Presbyopia management with Q-factor modulation without additive monovision: One-year visual and refractive results

Fabien Rouimi, Sofiane Ouanezar, Isabelle Goemaere, Anne Charlotte Bayle, Vincent Borderie, Laurent Laroche, Nacim Bouheraoua

► To cite this version:

Fabien Rouimi, Sofiane Ouanezar, Isabelle Goemaere, Anne Charlotte Bayle, Vincent Borderie, et al.. Presbyopia management with Q-factor modulation without additive monovision: One-year visual and refractive results. Journal of Cataract and Refractive Surgery, 2019, 45, pp.1074 - 1083. 10.1016/j.jcrs.2019.02.039 . hal-03487913

HAL Id: hal-03487913

<https://hal.science/hal-03487913>

Submitted on 20 Dec 2021

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Distributed under a Creative Commons Attribution - NonCommercial| 4.0 International License

Presbyopia management with Q-factor modulation without additive monovision: one-year visual and refractive results

Fabien Rouimi, M.D.¹, Sofiane Ouanezar, M.D.¹, Isabelle Goemaere, M.S.¹, Anne Charlotte Bayle, M.S.¹, Vincent Borderie, M.D, Ph.D.^{1, 2}, Laurent Laroche, M.D.^{1, 2}, Nacim Bouheraoua M.D, Ph.D.^{1, 2}

¹Quinze-Vingts National Ophthalmology Hospital, UPMC - Sorbonne Université, Paris, France.

²Institut de la Vision, INSERM UMR S 968, UPMC - Sorbonne Université, Paris, France

Corresponding author: Nacim Bouheraoua, M.D., Ph.D.

Quinze-Vingts National Ophthalmology Hospital. 28, rue de Charenton, 75012 Paris, France.

Tel: +33 1 40 02 15 07, FAX: +33 1 40 02 15 99. E-mail: nacim.bouheraoua@gmail.com

Running title: Presbylasik by Q-factor modulation

Keys words: Cornea; presbyLASIK; presbyopia; Q factor; corneal asphericity; spherical aberration; LASIK; aberrometry; topography

Financial disclosure: The authors have no conflict of interest to declare.

Abstract

Purpose: To analyze refractive results after hyperopic presbyopia surgery by Q-factor modulation without additive monovision.

Setting: Quinze-Vingts National Ophthalmology Hospital, Paris, France.

Design: Prospective non-randomized study.

Methods: We included 90 eyes from 45 hyperopic presbyopic patients not tolerating monovision. The target for the dominant eye (DE) was emmetropy, whereas that for the non-dominant eye (NDE) was emmetropy associated with a target Q-factor of -0.8. Postoperative follow-up included assessments of spherical equivalent refraction (SEQ), monocular and binocular corrected (CDVA) and uncorrected (UDVA) distance, binocular corrected (CNVA) and uncorrected (UNVA) near visual acuities. Corneal pachymetry, topography, aberrometry and an analysis of patient satisfaction were performed at the 12-month examination.

Results: Mean age at surgery was 53.8 ± 4.99 years. Mean preoperative SEQ was $+2.33 \pm 1.16$ diopters (D) for the DE and $+2.26 \pm 1.17$ D for the NDE. At 12 months, 93% of patients had a binocular UDVA of Snellen 20/20 and 82% had a binocular UNVA of Jaeger 2 (Parinaud 3). Mean SEQ at 12 months was -0.22 ± 0.35 D ($P < 0.0001$) for the DE and -0.83 ± 0.50 D ($P < 0.0001$) for the NDE. Two eyes required retreatment. Overall, 87% of the patients said that they were satisfied and would recommend the intervention.

Conclusion: Q-factor modulation without additive monovision aims to compensate for presbyopia by changing the Q-factor of the NDE to generate a greater depth of field in hyperopic presbyopic patients unable to tolerate monovision. Visual outcome and quality of vision were satisfactory and few patients required additional correction.

Introduction

The management of presbyopia has long been a subject of interest to ophthalmologists. As the population ages, this progressive decrease in the ability to focus on nearby objects becomes more prevalent, together with an increasing need for the correction of both near and intermediate vision. Both ophthalmologists and patients are seeking a safe, effective procedure to replace accommodation, to restore a full range of vision. The correction of presbyopia and the restoration of accommodation are therefore considered to be major issues in the field of refractive surgery. The surgical correction of presbyopia is a hot topic in refractive surgery, for which rapid progress has been made over the last few years.

Various approaches for the correction of this disability have been evaluated, including multifocal intraocular lenses, accommodative intraocular lenses, laser-assisted corneal surgery and intracorneal inlays¹. Laser *in situ* keratomileusis (LASIK) is the most widely performed corneal refractive procedure worldwide, and recent improvements in our understanding of corneal aberrometry have paved the way for laser-assisted procedures involving changes in corneal asphericity^{2, 3}. The increase in depth of field obtained in this way could improve intermediate and near vision, to the extent that the patient may no longer be dependent on spectacles⁴. Many multifocal or aspherical laser-assisted corneal surgery techniques have been developed, some uni or bilateral, peripheral, centered or off-center, and they are all grouped together under the umbrella term presbyLASIK. Central multifocal⁵⁻¹⁰ or aspherical¹¹⁻¹⁶ presbyLASIK is the technique of choice today, and may be combined with monovision to enable patients to benefit from both techniques. Results have been reported for F-CAT associated with monovision on the non-dominant eye (NDE)¹²⁻¹⁶, but visual results are lacking for isolated aspheric treatment on the NDE in patients unable to tolerate monovision.

In this study, we assessed, in hyperopic patients, the visual and refractive outcome of presbyopia surgery based on central presbyopic LASIK with corneal asphericity modulation

by Q-factor modification of the F-CAT program on the NDE without additive monovision, associated with emmetropy for the dominant eye (DE), focusing, in particular, on postoperative quality of vision.

Materials and Methods

This prospective non-randomized observational study of consecutive hyperopic patients with presbyopia was performed between February 2012 and November 2015 at the Quinze-Vingts National Ophthalmology Hospital in Paris, France. Informed consent was obtained from each patient before inclusion in the study, in accordance with the Declaration of Helsinki, and the study was approved by the Ethics Committee of the French Society of Ophthalmology (Institutional Review Board 00008855).

