Changes to Corneal Aberrations and Vision After Monovision in Patients With Hyperopia After Using a Customized Aspheric Ablation Profile to Increase Corneal Asphericity (Q-factor)

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ABSTRACT

PURPOSE: To evaluate the visual outcomes and fourth-order Zernike spherical aberrations induced with a customized change in corneal asphericity (ΔQ) correction of presbyopia combined with monovision for hyperopic patients.

METHODS: Consecutive hyperopic patients who underwent presbyopic LASIK between September 2013 and July 2014 were included. For the non-dominant eyes, the aspheric ablation profile associated with a myopic refraction was planned using the Custom-Q nomogram (Alcon Laboratories, Inc., Fort Worth, TX). Uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), spherical equivalent refraction, ΔQ, and change in corneal spherical aberration coefficient (ΔC₄) were analyzed. Postoperative data were collected at 1, 3, and 6 months.

RESULTS: Sixty-five patients were included. The mean age was 56.5 ± 5.7 years (range: 47 to 70 years). At the 6-month follow-up, the spherical equivalent refraction for non-dominant and dominant eyes was -1.07 ± 0.74 and 0.32 ± 0.55 diopters (D), respectively. The mean binocular UDVA was 0.01 ± 0.04 logMAR (range: -0.12 to 0.30 logMAR); 91% of patients achieved 20/20 or better binocular UDVA and 83% of patients had Jaeger 3 (Parinaud 4) or better binocular UNVA. The ΔQ for non-dominant and dominant eyes was -0.61 ± 0.15 and -0.33 ± 0.25, respectively, for a 6-mm pupil diameter and was significantly higher for non-dominant eyes (P < .0001). The achieved ΔC₄ was -0.49 ± 0.23 μm for non-dominant eyes (for a theoretical ideal value of -0.40 μm) and -0.30 ± 0.18 μm for dominant eyes. For non-dominant eyes, the attempted ΔQ (-0.60) was close to the achieved value (-0.61 ± 0.15).

CONCLUSIONS: For hyperopic patients, combining the customized corneal aspheric ablation profile with monovision is safe, effective, and reproducible, inducing intended changes in corneal spherical aberrations.

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of $\Delta C_4^0 = -0.4 \mu m$ using the Custom Q (F-CAT) treatment planning available on the WaveLight Refractive Suite platform (Alcon Laboratories, Inc., Fort Worth, TX).

**PATIENTS AND METHODS**

This prospective study included 130 eyes of 65 consecutive patients (45 women, 20 men) who underwent bilateral presbyopic LASIK at the Noémie de Rothschild Laser Institute, Paris, France, between September 2013 and July 2014. Inclusion criteria were hyperopic patients with presbyopia measured by a binocular distance-corrected near visual acuity worse than Jaeger 5 (Parinaud 4) at 40 cm. Exclusion criteria were LASIK contraindications, amblyopia with a corrected distance visual acuity (CDVA) no worse than 20/25 in either eye, hyperopia greater than +6.00 diopters (D), visually significant cataract, or photopic pupil diameter smaller than 3.5 mm.

All patients underwent complete preoperative and postoperative assessments, and none had remarkable ocular conditions (eg, ocular surface disease or eyelid disorders) before surgery or postoperative complications. Patients were observed for 6 months postoperatively. The local ethical committee approved this research and informed consent was obtained from all patients before their participation.

**PREOPERATIVE EVALUATION**

Ophthalmologic examination performed on all patients preoperatively included manifest refraction, cycloplegic refraction, non-contact intraocular pressure evaluation, slit-lamp microscopic evaluation of the anterior segment, and dilated fundoscopy. Preoperative examination included keratometry, elevation and curvature topography analysis with Orbscan II (Bausch & Lomb, Salt Lake City, UT), wavefront aberrometry, and pupillometry analysis with OPD-Scan III (Nidek, Inc., Fremont, CA).

