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Relationship between Induced Spherical Aberration and Depth of Focus after Hyperopic LASIK in Presbyopic Patients

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Objective: To evaluate to what extent the modification of corneal asphericity to induce spherical aberration (SA) can improve the depth of focus and to determine whether preoperative adaptive optics assessment (Voptica SL) can predict an optimal SA value for each patient.

Design: Comparative, prospective clinical trial with paired eye control.

Participants: Patients ≥45 years old who are hyperopic from +1.00 to +2.50 diopters (D), with eyes suitable for LASIK surgery.

Intervention: Bilateral hyperopic LASIK surgery using a 200-Hz Allegretto excimer laser. The dominant eye was operated using a conventional profile. The nondominant eye was programmed with an aspheric ablation profile and −0.75 D monovision.

Main Outcome Measures: Primary outcome was the correlation between postoperative SA and depth of focus, defined as the pseudo-accommodation value (PAV = [1/reading distance {m}] − minimum addition [D]). Main secondary outcome was the comparison of depth of focus between patients with an induced SA close to the optimal one (group 1), patients with an induced SA far from the optimal one (group 2), and patients for whom SA induction did not increase the depth of focus (control group).

Results: We included 76 patients. Between preoperative and postoperative assessment, the mean increase of distance-corrected PAV for near vision was +0.25±0.64 D ($P < 0.001$) for dominant eyes and +0.63±0.55 D ($P < 0.001$) for nondominant eyes. As the level of negative or positive postoperative SA increased, PAV for intermediate and near vision increased. Among the 37 eyes that followed the preoperative adaptive optics assessment, the mean PAV increase at near was significantly higher ($P < 0.05$) in group 1 (0.93±0.50 D) than in group 2 (0.46±0.42 D) and than in the control group (0.35±0.32 D). The mean optimal SA value determined by the dynamic simulation procedure to optimize the depth of focus was −0.18±0.13 μm at 4.5 mm.

Conclusions: Aspheric hyperopic LASIK can increase the depth of focus without impairing far vision, but this benefit would be maximal and reproducible if we could define and achieve an optimal SA value determined by preoperative assessment using an adaptive optics instrument. *Ophthalmology 2015;122:233-243 © 2015 by the American Academy of Ophthalmology.*

Refractive correction for presbyopia with the Excimer laser system has recently been among the most discussed topics in refractive surgery. Several principles have been defined. Monovision LASIK is an extended technique published for the first time in 1999.[1] This procedure has been found to produce high levels of patient satisfaction in many studies.[2] However, the success of this technique has been limited by the ability of individuals to adapt to monovision itself and works best for people who are only mildly presbyopic. Nonetheless, to date, that kind of procedure does not prevent visual acuity (VA) at reading distance from diminishing with advancing age.

McDonnell et al[3] described improved VA from a multifocal effect after radial keratotomy. This opened new concepts for correction of presbyopia based on the induction of pseudoaccommodative cornea. Moreira et al[4] were the first to report the use of laser refractive surgery to reduce symptoms of presbyopia. Attempts based on inferior off-center ablation[5,6] have been abandoned owing to the decrease of the best spectacle-corrected VA. Ablation profiles in the form of a peripheral near zone[7–10] (concentric ring for near vision) or in the form of a central near zone[11–13] (central disk for near vision) are other used options. Even if presbyopia LASIK surgery is common, the coexistence of so many different and opposing techniques for approaching the same presbyopic problem shows that a satisfying corneal laser correction is yet to be found.

Many recent LASIK techniques for correcting hyperopia and presbyopia are based on corneal asphericity and the related induction of spherical aberration (SA) to increase the depth of focus.[14] Reinstein et al[15] combined extended depth of focus with monovision in a micro-monovision protocol,

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whereas Epstein and Gurgos[16] combined monocular peripheral presbyLASIK on the nondominant eye with monofocal distance correction on the dominant eye. Jackson et al[17] performed bilateral aspheric treatment and observed that negative SA was highly correlated with postoperative improvement of distance-corrected near VA. Despite their generally satisfactory results, these techniques present an unsatisfactory predictability concerning the induced depth of focus and consequent patient satisfaction.

In this context, we studied the relationship between corneal asphericity, SA, and depth of focus before and after the operative procedure to determine an optimal SA value. The primary objective of our study was to evaluate to what extent the modification of corneal asphericity and SA value could increase the depth of focus. The secondary objective was to determine whether preoperative assessment by using an adaptive optics instrument was able to predict the most useful SA value for each patient.

Methods

Study Design and Patients

This comparative, prospective study was conducted in the Department of Ophthalmology, Purpan Hospital, Toulouse, France. We included 76 consecutive hyperopic patients from December 1, 2012, to September 1, 2013. Study inclusion criteria were as follows: ≥45 years old, spherical hyperopia between +1.00 and +2.50 diopters (D) with an astigmatism lower than 1.25 D, a best-corrected VA of 10/10 Parinaud 2 (40 cm) or better for each eye, cornea suitable for LASIK with central corneal pachymetry of ≥520 μm, and a normal corneal topographic pattern.