Patients with minimum of + 1.00 diopters (D) of hyperopic manifest refraction and clinically significant presbyopia were included. The inclusion criteria were as follows: corrected distance visual acuity (CDVA) of Snellen 20/20 or better, demonstrated stable manifest refraction for at least one year, a clear lens, no ocular condition or history of ocular surgery, and a poor tolerance of monovision which was defined by a marked discomfort after wearing a day contact lens with +1.00 D added to the non-dominant eye. Patients with a high risk of post-LASIK ectasia according to the Ectasia Risk Score System designed by Randleman and colleagues were not included in this series¹⁷. The other exclusion criteria were systemic chronic disease and corectopia. The minimum required follow-up was fixed at 12 months post-surgery.

Before surgery, all patients underwent a complete ophthalmologic examination, including manifest refraction, cycloplegic refraction, determination of DE in the hole-in-the-card test and the preferential blur test, monovision test with contact lens for a day with +1.00 added to the non-dominant eye, slit-lamp microscopy of the anterior segment, dilated fundus examination, intraocular pressure measurement, corneal topography, pachymetric mapping

and aberrometry. Monocular and binocular uncorrected distance visual acuity (UDVA), CDVA and binocular uncorrected near visual acuity (UNVA) and corrected near visual acuity (CNVA) were measured in the following conditions. Near vision was recorded as the smallest print the patient could read fluently and comfortably on the Parinaud reading chart at 35 cm with and without correction.

Corneal topography was performed with the Orbscan IIz system (Orbscan II, Bausch and Lomb surgical, Rochester, NY). Corneal pachymetry was performed by high-resolution anterior segment optical coherence tomography (AS-OCT) (RTVue, OptoVue, Inc, Fremont, CA, USA). Wavefront aberrometry measurements were obtained with an ITrace aberrometer (Hoya, Tokyo, Japan) on the undilated pupil in scotopic condition without pharmacological dilatation knowing that the study examines corneal wavefront aberrations and that the pupil diameter is not critical. The main outcome measurements were the efficacy, accuracy, stability and safety of the procedure. Patient satisfaction was also assessed at the last follow-up visit. Efficacy was evaluated by measuring binocular UDVA and UNVA. Accuracy was evaluated by comparing the target and achieved spherical equivalent refraction (SEQ) and Q-factor. Pachymetry, central keratometry, and the root mean square (RMS) values of the Zernike corneal spherical aberration coefficient (C_4^0) were also evaluated. Stability was evaluated by analyzing changes in SEQ over the year following surgery. Safety was evaluated by slit-lamp examination, near and distance CDVA for both eyes, and changes in CDVA between the preoperative and postoperative examinations. Patients were asked whether they were satisfied with their visual comfort for everyday activities and whether they would recommend the surgery, 12 months after the intervention (or 12 months after the first procedure in cases of retreatment). All procedures were performed with an IntraLase™ femtosecond laser (Abbott Medical Optics, Santa Ana, USA) and the WaveLight EX500 Allegretto Wave™ Excimer Laser System (Alcon, Fort Worth, TX Inc) in the same dedicated

operating room. All patients underwent a standard LASIK procedure on both eyes on the same day with similar settings, under topical anesthesia with oxybuprocaine (1.6 mg/0.4 ml; oxybuprocaine chlorhydrate, Thea, Clermont-Ferrand, France). A 9-mm flap with a target depth of 110 microns was created in each case. The target optical zone was 6.5 mm in all cases, with a transition zone of 1.0 mm.

For the DE, a standard Wavefront Optimized treatment was performed, aiming for emmetropy and distance vision. For the NDE, an aspheric treatment was performed with the F-CAT treatment planning module. The target Q-factor setting was -0.8 for all patients, regardless of the preoperative Q-factor. This treatment aimed to modify mean asphericity by adjusting the number of midperipheral laser pulses. A readjustment of target refraction by myopization was required to compensate for the defocusing induced by Q-factor modification, but without additional myopization (no additive monovision).

The postoperative treatment was topical tobramycin and dexamethasone (Tobradex®, Alcon Laboratories, Inc.), three times daily for one week and lubricant for one month. Postoperative check-ups were scheduled for one day, one week, one month, and at least 12 months after surgery. Postoperative follow-up included slit-lamp examination, monocular and binocular UDVA and CDVA, binocular UNVA and CNVA measurements. Corneal pachymetry, corneal topography, and aberrometry and an assessment of satisfaction were also performed at the 12-month visit.

Safety and efficacy

The safety and efficacy indices were assessed. The efficacy index was defined as mean postoperative UDVA divided by mean preoperative CDVA. The safety index was defined as mean postoperative CVDA divided by mean preoperative CDVA.

Statistical analysis

The results are presented as means and standard deviations for continuous variables and as proportions for discrete variables. We used the D'Agostino-Pearson test to assess the normal distribution of our data and then used parametric statistics. We used *t*-tests to compare continuous data, as appropriate, and *t*-tests for paired data to evaluate the significances of differences in continuous data before and after surgery. We used Spearman's correlation coefficient test to explore the relationships between values. Snellen visual acuities were converted into logarithm of the minimum angle of resolution (logMAR) units for analysis. Corrected *P* values < 0.05 were considered statistically significant. Statistical analysis was performed with SPSS for Windows version 20.0 (SPSS, Inc, Chicago, IL).