UDVA and CDVA were assessed with Monoyer charts in decimals converted to Snellen equivalents. UNVA was evaluated with Parinaud near reading charts converted to Jaeger units. The necessary addition for reading Parinaud 2 (Jaeger 1) at 40 cm was obtained using the “minimal addition” method. Ocular dominance was determined using the pinhole test and the lens fogging technique. The patient fixated on a distant object with both eyes open and appropriate correction, then a +0.75 D lens was alternately introduced in front of each eye. The dominant eye was determined as the eye for which the blur was most noticeable. Corneal asphericity (at 6-mm diameter) and corneal spherical aberration $C_4^0$ root mean square (RMS) values (at 6-mm diameter) were analyzed according to Optical Society of America (OSA) recommendations.

**PRINCIPLES OF THE NON-DOMINANT EYE ASPHERIC LASER CORRECTION**

Theoretically, a pure change in corneal Zernike spherical aberration would change the paraxial power because of the presence of a defocus quadratic term ($r^2$) in its analytic expression ($r$ being the radial distance from the pupil center in polar coordinates). Zernike spherical aberration differs from Seidel spherical aberration, which is pure in $r^2$ terms and does not contain quadratic terms. In the analytical expression of a wavefront expansion, the terms in $r^2$ control for the paraxial defocus, whereas the $r^4$ terms have more impact on the local refraction toward the periphery of the entrance pupil zone. With modern commercially available corneal topographs and wavefront instruments, spherical aberration is expressed as a weighted Zernike polynomial expansion, in which $r^2$ terms are embedded in rotationally symmetrical spherical aberration higher order terms. On the other hand, platforms such as the EX500 excimer laser do not allow for titrating the postoperative amount of corneal Zernike spherical aberration. However, using the “custom-Q” program mode, the surgeon can select a target refraction (paraxial change) and a target corneal asphericity (custom-Q) value. The relationship between the impact of the change in corneal asphericity and apical radius of curvature on lower (eg, second order) and fourth-order Zernike terms has been examined in a previous study. Of importance was the fact that the required change in asphericity for hyperopic corrections and an intended change in spherical aberration ($\Delta C_4^0 = -0.4 \mu m$) ranged between $\Delta Q = -0.55$ and -0.70, depending on the preoperative corneal asphericity and paraxial defocus correction.

In the case of paraxial emmetropization, inducing some level of ocular negative spherical aberration incurred by peripheral corneal flattening would cause some hyperopic defocus for non-paraxial rays. In the context of presbyopia compensation, the increase in negative ocular spherical aberration may become valid only if the paraxial defocus correction (controlled by the change in the apical radius of curvature of the cornea in our model) aims at some level of negative (myopic) defocus, to improve unaided near vision. Subsequently, modifying the corneal asphericity toward increased prolateness would not change the apical power of the cornea operated on, but would reduce its refractive power toward the periphery, outside the paraxial zone. Hence, the modification of the corneal asphericity conforms to a direct modification of a Seidel spherical aberration term, which does not affect the apical corneal power. Although ensuring a paraxial myopic refraction, inducing an increment of negative spherical aberration via increased prolateness of the corneal contour would
reduce the myopic error toward the edge of the pupil. This served as a basis to develop a custom aspheric nomogram for inducing multifocality in the non-dominant eye for the correction of presbyopia and hyperopia.

**Surgical Procedure and Treatment Planning**

LASIK procedures were performed by two experienced surgeons (DG and AS) using the WaveLight Refractive Suite platform (Alcon Laboratories, Inc.). The flap creation was performed with the WaveLight FS200 femtosecond laser, using standard treatment settings (9.2-mm flap diameter and 130- to 140-µm flap thickness).

Photoablation was performed with the WaveLight EX500 excimer laser. For the dominant eye, a standard ablation profile (T-CAT) was planned with a plano target refraction and ablation 6.5-mm optical zone. For the non-dominant eye, the aspheric ablation profile was planned with the Custom Q (F-CAT) treatment option. The planned correction at the spectacle plane was determined as the addition of the distance manifest refraction correction with the near addition value required to obtain Jaeger 2 (Parinaud 3). For example, if the distance correction was +2.00 D and the near addition was +2.50 D, the correction entered was +4.50 D. The target Q-value was planned to achieve a change in corneal asphericity (ΔQ) value between -0.60 and -0.70 to induce, according to the theoretical model, an adequate variation in fourth-order Zernike spherical aberration coefficient (ΔC₄⁰) of -0.4 µm for a normalized 6-mm pupil size. The optical zone of photoablation was adjusted to 6 mm.