We excluded patients with clinically significant ocular disease such as cataract or glaucoma, corneal diseases such as keratoconus or previous herpes keratitis, and previous corneal or intraocular surgery. The study was approved by the Ethical Committee of Purpan Hospital (HyperVOPTICA study no. 2012-AO1278-35) and conducted in accordance with the Declaration of Helsinki.

Patient Examinations

The evaluators (C.T. and B.L.) did not participate in the surgical process and the surgeon (F.M.) was not involved in postoperative data collection and analyses. The investigators (B.L. and M.C.) were asked to complete standardized data forms on all patients.

Patients were examined preoperatively and postoperatively at day 1, week 1, and month 3. All of the following analyses were performed preoperatively and 3 months after surgery for all patients: ocular dominance determination, manifest refraction, cycloplegic refraction, slit-lamp microscopy of the anterior segment, dilated fundoscopy, applanation tonometry, corneal topography with determination of Q factor at 6 mm and keratometry (Pentacam, Oculus Inc, Arlington, WA), pupillometry (Tonoref 2, Nidek), aberrometry at 4.5 and 6 mm (AOVIS-1, Voptica SL, Murcia, Spain), handheld ultrasound pachymetry (Corneo-Gage Plus; Sonogage, Cleveland, OH), and contrast sensitivity (CVS-1000; Vector Vision, Greenville, OH).

The visual assessment was performed using an adaptive optics–based instrument[18] preoperatively for the last 37 patients because of the unavailability of the instrument at the beginning of the study.

At the 1-day and 1-week time points after surgery, we performed a biomicroscopic examination, including a complete record of potential complications, such as interface fibrosis, epithelial ingrowth, folds, and opacities. Moreover, at each visit patients completed a subjective satisfaction questionnaire, reporting adverse events such as glare and halos and their vision quality in daily life on a scale of 3 to 0 (3, no change; 2, slight impact; 1, moderate impact; 0, intense impact).

Ocular Dominance Testing

Ocular dominance was assessed using 3 methods: the "hole test" and determining which eye was used for aiming through a camera and a rifle. The hole test involved the patient binocularly aligning a distant object through a hole in a sheet of white A4 paper, held at arm's length in landscape format, with each hand holding either end. The eyes were alternately covered while looking through the hole. The eye with which the object seemed to be centered through the hole was considered the dominant eye. Dominance was confirmed if the result was the same for all tests. If the 3 tests were inconclusive, the monovision assessment was repeated with each eye in turn as the dominant eye and the dominance was determined according to which setup felt more natural for the patient.

VA and Depth of Focus Examination

Concerning far vision testings, distance VA was assessed using a standardized scotopic Monoyer projection chart at a viewing distance of 5 m converted into minimum angle of resolution notation. A line of acuity was considered read if ≥3 of the 5 letters of that line were recognized correctly.

Concerning reading tests, we used standard procedures. The reading chart was the Parinaud scale. The results were also converted into minimum angle of resolution notation. Measurements were recorded for each eye separately and binocularly at a viewing distance of 40 cm (near vision) and 67 cm (intermediate vision). The reading distance between the trial frame and the reading chart was precisely determined using a graduated ruler.

All tests were performed under the same conditions of luminance. The luminance of the chart and the background was measured with a luminance meter (LS100; Minolta, Osaka, Japan). The luminance of the chart and the walls were 64.71 and 0.884 cd/m^2, respectively. Uncorrected and best-corrected VA were determined for distance vision and for near vision.

For the evaluation of the depth of focus, we decided not to use dynamic clinical methods (push up, push down, and minus lens procedure) owing to the great variability in the measurements. We used the minimum addition for reading. The minimum addition was determined by adding positive lenses by step of 0.25 D over the best distance correction until the patient reported he could read Parinaud 2 for near vision and Parinaud 3 for intermediate vision. The pseudo-accommodation value (PAV) was defined as (1/reading distance [m]) − minimum addition (D).

Adaptive Optics Visual Assessment Procedure

The instrument used in the study was the monocular Adaptive Optics Visual Analyzer (Voptica SL). It is a clinical instrument to perform visual testing with full control of the optical aberrations noninvasively induced in the patient's eye. It includes a Hartmann-Shack wave-front sensor to measure refraction and aberrations,[19] a liquid crystal on a silicon spatial light modulator to induce any desired aberration profile on the patient's eye, and a microdisplay to present the visual stimuli to the patient.[20] The instrument allows the operator to perform visual testing after induction of any optical aberration, particularly different amounts of SA.

All measurements were performed after instillation of cyclopentolate (repeated 3 times) 45 minutes before the procedure. The procedure was conducted in 2 phases. During the first phase, the aberrations were measured in both eyes at 4.5- and 6-mm pupil sizes.