Results

Preoperative assessment

We treated 90 eyes in 45 consecutive patients. There were 20 men and 25 women and the mean age of the patients was 53.8 ± 4.99 years. Mean preoperative SEQ was $+2.33 \pm 1.16$ D for the DE and $+2.26 \pm 1.17$ D for the NDE. The mean addition for binocular near vision was $+2.3 \pm 0.48$. There was no significant difference in refraction between the two eyes in any of the patients. Mean minimal pachymetric corneal thickness was 541 ± 30 μ m for the DE and 539 ± 30 μ m for the NDE. Mean Kmax was 44.3 ± 1.47 D for the DE and 44.1 ± 1.45 D for the NDE. The mean corneal Q factor at 6 mm before surgery was -0.19 ± 0.05 for the NDE and -0.18 ± 0.04 for the DE. The RMS values of the Zernike corneal spherical aberration coefficient (C_4^0) on a pupil of 6 mm in diameter were 0.21 ± 0.13 μ m for the DE and 0.20 ± 0.12 μ m for the NDE. Mean preoperative UDVA was 20/63 (logMAR 0.45 ± 0.28) for the DE and 20/63 (logMAR 0.45 ± 0.29) for the NDE. Mean preoperative CDVA was 20/16 (logMar -0.084 ± 0.076) for the DE and 20/16 (logMar -0.098 ± 0.076) for the NDE. Mean preoperative binocular CNVA was Jaeger 1 (Parinaud 2) (logMAR 0.16 ± 0.046). The

readjustment of target refraction by myopization necessary to compensate for the defocusing induced by Q-factor modification was about -1.3 ± 0.79 D on average in our study. The results of the preoperative assessments are summarized in Table 1.

Efficacy

Mean binocular UDVA at 12 months after surgery was 20/20 (logMAR -0.072 ± 0.07). Mean binocular UNVA was Jaeger 2 (Parinaud 3) (logMAR 0.28 ± 0.14). At 12 months of follow-up, 93% of patients had a binocular UDVA of Snellen 20/20 or better (figure 1) and 82% had a binocular UNVA of Jaeger 2 (Parinaud 3) or better, with 51% achieving a binocular UNVA of Jaeger 1 (Parinaud 2) or better (figure 2). The distributions of binocular and monocular UDVA and binocular UNVA are presented in figures 1 and 2, respectively. The mean efficacy index was 0.809 for the DE.

Accuracy

At one year, the mean manifest refraction spherical equivalent (SEQ) was -0.22 ± 0.35 and -0.83 ± 0.5 for the DE and the NDE, respectively. SEQ differed significantly between the two eyes of each patient after surgery ($P < 0.001$). Accuracy data for DE and NDE SEQ are presented in figures 3 and 4.

For keratometry, measured Kmax had significantly changed for both the DE (44.3 ± 1.47 D vs. 45.34 ± 1.29 D ($P < 0.0001$)) and for the NDE (44.14 ± 1.45 D vs. 45.47 ± 1.37 D ($P < 0.0001$)) 12 months after surgery. Minimal pachymetric corneal thickness had changed from 541 ± 30 μ m to 522 ± 24 μ m ($P < 0.0001$) for the DE, and from 539 ± 30 μ m to 524 ± 28 μ m ($P < 0.0001$) for the NDE. The results of the one-year assessment are summarized in Table 1.

Corneal asphericity and spherical aberrations

The corneal Q factor at 6 mm before surgery was -0.19 ± 0.05 for the NDE and -0.18 ± 0.04 for the DE. This factor was significantly modified by surgery, to -0.78 ± 0.04 for NDE

($P < 0.0001$) and -0.48 ± 0.03 for DE ($P < 0.0001$) (figure 5). The difference in Q achieved at 12 months was significantly greater for the NDE than for the DE (-0.58 ± 0.22 vs. -0.31 ± 0.17 , $P < 0.0001$) (figure 5).

Twenty-four of the 45 patients underwent aberrometry at 12 months of follow-up. The RMS values for the Zernike corneal spherical aberration coefficient (C_4^0) for a pupil of 6 mm in diameter were $0.21 \pm 0.13 \mu\text{m}$ for the DE and $0.20 \pm 0.12 \mu\text{m}$ for the NDE. These values had become negative 12 months after surgery, at $-0.06 \pm 0.17 \mu\text{m}$ and $-0.24 \pm 0.12 \mu\text{m}$, respectively (figure 6). At 12 months the changes in C_4^0 RMS values after surgery were significantly greater for the NDE than for the DE (-0.43 ± 0.17 vs. $-0.26 \pm 0.15 \mu\text{m}$, respectively; $P = 0.002$) (figure 6).

Stability

SEQ refraction stability is presented in figure 7. The SEQ of the DE was stable over the 12 months following surgery, with a non-significant mean change from -0.3 ± 0.3 D at 1 month to -0.22 ± 0.35 D ($P = 0.1$) at 1 year, and a progressive shift in myopia toward emmetropia for the NDE was observed, with a significant mean change from -1.07 ± 0.45 D at 1 month to -0.83 ± 0.5 D ($P = 0.04$) at 1 year.

Safety and complications

Mean CDVA for the DE was logMAR -0.084 ± 0.076 (Snellen 20/16) before and logMAR -0.092 ± 0.06 (Snellen 20/16) after surgery. For the NDE, mean CDVA was logMAR -0.098 ± 0.075 (Snellen 20/16) before and logMAR -0.091 ± 0.067 (Snellen 20/16) after surgery. For each treatment, the monocular loss of CDVA was minimal: three patients (7%) lost one line of Snellen CDVA for the DE and 10 patients (22%) lost one line of Snellen CDVA for the NDE (Figure 8).

All of the patients attained a CDVA of at least logMAR 0 (20/20 Snellen lines) for the DE and the NDE; 91% of UDVA values for the DE were within one line of Snellen CDVA and

94% of the binocular UDVA values were within one line of Snellen CDVA. The difference between postoperative UDVA and preoperative CDVA is presented in figure 9. The safety indices were 0.929 for the NDE and 1.095 for the DE. No intraoperative or postoperative complications occurred.

Two eyes required retreatment. The first patient underwent retreatment four months after initial surgery, on an overcorrected DE, to improve UDVA. The DE SEQ improved from -0.75 to 0 D after this intervention. Binocular UDVA improved from 20/80 to 20/20 after surgery (12-month visit). The second patient underwent retreatment six months after initial surgery, on the NDE, to improve UNVA by an additional +1D because the postoperative NDE SEQ was 0 D. Binocular UDVA and UNVA were 20/16 and Jaeger 3 (Parinaud 4), respectively, before retreatment. Six months after retreatment, binocular UNVA increased to Jaeger 1 (Parinaud 2), and there was no change in binocular UDVA.