Because of a greater deviation between the pupillary axis and the visual axis (Kappa angle) in hyperopic eyes, preoperative corneal vertex and pupil axis were measured with the WaveLight Topolyzer VARIO linked with the EX500 laser. A valid assumption is to consider that the optimal centration for corneal refractive surgical procedures may be located close to or midway between the corneal vertex (first Purkinje image) and the pupil center. However, in some eyes, especially with hyperopia, the distance between these points can be as high as 500 to 600 µm. This reflects the existence of a large Kappa angle. Defining the proper axis for centration may become of critical importance in eyes that exhibit a large distance between the pupil center and the corneal vertex. The EX500 excimer laser software enables centration of the excimer profile of ablation from the pupil center (0%) to the corneal reflex (100%) or in between, by 10% step distance along the line joining the pupil center and the corneal reflex. That is why we planned to center the profile of ablation at equidistance between the pupil center and the corneal reflex (50%) for most cases and slightly decentered to the corneal reflex (60% to 70%) when the distance between these two points was more than 500 µm.

**Postoperative Evaluation and Re-treatment**

Data were collected 1, 3, and 6 months postoperatively. At every follow-up manifest refraction, monocular and binocular UNVA, UDVA, distance-corrected near visual acuity, and CDVA examinations were performed. Corneal asphericity (at 6-mm pupil diameter) and corneal spherical aberration (at 6-mm pupil diameter) were measured with OPD-Scan III.

Re-treatment was performed for UNVA or UDVA, respectively, measuring worse than Parinaud 6 (Jaeger 5) and 20/30 or for patients unsatisfied with their visual acuity for near, intermediate, or distance visual acuity after 3 postoperative months and once refractive stability was observed. Patients received complete information about the risks associated with LASIK re-treatment.

**Statistical Analysis**

All data were collected in a Microsoft Excel 2011 database (Microsoft Corporation, Redmond, WA). Statistical analyses were performed on XLSTAT software (Addinsoft, New York, NY). Graphs were made using Microsoft Excel 2011. Preoperative and postoperative data at 1, 3, and 6 months of follow-up were compared with the Student’s paired t tests, and linear regression was used for the subsidiary analysis. Outcomes measured were analyzed for final results, including the eyes that underwent postoperative enhancements. Bivariate correlations were computed with the Pearson’s correlation coefficient. Data were expressed as the means ± standard deviation. A P value of less than .05 was considered statistically significant.

**Results**

The mean age was 56.5 ± 5.7 years (range: 47 to 70 years). The mean preoperative spherical equivalents were +1.91 ± 0.94 D (range: +0.125 to +4.50 D) and +1.87 ± 0.86 D (range: +0.25 to 4.25 D) in the non-dominant and dominant eye, respectively. The mean spectacle near addition was +2.12 ± 0.33 D (range: +0.25 to +4.25 D).

**Efficacy**

Fifty-eight of 65 patients completed follow-up through 1 month, 42 patients through 3 months, and 49 patients through 6 months. UDVA, UNVA, spherical equivalent (SE) refraction, corneal asphericity, and corneal spherical aberration of 50 patients were analyzed. The distribution of binocular UDVA and UNVA are presented in Figure 1. At 6 months of follow-up, 91% of patients achieved 20/20 or better binocular UDVA and 83% achieved Parinaud 2 (Jaeger 1) or bet-
ter binocular UNVA. Seventy-three percent of patients achieved Parinaud 2 (Jaeger 1) or better monocular UNVA with non-dominant eyes (Figure 2) and 76% achieved 20/20 or better monocular UDVA for dominant eyes (Figure 3) at 6 months postoperatively.

**Safety**

At 6 months postoperatively, no eyes lost two Snellen lines or more of CDVA. One patient lost one line of CDVA due to a persistent intense glare in the non-dominant eye.

