 days postoperatively in approximately 87% of patients.

The authors’ claim of outcome accuracy within ± 0.25 D at 1 year postoperatively also seems extraordinary and suspect, given that this is better than the repeatability for manifest refraction in a controlled environment. For example, Raasch et al.³ reported the

95% confidence interval for intra-observer repeatability of manifest refraction to be 0.62 D,¹ and Shah et al.⁴ reported it to be ± 0.25 D in 81% of eyes. Zadnik et al.⁵ reported the best comparison measure of the refraction measurement of 95% limits of agreement to be ± 0.32 D. Did Kanellopoulos and Asimellis intend to report outcome accuracy as spherical equivalent or actual myopic sphere? Did they intend for this to be 93% within ± 0.50 D spherical equivalent?

REFERENCES

1. Kanellopoulos AJ, Asimellis G. Longitudinal postoperative LASIK epithelial thickness profile changes in correlation with degree of myopia correction. *J Refract Surg*. 2014;30:166-171.
2. Reinstein DZ, Silverman RH, Raevsky T, et al. Arc-scanning very high-frequency digital ultrasound for 3D pachymetric mapping of the corneal epithelium and stroma in laser in situ keratomileusis. *J Refract Surg*. 2000;16:414-430.
3. Raasch TW, Schechtman KB, Davis LJ, Zadnik K; CLEK Study Group. Repeatability of subjective refraction in myopic and keratoconic subjects: results of vector analysis. *Ophthalmic Physiol Opt*. 2001;21:376-383.
4. Shah R, Edgar DF, Rabbetts R, Harle DE, Evans BJ. Standardized patient methodology to assess refractive error reproducibility. *Optom Vis Sci*. 2009;86:517-528.
5. Zadnik K, Mutti DO, Adams AJ. The repeatability of measurement of the ocular components. *Invest Ophthalmol Vis Sci*. 1992;33:2325-2333.

David A. Wallace, MD
Los Angeles, California

The author has no financial or proprietary interest in the materials presented herein.

Reply:

We welcome the letter by Dr. Wallace commenting on our recent study.¹ In response to the points made, we did note in our results that all patients had corrected distance visual acuity of 20/20 as a means of assessing the safety of the procedure studied and not uncorrected distance visual acuity. Perhaps the term “corrected” was inadvertently misread by Dr. Wallace as “uncorrected.” We have correctly stated that 57 of 61 cases studied in our report were within ± 0.25 of spherical equivalent error at 1 year, comprising 93.4% of the study population. When considering all cases, the average drops to less than 85% and it is the patients with higher myopia who “skew” these numbers.

We would welcome peer-reviewed publication of reports documenting the “wavefront-optimized” data that Dr. Wallace notes that he has experience with. Although we generally agree with the data mentioned anecdotally in his letter, topography-guided treatments with the WaveLight platform (Alcon Surgical, Fort Worth, TX) appear to offer superior visual acuity LASIK results, also documented in the recent multicenter U.S. Food and Drug Administration trial on to-

pography-guided myopic LASIK with the WaveLight Allegretto Wave Eye-Q Excimer Laser (Alcon Surgical) conducted in the United States, and posted on the U.S. Food and Drug Administration's official web site.² In our experience in Europe with a more advanced (as far as frequency and tracker response time) subsequent excimer laser model (WaveLight EX500; Alcon Surgical), this may be the result of addressing cornea-related aberrations, a better transition zone for the ablation, and/or better adjustment to the centroid shift, which is not addressed in the standard wavefront-optimized treatments currently available in the United States and referred to by Dr. Wallace.

We do not agree on 3 months as a valid postoperative assessment point following LASIK, because inadvertent transient tear imbalance manifested in our experience in the first 3 to 6 months postoperatively, which is well illustrated in the epithelial remodeling and also documented in cataract³ and corneal transplant cases⁴ and investigated with anterior segment optical coherence tomography, which may significantly bias the refractive and visual function results.