Satisfaction

Twelve months after the initial intervention, 39 patients (87%) declared themselves satisfied with their visual comfort for everyday activities and said that they would recommend this surgery. The patients declaring themselves not satisfied included the two cases requiring retreatment. At the last follow-up visit, two patients (4%) still required glasses, with a minimal correction of about -0.50 D for the non-dominant eye, to improve distance vision for activities requiring sustained concentration. Three patients (7%) needed glasses for near vision, with an additional correction of about +1 D. Two patients reported halos, particularly when driving at night. None of the patients spontaneously complained of eye dryness.

Discussion

The technique used here was expected to combine the benefits of classic hyperopic Lasik on the DE to improve distance vision and to induce myopic defocus and a negative spherical aberration value in the NDE, to increase depth of field and improve near vision. This method

can also be combined with monovision to reduce the degree of myopia and increase tolerability^{18, 19}. A number of concerns, including optical and visual distortion, and a decline in uncorrected distance vision¹¹, have prevented the widespread acceptance of these procedures. Hyperopic presbyopic individuals seem to be good candidates for these procedures, as standard Excimer ablation profiles already induce corneal prolatization^{20, 21}. The achievement of a more negative Q-factor value may increase corneal asphericity, increasing the negative aberration and potentially improving depth of field^{22, 23}. However, this change in asphericity involves a hyperopic defocus for peripheral incoming light rays. This must be corrected when setting the laser parameters, by aiming for a negative refractive target, so as to keep the defocus Zernike coefficient unchanged.

By comparison with classic monovision treatment, the change in asphericity induces a certain degree of multifocality in the NDE, potentially combining an improvement of near vision with a limited impairment of binocular distance vision. Indeed, a loss of visual quality for near or distance vision has been reported in service series of classic monovision cases²⁴.

The LASIK correction of presbyopia with different software suites for treatment planning software has frequently been evaluated. Most of these techniques, referred to collectively as *presbyLASIK*, involve monocular or binocular asphericity changes to improve the depth of field. For our study, we performed on the dominant eye a classical hypermetropic treatment leading to emmetropisation for far vision, and for the non-dominant eye, an aspheric treatment with a target Q factor of -0.8 and hypermetropic induced defocus readjustment with no monovision added. 93% of the patients achieved a binocular UDVA of Snellen 20/20 or better and 82% achieved a binocular UNVA of Jaeger 2 (Parinaud 3) or better, with 51% achieving a binocular UNVA of Jaeger 1 (Parinaud 2). Good visual acuity was obtained for distance vision, together with a close vision sufficient for everyday activities, such as reading the newspaper (Jaeger 2/Parinaud 3). However, for activities requiring some accuracy,

additional optical correction may be required for some patients. This is probably due to the absence of programmed additive monovision in the patients studied¹⁵.

These findings are consistent with those for a published series on the Wavelight Allegretto EX500 F-CAT program. In a recent series reported by Leray and colleagues¹², 93% of patients achieved a binocular UDVA of 20/20 and 71% achieved a binocular UNVA of Parinaud 2 or better three months after surgery. The laser parameters were different from those used here, with a refractive target for the NDE of -0.75 D and a target Q factor of -0.8D to induce monovision in addition to multifocality. Near vision was better in this previous study, probably due to the very slight monovision added. In another series reported by Ho Wang Yin and colleagues¹⁴, 100% at one year of follow-up had a binocular UDVA of 20/20 or better and 70% had a binocular UNVA of Jaeger 2 (Parinaud 3) or better. The refractive target and the target Q factor for the NDE were set at -0.50 D and between -0.6 and -0.8. In another series described by Courtin and colleagues¹³, 91% of patients had a binocular UDVA of 20/20 or better, 89% had a binocular UNVA of Jaeger 2 (Parinaud 3) or better and 83% had a binocular UNVA of Jaeger 1 (Parinaud 2) or better at 6 months, with a target ΔQ for the NDE of -0.6 to -0.7 (corresponding to a postoperative Q-factor of about 0.8 to 0.9) and a variable refractive target for the NDE depending on the addition to near vision required for reading. The added monovision induced better near visual acuity for activities requiring precision (Jaeger 1/Parinaud 2) than was achieved in our study. The setting of the target Q value is a matter of debate¹⁹ in the absence of a consensus, but considering the natural asphericity of the cornea, we set a target Q value of -0.8, which seems to be widely used for presbyopia correction in hyperopic patients and is typical of other published studies on the Q factor. However, unlike these other studies, we did not target postoperative myopia in addition to defocus compensation, but nevertheless achieved to a greater myopisation on the dominant eye (-0.83 D) compared to the dominated eye (-0.22 D). Knowing that the

measurement of the spherical equivalent is made on the central 3 mm by the
 autorefractometer, it can be deduced that performing a Q-factor treatment with hypermetropic
 defocus readjustment induces a slight central myopization responsible for a mini-monovision,
 which contributes in addition to the NDE induced multifocality to improving near-vision. The
 procedure resulted in good close visual acuity for activities of daily living, but with less
 accuracy. Gatinel and colleagues determined a theoretical target of change in the Q factor (ΔQ),
 required to achieved a corneal spherical aberration variation C_4^0 of $-0.40 \mu\text{m}$ for a pupil size
 of 6 mm: -0.60 to -0.70 ³. If we consider the mean Q factor in the population to be about -
 0.20, then we need to target a postoperative Q factor of between -0.8 and -0.9. The choice of
 this change in spherical aberration (ΔC_4^0 : $-0.40 \mu\text{m}$) is based on clinical practice, in which a
 larger negative change has been found not to increase depth of focus but to decrease the
 quality of vision²⁵. We set the target Q factor to -0.8 for all patients and achieved a ΔQ close
 to the target value in the NDE (-0.58 ± 0.22 vs. -0.60 to -0.70) and similar results for ΔC_4^0 ($-$
 0.43 ± 0.17 vs. $-0.40 \mu\text{m}$). As expected with the classic hyperopic LASIK procedure²¹ on the
 DE, corneal prolateness increased significantly (ΔQ of -0.31 ± 0.17). One of the limitations of
 this study is that only 24 of the 45 patients were able to benefit from wavefront aberrometry
 measurements because of the unavailability of the aberrometer during part of the follow-up.
 A progressive shift in myopia toward emmetropia was observed for the SEQ of the NDE,
 which displayed a mean change from -1.07 D at 1 month to -0.83 D ($p=0.04$) at one year
 whereas DE SEQ refraction seemed to remain stable over this period ($p=0.1$). A similar
 pattern can be observed in the series published by Ho Wang Yin and colleagues, in which
 NDE SEQ changed from -1.3 ± 1.0 D at 1 month after surgery to -0.7 ± 0.7 D at 1 year after
 surgery¹⁴ and in the series published by Courtin and colleagues, in which SEQ changed from -
 1.40 D at 1 month to -1.07 D at 6 months after surgery¹³. The effectiveness of this procedure
 probably decreases over time, probably due to the natural regression of hypermetropic LASIK