**Accuracy**

The mean SE refraction is presented in Figure 4. There was no statistically significant difference in preoperative SE between the non-dominant and dominant eyes, with 1.91 ± 0.94 and 1.87 ± 0.86 D (P < .0001), respectively. At the 6-month follow-up, SE refraction was significantly different, as expected, for distance and near eyes (-1.06 ± 0.74 vs 0.32 ± 0.56 D, P < .001).

Compared to preoperative measures, postoperative examinations showed corneal asphericity was more prolate after surgery for non-dominant and dominant eyes (P < .0001) (Figure 5A). The change in corneal asphericity (ΔQ) achieved at 6 months was significantly different than preoperative values for non-dominant and dominant eyes. As expected, the measured ΔQ was significantly higher in non-dominant eyes than in dominant eyes (-0.61 ± 0.15 vs -0.33 ± 0.25, P < .0001) (Figure 5B). The difference between attempted and achieved ΔQ is presented in Figure 6.

**Spherical Aberration**

Sixty-three of 65 patients completed 1 month of follow-up, 36 completed 3 months, and 50 completed 6 months. RMS values of the Zernike corneal spherical aberration coefficient (ΔC₄⁰) on a 6-mm diameter pupil size were positive preoperatively and became negative for non-dominant and dominant eyes at 1, 3, and 6 months postoperatively (Figure 7A). Changes in ΔC₄⁰ RMS value were significantly higher for non-dominant than for dominant eyes (-0.49 ± 0.23 vs -0.30 ± 0.19 μm, respectively; P < .0001) at the 6-month follow-up (Figure 7B).

A statistically significant correlation was found be-
Customized Aspheric Ablation Profile/Courtin et al

The mean binocular UDVA was 0.03 ± 0.06, 0.01 ± 0.03, and 0.01 ± 0.04 logMAR at 1, 3, and 6 months postoperatively, respectively. Figures 1-3 show the binocular and monocular (for distance and near eyes) UDVA and UNVA at 1, 3, and 6 months of follow-up.

The stability of the ΔQ and ΔC₄₀ RMS value parameters during the 6-month follow-up is presented in Figures 5B and 7B. For the non-dominant eye, there were no significant differences in ΔQ and ΔC₄₀ RMS values between 3 and 6 months of follow-up (P = .848 and .298).

**STABILITY**

The SE refraction was stable between the 3- and 6-month follow-up for the non-dominant and dominant eyes (P = .499 and .302, respectively) (Figure 4).

**RE-TREATMENT**

The re-treatment rate was 10.8% (7 patients) after 6 months from the first attempt. Five patients (71.4%) were re-treated in the non-dominant eye, and 2 patients (28.6%) in the dominant eye. Of the 7 patients who underwent re-treatment, only one received bilateral re-treatment for unsatisfying near and intermediate distance. Preoperative (age, SE refraction, addition, corneal asphericity, and corneal spherical aberration) or intraoperative (SE target and ΔQ planned) data were not significantly correlated with re-treatment. However, the study of all re-treatment cases showed a preoperative SE...
refraction higher than 3.00 D for 3 patients, but no statistically significant correlation could be demonstrated. All re-treatments were performed after at least 4 months of follow-up and after the initial treatment (stability of 1 month after control of the third month). No reversal treatment was performed.

**DISCUSSION**

Using a modeled corneal profile, Gatinel et al. determined that the theoretical target change in the Q-value \( (\Delta Q) \) required for an intended variation in the corneal spherical aberration on a 6-mm pupil size \( (\Delta C_{40} = -0.40 \mu m) \) was between -0.60 and -0.70, with a negligible influence of the preoperative keratometry and corneal asphericity values. Using ray tracing in a Navarro eye model, Amigó et al. have shown that, at 6-mm pupil diameter, exceeding a more negative spherical aberration than \(-0.40 \mu m\) does not increase the amount of accommodation. This spherical aberration value of \(-0.40 \mu m\) was also found and consistent with clinical practice, retrieving a similar value for patients who underwent hyperopic LASIK, after which an improvement in near vision without change in planned corneal asphericity was noted (unpublished data).

