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

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18 **Running title:** Presbylasik by Q-factor modulation

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20
21 **Keys words:** Cornea; presbyLASIK; presbyopia; Q factor; corneal asphericity; spherical
22 aberration; LASIK; aberrometry; topography

23
24
25 **Financial disclosure:** The authors have no conflict of interest to declare.

26

27 **Abstract**

28
29 **Purpose:** To analyze refractive results after hyperopic presbyopia surgery by Q-factor
30 modulation without additive monovision.

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

32 **Design:** Prospective non-randomized study.

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

40 **Results:** Mean age at surgery was 53.8 ± 4.99 years. Mean preoperative SEQ was $+2.33 \pm$
41 1.16 diopters (D) for the DE and $+2.26 \pm 1.17$ D for the NDE. At 12 months, 93% of patients
42 had a binocular UDVA of Snellen 20/20 and 82% had a binocular UNVA of Jaeger 2
43 (Parinaud 3). Mean SEQ at 12 months was -0.22 ± 0.35 D ($P < 0.0001$) for the DE and $-0.83 \pm$
44 0.50 D ($P < 0.0001$) for the NDE. Two eyes required retreatment. Overall, 87% of the patients
45 said that they were satisfied and would recommend the intervention.

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

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55 **Introduction**

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

65 Various approaches for the correction of this disability have been evaluated, including
66 multifocal intraocular lenses, accommodative intraocular lenses, laser-assisted corneal surgery
67 and intracorneal inlays¹. Laser *in situ* keratomileusis (LASIK) is the most widely performed
68 corneal refractive procedure worldwide, and recent improvements in our understanding of
69 corneal aberrometry have paved the way for laser-assisted procedures involving changes in
70 corneal asphericity^{2, 3}. The increase in depth of field obtained in this way could improve
71 intermediate and near vision, to the extent that the patient may no longer be dependent on
72 spectacles⁴. Many multifocal or aspherical laser-assisted corneal surgery techniques have
73 been developed, some uni or bilateral, peripheral, centered or off-center, and they are all
74 grouped together under the umbrella term presbyLASIK. Central multifocal⁵⁻¹⁰ or aspherical
75 ¹¹⁻¹⁶ presbyLASIK is the technique of choice today, and may be combined with monovision to
76 enable patients to benefit from both techniques. Results have been reported for F-CAT
77 associated with monovision on the non-dominant eye (NDE)¹²⁻¹⁶, but visual results are
78 lacking for isolated aspheric treatment on the NDE in patients unable to tolerate monovision.
79 In this study, we assessed, in hyperopic patients, the visual and refractive outcome of
80 presbyopia surgery based on central presbyopic LASIK with corneal asphericity modulation

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

84 **Materials and Methods**

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

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

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

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

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

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

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

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

150 Safety and efficacy

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

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156 Statistical analysis

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

166 **Results**

167 Preoperative assessment

168 We treated 90 eyes in 45 consecutive patients. There were 20 men and 25 women and the
169 mean age of the patients was 53.8 ± 4.99 years. Mean preoperative SEQ was $+2.33 \pm 1.16$ D
170 for the DE and $+2.26 \pm 1.17$ D for the NDE. The mean addition for binocular near vision was
171 $+2.3 \pm 0.48$. There was no significant difference in refraction between the two eyes in any of
172 the patients. Mean minimal pachymetric corneal thickness was 541 ± 30 μ m for the DE and
173 539 ± 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
174 NDE. The mean corneal Q factor at 6 mm before surgery was -0.19 ± 0.05 for the NDE and -
175 0.18 ± 0.04 for the DE. The RMS values of the Zernike corneal spherical aberration
176 coefficient (C_4^0) on a pupil of 6 mm in diameter were 0.21 ± 0.13 μ m for the DE and $0.20 \pm$
177 0.12 μ m for the NDE. Mean preoperative UDVA was 20/63 (logMAR 0.45 ± 0.28) for the
178 DE and 20/63 (logMAR 0.45 ± 0.29) for the NDE. Mean preoperative CDVA was 20/16
179 (logMar -0.084 ± 0.076) for the DE and 20/16 (logMar -0.098 ± 0.076) for the NDE. Mean
180 preoperative binocular CNVA was Jaeger 1 (Parinaud 2) (logMAR 0.16 ± 0.046). The

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

184 Efficacy

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

192 Accuracy

193 At one year, the mean manifest refraction spherical equivalent (SEQ) was -0.22 ± 0.35 and
194 -0.83 ± 0.5 for the DE and the NDE, respectively. SEQ differed significantly between the two
195 eyes of each patient after surgery ($P < 0.001$). Accuracy data for DE and NDE SEQ are
196 presented in figures 3 and 4.

197 For keratometry, measured Kmax had significantly changed for both the DE (44.3 ± 1.47 D
198 vs. 45.34 ± 1.29 D ($P < 0.0001$)) and for the NDE (44.14 ± 1.45 D vs. 45.47 ± 1.37 D
199 ($P < 0.0001$)) 12 months after surgery. Minimal pachymetric corneal thickness had changed
200 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
201 μ m ($P < 0.0001$) for the NDE. The results of the one-year assessment are summarized in Table
202 1.