associated with a gradual loss of accommodative power. The long-term regression of classic hyperopic LASIK refractive correction was revealed by two studies^{26, 27}, but longer term studies are required to evaluate the long-term stability of this surgical technique for modulating Q factor.

No surgical complications were reported in our series and two patients required retreatment (5%). Courtin and colleagues reported a retreatment rate of 10.7%¹³ and Ho Wang Yin and colleagues reported a retreatment rate of 23%¹⁴. However, the indication for retreatment differs considerably between surgeons and is not really comparable between studies. Also, we can note in our study that the loss rate of one line of CDVA for the NDE (22%) is much higher than for the DE (7%). This is explained by the fact that the NDE present, as expected, a corneal asphericity much more marked compared to the DE postoperatively. This corneal asphericity degrades the quality of vision which cannot be compensated by glasses which explains this difference of CDVA between the 2 eyes.

In our series, subjective satisfaction with visual comfort for everyday activities was good at the last follow-up visit; 87% of our patients were satisfied and would recommend this operation. However, satisfaction is highly subjective and depends on the personal needs of the patient concerned. Some patients will be satisfied with an imperfect near vision and will not need glasses, whereas others will be more demanding and will not be able to read without glasses. We also report a good rate of spectacle independence, with 89% of our patients no longer requiring glasses for any distance.

Several Excimer laser platforms have been evaluated for the treatment of both hyperopia and presbyopia, with good results^{5, 8, 11, 28}. Using the Carl Zeiss Meditec MEL80 platform, Reinstein and colleagues obtained similar efficacy results, with 81% of patients achieving a binocular UNVA of Jaeger 2 and 95% achieving a binocular UDVA of 20/20 one year after surgery¹¹. Similarly, Supracor modulates corneal asphericity simultaneously in both eyes. In

recent studies, visual outcome and global satisfaction with this technique were similar to our results, with retreatment rates ranging from 13% to 22%^{5,28}.

Other surgical approaches for presbyopic compensation have been studied. Several studies reported satisfactory efficacy and safety results for corneal inlays for the treatment of presbyopia in emmetropic or previously LASIK-treated patients²⁹⁻⁴⁰. There are still concerns about the risks of infection, stromal fibrosis or melting after implantation⁴¹.

Finally, another widespread alternative for correcting both sphero-cylindrical ametropia and presbyopia is intraocular lens implantation. Multifocal intraocular lenses have been widely studied and shown to be effective, with patients frequently no longer requiring spectacles for intermediate vision⁴². However, intraocular implantation is a more invasive procedure, raising questions not only about the risk of infection, but also about that of retreatment in cases of poor visual outcome⁴³.

We chose to focus on hyperopic presbyopic patients unable to tolerate monovision. Although we did not therefore increase myopization beyond the readjustment of target refraction to compensate for the defocus induced by Q-factor modification, this treatment induces a slight central myopization responsible for a mini-monovision. The beneficial effects for near vision would therefore be expected to fade more rapidly with aging and the progressive loss of accommodation than in patients with associated monovision, but our results for distance and near visual acuities were nevertheless good, with low rates of retreatment and high levels of satisfaction. In conclusion, the treatment of both hyperopia and presbyopia with a Wavefront Optimized ablation program on the DE and the Wavelight Allegretto F-CAT program on the NDE, without additive monovision, seems to be a safe and efficient technique for achieving spectacle independence.

What was known?

- Q-factor modulation, including increased negativity of the Q factor (hyperprolateness), improves depth of focus, which is useful for near vision.
- Presbyopia management with Q-factor modulation (F-CAT) with moderate additive monovision (around 0.50-1.0 D) provides good results for distance and near vision, with high rates of spectacle independence for presbyopic hyperopic patients.

What does this paper add?

- We evaluated Q-factor modulation (F-CAT) without additive monovision.
- Q-factor modulation (F-CAT) without additive monovision may be used in hyperopic presbyopic patients who do not tolerate monovision.

Bibliography

1. Waring GO, Berry DE. Advances in the surgical correction of presbyopia. *Int Ophthalmol Clin* 2013;53:129–52.
2. Calossi A. Corneal asphericity and spherical aberration. *J Refract Surg* 2007;23:505–14.
3. Gatinel D, Azar DT, Dumas L, Malet J. Effect of anterior corneal surface asphericity modification on fourth-order zernike spherical aberrations. *J Refract Surg* 2014;30:708–15.
4. Charman WN. Ablation design in relation to spatial frequency, depth-of-focus, and age. *J Refract Surg* 2004;20:542–549.
5. Ryan A, O’Keefe M. Corneal approach to hyperopic presbyopia treatment: six-month outcomes of a new multifocal excimer laser in situ keratomileusis procedure. *J Cataract Refract Surg* 2013;39:1226–33.
6. Baudu P, Penin F, Arba Mosquera S. Uncorrected binocular performance after biaspheric ablation profile for presbyopic corneal treatment using AMARIS with the PresbyMAX module. *Am J Ophthalmol* 2013;155:636–47.
7. Garcia-Gonzalez M, Teus MA. Uncorrected binocular performance after biaspheric ablation profile (PresbyMAX) for presbyopic corneal treatment. *Am J Ophthalmol* 2013;156:847–8.
8. Uthoff D, Pölzl M, Hepper D, Holland D. A new method of cornea modulation with excimer laser for simultaneous correction of presbyopia and ametropia. *Graefes Arch Clin Exp Ophthalmol Albrecht Von Graefes Arch Klin Exp Ophthalmol* 2012;250:1649–61.
9. Jackson WB, Tuan K-MA, Mintsoulis G. Aspheric wavefront-guided LASIK to treat hyperopic presbyopia: 12-month results with the VISX platform. *J Refract Surg* 2011;27:519–29.
10. Jung SW, Kim MJ, Park SH, Joo CK. Multifocal corneal ablation for hyperopic presbyopes. *J Refract Surg* 2008;24:903–10.