Our presbyopic LASIK strategy was expected to combine the benefits of multifocal ablation for a wider range of intermediate vision and monovision for enhanced depth of focus and improved near, intermediate, and distance visual acuity. This enables the surgeon to keep the induced anisometropia to a minimum, which minimizes cross-blurring (the blur difference according to the patient between the dominant eye used for distance vision and the non-dominant eye used for near vision) and optimizes binocular distance and near acuity. The myopic shift targeted on non-dominant eyes is an essential condition to obtain a useful and effective near vision. Indeed, changing the corneal asphericity toward a more prolate value does not change the central (paraxial) corneal curvature but induces a peripheral curvature flattening. Thus, the central corneal refractive power is not expected to change significantly, whereas the corneal peripheral refractive power is reduced. Therefore, targeting a paraxial myopic refraction is necessary to improve near vision.

Because the intended paraxial refractive power was deliberately targeted to be myopic in the non-dominant eye, the modification of the corneal asphericity (increased prolateness) aimed at reducing the amount of induced myopia toward the edge of the pupil area. We referred to this refractive change as a “demyopization” toward the edge of the pupil, which serves as a basis to consider the non-dominant eye as multifocal. The most appropriate postoperative paraxial refraction was determined by summing the distance and near spectacle addition values to obtain central myopic shift. Older patients might require more addition power for near vision preoperatively because of lower accommodative reserve in advanced presbyopia.

At 6 months postoperatively, 91% of patients achieved 20/20 or better binocular UDVA and 83% achieved Parinaud 2 (Jaeger 1) or better UNVA. All patients achieved a binocular UDVA of 20/30 and 98%

![Figure 6](image1.png) **Figure 6.** The relationship between planned and achieved change in corneal asphericity \( (\Delta Q) \) at the 6-month follow-up.

![Figure 7](image2.png) **Figure 7.** (A) Root mean square (RMS) value and (B) change in RMS value of the Zernike corneal spherical aberration coefficient \( C_{40} \) at 6-mm diameter for non-dominant eyes (NDE) and dominant eyes (DE) at 1, 3, and 6 months of follow-up.
could read most newspaper print with a binocular UNVA of Parinaud 4 (Jaeger 3) or better.

The change in corneal asphericity (ΔQ) achieved at the 6-month follow-up was significantly different for non-dominant and dominant eyes. The achieved ΔQ was close to the attempted value (-0.61 ± 0.15 vs -0.60 to -0.70) in the non-dominant eyes, in which the measured ΔC, was slightly more important than targeted (-0.49 ± 0.23 vs 0.4 μm). However, the relationship between achieved and attempted change in corneal asphericity was lower than expected (r² = 0.22), and can probably be explained by a large dispersion of achieved values related to epithelial remodeling during wound healing that reduced the aspheric profile of the cornea.\(^\text{15,16}\) Interestingly, there was a significant but lesser increase of the corneal prolateness in the dominant eyes (-0.30 ± 0.18 μm) according to the study by Llorente et al.\(^\text{17}\) evaluating changes induced by standard LASIK for hyperopia on corneal asphericity and spherical aberration. The procedure was safe with no loss greater than one Snellen line of CDVA reported at 6 months of follow-up. No patients requested to reduce the myopization, indicating each one tolerated refractive anisometropia.

**Limitations**

Pupil size in photopic and mesopic dynamic and shift probably plays a significant role in visual outcomes, independent of the corneal asphericity achieved. In fact, the principle of the modulation of negative spherical aberration is based on a coaxial optical system theory where the corneal vertex and the pupil center are coincident (angle ν = 0). This approximation is valid when the angle ν is minimal but may become less accurate when it is more important, as is common for hyperopic patients.\(^\text{9}\) To minimize this risk, corneal vertex and pupil axis were measured by the WaveLight Topolyzer VARIO linked with the EX500 laser, and the ablation profile was centered toward the corneal vertex with a pupil offset value of 50% to 70% to approximate the visual axis.\(^\text{12,13}\) However, we have not studied the effect of Kappa angle on postoperative outcomes. Nonetheless, a small pupil diameter could reduce the effectiveness of the aspheric shape and induce spherical aberrations while increasing the depth of field. The excimer laser ablation profile was not adapted to the preoperative pupil diameter dynamics. Patients should be required to have pupil diameters larger than 3 mm in photopic conditions (for effectively using the near central corneal zone) and larger than 4.5 mm in mesopic conditions (for effectively using the pericentral intermediate and distant corneal zone), as proposed by Luger et al.\(^\text{5}\) For smaller pupils, the ablation zone should theoretically be reduced to obtain an effective multifocality within the entrance pupil area. Our mathematical model\(^\text{16}\) used an optical zone of 6 mm. It would therefore be interesting to investigate the theoretical and clinical consequences of pupil size and the dynamic on the aspheric profile ablation.