Nevertheless, we believe that the novelty and main message of our findings lies in the epithelial remodeling assessment in the cohort reported. We beg to differ with the statement made: "In their article, 'Longitudinal Postoperative LASIK Epithelial Thickness Profile Changes in Correlation With Degree of Myopia Correction,' Kanellopoulos and Asimellis describe the importance of epithelial thickness mapping after LASIK and confirm that epithelial thickness profile changes can be lenticular in shape after myopic LASIK, as measured by spectral-domain ocular coherence tomography. This confirms the results of previous reports using high-frequency ultrasound⁵ and other methods." We actually reported topographic changes of the myopic LASIK central and paracentral epithelium that are not lenticular in shape, in contrast with previous reports using high-frequency ultrasound imaging. We actually observed a specific mid-periphery epithelial hypertrophy pattern more pronounced in higher myopic corrections and have since documented a significant ability to change this response when employing adjunct high fluence corneal cross-linking with the LASIK procedure.⁶ Our early experience of evaluating patients in an anterior segment practice with epithelial mapping over the past 3 years has made its capture and clinical evaluation an integral part of our clinical assessment

of every patient we observe⁷⁻¹⁰ and we strongly recommend its use when assessing refraction and visual performance in any patient, by clinicians who have access to similar technology.

We hope that we have been able to address the questions noted and clear possible elements of "suspicion" for Dr. Wallace.

REFERENCES

1. Kanellopoulos AJ, Asimellis G. Longitudinal postoperative LASIK epithelial thickness profile changes in correlation with degree of myopia correction. *J Refract Surg*. 2014;30:166-171.
2. WaveLight Allegretto Wave Eye-Q Excimer Laser - P020050/S012, Summary of Safety and Effectiveness Data (SSED). Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020050S012b.pdf. Accessed August 27, 2014
3. Kanellopoulos AJ, Asimellis G. Corneal epithelial remodeling following cataract surgery: three-dimensional investigation with anterior-segment optical coherence tomography. *J Refract Surg*. 2014;30:348-353.
4. Kanellopoulos AJ, Asimellis G. Anterior-segment optical coherence tomography investigation of corneal deturgescence and epithelial remodeling after DSAEK. *Cornea*. 2014;33:340-348.
5. Reinstein DZ, Silverman RH, Raevsky T, et al. Arc-scanning very high-frequency digital ultrasound for 3D pachymetric mapping of the corneal epithelium and stroma in laser in situ keratomileusis. *J Refract Surg*. 2000;16:414-430.
6. Kanellopoulos AJ, Asimellis G. Epithelial remodeling after femtosecond laser-assisted high myopic LASIK: comparison of stand-alone with LASIK combined with prophylactic high-fluence cross-linking. *Cornea*. 2014; 33:463-469.
7. Kanellopoulos AJ, Asimellis G. In vivo three-dimensional corneal epithelium imaging in normal eyes by anterior-segment optical coherence tomography: a clinical reference study. *Cornea*. 2013;32:1493-1498.
8. Kanellopoulos AJ, Asimellis G. Anterior segment optical coherence tomography: assisted topographic corneal epithelial thickness distribution imaging of a keratoconus patient. *Case Rep Ophthalmol*. 2013;4:74-78.
9. Kanellopoulos AJ, Asimellis G. In vivo 3-dimensional corneal epithelial thickness mapping as an indicator of dry eye: preliminary clinical assessment. *Am J Ophthalmol*. 2014;157:63-68.
10. Kanellopoulos AJ, Dupps WJ, Seven I, Asimellis G. Toric topographically customized transepithelial, pulsed, very high-fluence, higher energy and higher riboflavin concentration collagen cross-linking in keratoconus. *Case Rep Ophthalmol*. 2014;5:172-180.

Anastasios John Kanellopoulos, MD
New York, New York
Athens, Greece

The author has no financial or proprietary interest in the materials presented herein.

doi:10.3928/1081597X-20141113-01