420 **11.** Reinstein DZ, Couch DG, Archer TJ. LASIK for hyperopic astigmatism and presbyopia
 421 using micro-monovision with the Carl Zeiss Meditec MEL80 platform. *J Refract Surg*
 422 2009;25:37–58.

423 **12.** Leray B, Cassagne M, Soler V, et al. Relationship between induced spherical aberration
 424 and depth of focus after hyperopic LASIK in presbyopic patients. *Ophthalmology*
 425 2015;122:233–43.

426 **13.** Courtin R, Saad A, Grise-Dulac A, Guilbert E, Gatinel D. Changes to corneal aberrations
 427 and vision after monovision in patients with hyperopia after using a customized aspheric
 428 ablation profile to increase corneal asphericity (Q-factor). *J Refract Surg* 2016;32:734–41.

429 **14.** Wang Yin GH, McAlinden C, Pieri E, Giulardi C, Holweck G, Hoffart L. Surgical
 430 treatment of presbyopia with central presbyopic keratomileusis: One-year results. *J Cataract*
 431 *Refract Surg* 2016;42:1415–23.

432 **15.** Alarcón A, Anera RG, Villa C, Jiménez del Barco L, Gutierrez R. Visual quality after
 433 monovision correction by laser in situ keratomileusis in presbyopic patients. *J Cataract*
 434 *Refract Surg* 2011;37:1629–35.

435 **16.** Gordon M. Presbyopia corrections with the WaveLight ALLEGRETTO: 3-month results.
 436 *J Refract Surg* 2010;26:824-826.

437 **17.** Randleman JB, Trattler WB, Stulting RD. Validation of the Ectasia Risk Score System for
 438 preoperative laser in situ keratomileusis screening. *Am J Ophthalmol* 2008;145:813–8.

439 **18.** Zheleznyak L, Sabesan R, Oh J-S, MacRae S, Yoon G. Modified monovision with
 440 spherical aberration to improve presbyopic through-focus visual performance. *Invest*
 441 *Ophthalmol Vis Sci* 2013;54:3157–65.

442 **19.** Villegas EA, Alcón E, Mirabet S, Yago I, Marín JM, Artal P. Extended depth of focus
 443 with induced spherical aberration in light-adjustable intraocular lenses. *Am J Ophthalmol*
 444 2014;157:142–9.

445 **20.** Bottos KM, Leite MT, Aventura-Isidro M, et al. Corneal asphericity and spherical
446 aberration after refractive surgery. *J Cataract Refract Surg* 2011;37:1109–15.

447 **21.** Llorente L, Barbero S, Merayo J, Marcos S. Total and corneal optical aberrations induced
448 by laser in situ keratomileusis for hyperopia. *J Refract Surg* 2004;20:203–16.

449 **22.** Benito A, Redondo M, Artal P. Laser in situ keratomileusis disrupts the aberration
450 compensation mechanism of the human eye. *Am J Ophthalmol* 2009;147:424-431.

451 **23.** Cantú R, Rosales MA, Tepichín E, Curioca A, Montes V, Ramirez-Zavaleta JG. Objective
452 quality of vision in presbyopic and non-presbyopic patients after pseudoaccommodative
453 advanced surface ablation. *J Refract Surg* 2005;21:603-605.

454 **24.** Soler Tomás JR, Fuentes-Páez G, Burillo S. Symmetrical versus asymmetrical
455 PresbyLASIK: results after 18 months and patient satisfaction. *Cornea* 2015;34:651–7.

456 **25.** Amigo A, Bonaque S, López-Gil N, Thibos L. Simulated effect of corneal asphericity
457 increase (Q-factor) as a refractive therapy for presbyopia. *J Refract Surg* 2012;28:413–8.

458 **26.** Jaycock PD, O’Brart DPS, Rajan MS, Marshall J. 5-year follow-up of LASIK for
459 hyperopia. *Ophthalmology* 2005;112:191–9.

460 **27.** Esquenazi S. Five-year follow-up of laser in situ keratomileusis for hyperopia using the
461 Technolas Keracor 117C excimer laser. *J Refract Surg* 2004;20:356–63.

462 **28.** Saib N, Abrieu-Lacaille M, Berguiga M, Rambaud C, Froussart-Maille F, Rigal-Sastourne
463 J-C. Central PresbyLASIK for hyperopia and presbyopia using micro-monovision with the
464 Technolas 217P Platform and SUPRACOR Algorithm. *J Refract Surg* 2015;31:540–6.

465 **29.** Beer SMC, Santos R, Nakano EM, et al. One-year clinical outcomes of a corneal inlay for
466 presbyopia. *Cornea* 2017;36:816–20.

467 **30.** Limnopoulou AN, Bouzoukis DI, Kymionis GD, et al. Visual outcomes and safety of a
468 refractive corneal inlay for presbyopia using femtosecond laser. *J Refract Surg* 2013;29:12–8.

469 **31.** Moshirfar M, Bean AE, Albarracin JC, Rebenitsch RL, Wallace RT, Birdsong OC.
 470 Retrospective comparison of visual outcomes after KAMRA corneal inlay implantation with
 471 simultaneous PRK or LASIK. *J Refract Surg* 2018;34:310–5.

472 **32.** Vukich JA, Durrie DS, Pepose JS, Thompson V, van de Pol C, Lin L. Evaluation of the
 473 small-aperture intracorneal inlay: three-year results from the cohort of the US Food and Drug
 474 Administration clinical trial. *J Cataract Refract Surg* 2018;44:541–56.