Our study was also limited to objective corneal parameters and high-contrast visual acuity. This analysis could be completed by subjective rating using some quality of vision scores and assessing symptoms or additional metrics such as contrast sensibility.

At 6 months of follow-up, 15 of the 65 patients included in the study were lost to follow-up, resulting in missing data that could introduce bias to the statistical analysis.

Finally, presbyopia results in progressive loss of accommodation, which increases until the age of 65 to 70 years. Thus, the addition required for near vision increases with age and our strategy creates a myopic shift adapted to the accommodative reserve at the time of surgery, although it could become insufficient over time. Moreover, two studies with long-term follow-up of 5 years highlighted a regression of hyperopic LASIK refractive correction.\(^\text{18,19}\) A 6-month follow-up is sufficient to confirm the safety and accuracy of our surgical strategy, but a longer follow-up time is required to assess the stability and durability of this treatment.

**Generalization and Perspective**

Creating a prolate ablation profile to induce spherical aberrations is an effective pseudo-accommodation strategy for presbyopic patients, consistently resulting in improved UDVA and UNVA.\(^\text{20}\) Different studies\(^\text{21,22}\) showed that monovision LASIK for correction of presbyopia was a valuable solution.

Our outcomes for UDVA, UNVA, and CDVA loss of two or more lines and re-treatment percentage were similar to recent published studies using presbyopic LASIK with central multifocal ablation profiles in hyperopic patients.\(^\text{2,4,5,23-28}\) The proportion of patients achieving 20/20 or better binocular UDVA varied from 36.6% to 93% in the study from Reinstein et al.\(^\text{4}\) (vs 91% in our study). The proportion of patients achieving Jaeger 3 (Parinaud 4) or better binocular UNVA varied from 60% to 100% in the study by Jackson et al.\(^\text{2}\) (vs 93% in our study). The proportion of patients with a loss of two or more lines of CDVA varied from 25% to 0.5% for Reinstein et al.\(^\text{4}\) (vs 0% in our study) and the re-treatment rate varied from 21.7% to 0% for Luger et al.\(^\text{24}\) (vs 10.8% in our study). Clinical outcomes using different techniques of presbyopic LASIK were reported and summarized in several recent studies.\(^\text{3,5,29,30}\) The current development throughout the corneal surgical compensation for presbyopia in
hyperopic patients indicates a converging trend toward hybrid techniques. Strategies involve a combination of different optical principles, including monovision, multifocality, asphericity modification, and pinhole, to improve visual outcomes. However, in future studies it could be interesting to establish common criteria to evaluate visual outcomes to compare more accurately the different techniques and platforms used in the treatment of presbyopia in refractive surgery.

Our results validate the theoretical prediction of the required change in corneal asphericity (ΔQ) to induce a controlled change in the fourth-order Zernike spherical aberration coefficient (ΔC₄⁰) with the customized aspheric refractive correction of hyperopia. The change in corneal asphericity associated with monovision using our nomogram with the WaveLight Refractive Suite, Custom Q (F-CAT) treatment planning combined the benefits of multifocality and the monovision technique as an effective and safe LASIK strategy for presbyopia correction in hyperopic patients.

AUTHOR CONTRIBUTIONS

Study concept and design (RC, AS, DG); data collection (RC); analysis and interpretation of data (RC, AS, AG-D, EG, DG); writing the manuscript (RC); critical revision of the manuscript (RC, AS, AG-D, EG, DG)

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