475 **33.** Dexl AK, Jell G, Strohmaier C, et al. Long-term outcomes after monocular corneal inlay
 476 implantation for the surgical compensation of presbyopia. *J Cataract Refract Surg*
 477 2015;41:566–75.

478 **34.** Tomita M, Kanamori T, Waring GO, et al. Simultaneous corneal inlay implantation and
 479 laser in situ keratomileusis for presbyopia in patients with hyperopia, myopia, or emmetropia:
 480 six-month results. *J Cataract Refract Surg* 2012;38:495–506.

481 **35.** Tomita M, Waring GO. One-year results of simultaneous laser in situ keratomileusis and
 482 small-aperture corneal inlay implantation for hyperopic presbyopia: comparison by age. *J*
 483 *Cataract Refract Surg* 2015;41:152–61.

484 **36.** Tomita M, Kanamori T, Waring GO, Nakamura T, Yukawa S. Small-aperture corneal
 485 inlay implantation to treat presbyopia after laser in situ keratomileusis. *J Cataract Refract*
 486 *Surg* 2013;39:898–905.

487 **37.** Yılmaz OF, Alagöz N, Pekel G, et al. Intracorneal inlay to correct presbyopia: long-term
 488 results. *J Cataract Refract Surg* 2011;37:1275–81.

489 **38.** Seyeddain O, Bacherneegg A, Riha W, et al. Femtosecond laser-assisted small-aperture
 490 corneal inlay implantation for corneal compensation of presbyopia: two-year follow-up. *J*
 491 *Cataract Refract Surg* 2013;39:234–41.

492 **39.** Seyeddain O, Grabner G, Dexl AK. Binocular distance visual acuity does not decrease
 493 with the Kamra intra-corneal inlay. *J Cataract Refract Surg* 2012;38:2062.

- 494 **40.** Dexl AK, Seyeddain O, Riha W, et al. Reading performance and patient satisfaction after
495 corneal inlay implantation for presbyopia correction: two-year follow-up. *J Cataract Refract*
496 *Surg* 2012;38:1808–16.
- 497 **41.** Duignan ES, Farrell S, Treacy MP, et al. Corneal inlay implantation complicated by
498 infectious keratitis. *Br J Ophthalmol* 2016;100:269–73.
- 499 **42.** Pepose JS, Qazi MA, Chu R, Stahl J. A prospective randomized clinical evaluation of 3
500 presbyopia-correcting intraocular lenses after cataract extraction. *Am J Ophthalmol*
501 2014;158:436–446.
- 502 **43.** Jabbarvand M, Hashemian H, Khodaparast M, Jouhari M, Tabatabaei A, Rezaei S.
503 Endophthalmitis occurring after cataract surgery: outcomes of more than 480 000 cataract
504 surgeries, epidemiologic features, and risk factors. *Ophthalmology* 2016;123:295–301.

Figure legends

Figure 1: Cumulative histogram of Snellen UDVA values before and one year after bilateral

hyperopic LASIK. The graph presents visual outcomes for: A: non-dominant eyes undergoing surgery with an aspherical ablation profile; B: dominant eyes corrected for distance vision; C: binocular vision. 93% of patients achieved a binocular UDVA of Snellen 20/20 or better one year after surgery. *VA: visual acuity; UDVA: uncorrected distance visual acuity*

Figure 2: Cumulative histogram of Jaeger binocular UNVA before and one year after bilateral hyperopic LASIK. The graph presents visual outcomes for binocular vision: 82% achieved a binocular UNVA of Jaeger 2 or better one year after surgery.

VA: visual acuity; UNVA: uncorrected near visual acuity

Figure 3: Scatterplots of attempted against achieved SEQ refraction one year after bilateral hyperopic LASIK for: A: non-dominant eyes; B: dominant eyes. The coefficients of determination are displayed. *SEQ: spherical equivalent; D: diopters*

Figure 4: Accuracy of SEQ with respect to the target for: A: non-dominant eyes; B: dominant eyes. For 87% of the dominant eyes, SEQ was within 0.50 D of the target value. *SEQ: spherical equivalent; D: diopters*

Figure 5: A: Corneal asphericity values (corneal Q factor) at a pupil size of 6 mm, before and 12 months after surgery, for the NDE and the DE. The NDE corneal Q factor changed from -0.19 ± 0.12 before surgery to -0.77 ± 0.16 12 months after surgery. The DE corneal Q factor changed from -0.18 ± 0.11 before surgery to -0.49 ± 0.13 at 12 months after surgery. B: Change in corneal asphericity values (ΔQ factor for a pupil size of 6 mm) from the presurgical value to the value 12 months after surgery for the NDE and the DE. Twelve months after surgery, the change in Q achieved at 12 months was significantly greater for the NDE than for the DE (-0.58 ± 0.22 vs. -0.31 ± 0.17 , $P < 0.0001$). *M12: 12 months after surgery; D: diopters; SD: standard deviation; NDE: non-dominant eye; DE: dominant eye*

Figure 6: A: Zernike corneal spherical aberration coefficient (C_4^0) at a pupil size of 6 mm before and 12 months after surgery, for the NDE and the DE. The NDE C_4^0 changed from $0.2 \pm 0.12 \mu\text{m}$ before surgery to $-0.24 \pm 0.12 \mu\text{m}$ 12 months after surgery. The DE C_4^0 changed from $0.21 \pm 0.13 \mu\text{m}$ before surgery to $-0.06 \pm 0.17 \mu\text{m}$ 12 months after surgery. B: Change in Zernike corneal spherical aberration coefficient (ΔC_4^0) from the value before surgery to that 12 months after surgery, for the NDE and the DE. Twelve months after surgery, the change in C_4^0 RMS value was significantly greater for the NDE than for the DE (-0.43 ± 0.17 vs. $-0.26 \pm 0.15 \mu\text{m}$, respectively; $P=0.002$). *M12: 12 months after surgery; SD: standard deviation; RMS: root mean square; NDE: non-dominant eye; DE: dominant eye*

Figure 7: Stability of spherical equivalent refraction over the 12 months after surgery for: A: the dominant eye. B: the non-dominant eye. The DE SEQ was stable over the 12 months of postoperative follow-up, with a non-significant mean change from -0.3 ± 0.3 D at 1 month to -0.22 ± 0.35 D ($P=0.1$) at 1 year. A progressive shift in myopia toward emmetropia was observed for the NDE SEQ, with a significant mean change from -1.07 ± 0.45 D at 1 month to -0.83 ± 0.5 D ($P=0.04$) at 1 year. *D: diopters; SD: standard deviation; NDE: non-dominant eye; DE: dominant eye; SEQ: spherical equivalent.*

Figure 8: Change in Snellen lines of CDVA for: A: the non-dominant eye; B: the dominant eye. No loss of Snellen lines of CDVA was observed for 78% of non-dominant eyes and 93% of dominant eyes. *CDVA: corrected distance visual acuity*

Figure 9: Difference between one-year postoperative UDVA and preoperative CDVA for: A: the dominant eye; B: the non-dominant eye; C: both eyes. Postoperative UDVA was within one Snellen line of preoperative CDVA for 91% of DE, and for 94% of both eyes. *UDVA:*

583 *uncorrected distance visual acuity; CDVA: corrected distance visual acuity; NDE: non-*
584 *dominant eye; DE: dominant eye*

585

586

587

588

589

A

45 eyes (Non-dominant eye)
1 year postop

B

45 eyes (Dominant eye)
1 year postop

C

90 Eyes (Binocular)
1 year postop

90 Eyes (Binocular)
1 year postop

Cumulative % of eyes

A **B**

A

45 eyes (Non-dominant eye)
1 year postop

± 0.50 D: 25%
 ± 1.00 D: 74%

B

45 eyes (Dominant eye)
1 year postop

± 0.50 D: 87%
 ± 1.00 D: 100%

A**Corneal asphericity values (Q)**

Preoperative

Postoperative

B**Change in corneal asphericity values M12-preop(ΔQ)**

Zernike corneal spherical aberration coefficient (C40)

A

Change in Zernike corneal spherical aberration coefficient M12 - preop (ΔC40)

B

A**Spherical equivalent refraction stability of dominant eye** **B****Spherical equivalent refraction stability of non-dominant eye**

A

45 eyes (Non-dominant eye)
1 year postop

B

45 eyes (Dominant eye)
1 year postop

A

45 eyes (Dominant eye)
1 year postop

UDVA within 1 line of CDVA: 91%
UDVA within 2 lines of CDVA: 100%

B

45 eyes (Non-dominant eye)
1 year postop

UDVA within 1 line of CDVA: 24%
UDVA within 2 lines of CDVA: 53%

C

90 eyes (Binocular)
1 year postop

UDVA within 1 line of CDVA: 94%
UDVA within 2 lines of CDVA: 100%

	Preoperative data		1 year after surgery	
Age (years)	53.8 ± 4.99 years			
Sex (M/F)	20 / 25			
	Dominant eyes	Non Dominant eyes	Dominant eyes	Non dominant eyes
	Mean ± SD (range)	Mean ± SD (range)	Mean ± SD (P value) (range)	Mean ± SD (P value) (range)
Sphere (D)	+2.47 ± 1.17 (+1 to +6)	+2.43 ± 1.14 (+1 to +5.5)	-0.022 ± 0.32 (P<0.0001) (-0.75 to +0.75)	-0.58 ± 0.54 (P<0.0001) (-1.5 to +0.75)
Cylinder (D)	-0.33 ± 0.35 (-1.5 to 0)	-0.36 ± 0.34 (-1.5 to 0)	-0.40 ± 0.25 (P=0.22) (-1.25 to 0)	-0.53 ± 0.24 (P=0.013) (-1.25 to 0)
Spherical equivalent (D)	+2.33 ± 1.16 (+0.75 to +6)	+2.26 ± 1.17 (+0.25 to +5.5)	-0.22 ± 0.35 (P<0.0001) (-1 to +0.5)	-0.83 ± 0.50 (P<0.0001) (-1.875 to +0.375)
Minimal pachymetry (µm)	541 ± 30 (500 to 600)	539 ± 30 (500 to 602)	522 ± 24 (P<0.0001) (480 to 575)	524 ± 28 (P<0.0001) (474 to 589)
Kmax (D)	44.3 ± 1.47 (40.7 to 47.1)	44.1 ± 1.45 (40.5 to 47.6)	45.3 ± 1.29 (P=0.0002) (43.1 to 47.7)	45.5 ± 1.37 (P<0.0001) (42.7 to 48.4)
Q-factor at 6 mm	-0.18 ± 0.04 (-0.27 to -0.11)	-0.19 ± 0.05 (-0.28 to -0.1)	-0.48 ± 0.03 (P<0.0001) (-0.74 to -0.42)	-0.78 ± 0.04 (P<0.0001) (-0.88 to -0.69)
Corneal spherical aberration C ₄ ⁰ at 6 mm (µm)	0.21 ± 0.13 (0.01 to 0.38)	0.20 ± 0.12 (0.01 to 0.34)	-0.06 ± 0.17 (P<0.0001) (-0.34 to +0.16)	-0.24 ± 0.12 (P<0.0001) (-0.45 to -0.05)
Mean UDVA (logMAR)	0.45 ± 0.28 (-0.1 to 1)	0.45 ± 0.29 (0 to 1)	-0.068 ± 0.07 (P<0.0001) (-0.2 to +0.1)	0.29 ± 0.17 (P=0.0003) (0 to 0.6)
Mean CDVA (logMAR)	-0.084 ± 0.076 (-0.2 to 0)	-0.098 ± 0.076 (-0.2 to 0)	-0.092 ± 0.06 (P=0.796) (-0.2 to 0)	-0.091 ± 0.067 (P=0.405) (-0.2 to 0)

Table 1: Ocular characteristics of the 45 patients at inclusion and 1 year after surgery. *M*: male; *F*: female; *SD*: standard deviation; *D*: diopters; *UDVA*: uncorrected distance visual acuity; *CDVA*: corrected distance visual acuity; *CNVA*: corrected near visual acuity. *t*-test for paired data (comparison of postoperative and preoperative values; *P*<0.5 indicates significance).