203 Corneal asphericity and spherical aberrations

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

206 ($P < 0.0001$) and -0.48 ± 0.03 for DE ($P < 0.0001$) (figure 5). The difference in Q achieved at
207 12 months was significantly greater for the NDE than for the DE (-0.58 ± 0.22 vs. $-0.31 \pm$
208 0.17 , $P < 0.0001$) (figure 5).

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

216 Stability

217 SEQ refraction stability is presented in figure 7. The SEQ of the DE was stable over the 12
218 months following surgery, with a non-significant mean change from -0.3 ± 0.3 D at 1 month
219 to -0.22 ± 0.35 D ($P = 0.1$) at 1 year, and a progressive shift in myopia toward emmetropia for
220 the NDE was observed, with a significant mean change from -1.07 ± 0.45 D at 1 month to -
221 0.83 ± 0.5 D ($P = 0.04$) at 1 year.

222 Safety and complications

223 Mean CDVA for the DE was logMAR -0.084 ± 0.076 (Snellen 20/16) before and logMAR -
224 0.092 ± 0.06 (Snellen 20/16) after surgery. For the NDE, mean CDVA was logMAR $-0.098 \pm$
225 0.075 (Snellen 20/16) before and logMAR -0.091 ± 0.067 (Snellen 20/16) after surgery. For
226 each treatment, the monocular loss of CDVA was minimal: three patients (7%) lost one line
227 of Snellen CDVA for the DE and 10 patients (22%) lost one line of Snellen CDVA for the
228 NDE (Figure 8).

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

231 94% of the binocular UDVA values were within one line of Snellen CDVA. The difference
232 between postoperative UDVA and preoperative CDVA is presented in figure 9. The safety
233 indices were 0.929 for the NDE and 1.095 for the DE. No intraoperative or postoperative
234 complications occurred.

235 Two eyes required retreatment. The first patient underwent retreatment four months after
236 initial surgery, on an overcorrected DE, to improve UDVA. The DE SEQ improved from -
237 0.75 to 0 D after this intervention. Binocular UDVA improved from 20/80 to 20/20 after
238 surgery (12-month visit). The second patient underwent retreatment six months after initial
239 surgery, on the NDE, to improve UNVA by an additional +1D because the postoperative
240 NDE SEQ was 0 D. Binocular UDVA and UNVA were 20/16 and Jaeger 3 (Parinaud 4),
241 respectively, before retreatment. Six months after retreatment, binocular UNVA increased to
242 Jaeger 1 (Parinaud 2), and there was no change in binocular UDVA.

243 Satisfaction

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

252 **Discussion**

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

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

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

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

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

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

306 measurement of the spherical equivalent is made on the central 3 mm by the
307 autorefractometer, it can be deduced that performing a Q-factor treatment with hypermetropic
308 defocus readjustment induces a slight central myopization responsible for a mini-monovision,
309 which contributes in addition to the NDE induced multifocality to improving near-vision. The
310 procedure resulted in good close visual acuity for activities of daily living, but with less
311 accuracy. Gatinel and colleagues determined a theoretical target of change in the Q factor (ΔQ),
312 required to achieved a corneal spherical aberration variation C_4^0 of $-0.40 \mu\text{m}$ for a pupil size
313 of 6 mm: -0.60 to -0.70 ³. If we consider the mean Q factor in the population to be about -
314 0.20, then we need to target a postoperative Q factor of between -0.8 and -0.9 . The choice of
315 this change in spherical aberration (ΔC_4^0 : $-0.40 \mu\text{m}$) is based on clinical practice, in which a
316 larger negative change has been found not to increase depth of focus but to decrease the
317 quality of vision²⁵. We set the target Q factor to -0.8 for all patients and achieved a ΔQ close
318 to the target value in the NDE (-0.58 ± 0.22 vs. -0.60 to -0.70) and similar results for ΔC_4^0 ($-$
319 0.43 ± 0.17 vs. $-0.40 \mu\text{m}$). As expected with the classic hyperopic LASIK procedure²¹ on the
320 DE, corneal prolateness increased significantly (ΔQ of -0.31 ± 0.17). One of the limitations of
321 this study is that only 24 of the 45 patients were able to benefit from wavefront aberrometry
322 measurements because of the unavailability of the aberrometer during part of the follow-up.
323 A progressive shift in myopia toward emmetropia was observed for the SEQ of the NDE,
324 which displayed a mean change from -1.07 D at 1 month to -0.83 D ($p=0.04$) at one year
325 whereas DE SEQ refraction seemed to remain stable over this period ($p=0.1$). A similar
326 pattern can be observed in the series published by Ho Wang Yin and colleagues, in which
327 NDE SEQ changed from -1.3 ± 1.0 D at 1 month after surgery to -0.7 ± 0.7 D at 1 year after
328 surgery¹⁴ and in the series published by Courtin and colleagues, in which SEQ changed from -
329 1.40 D at 1 month to -1.07 D at 6 months after surgery¹³. The effectiveness of this procedure
330 probably decreases over time, probably due to the natural regression of hypermetropic LASIK

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

335 No surgical complications were reported in our series and two patients required retreatment
336 (5%). Courtin and colleagues reported a retreatment rate of 10.7%¹³ and Ho Wang Yin and
337 colleagues reported a retreatment rate of 23%¹⁴. However, the indication for retreatment
338 differs considerably between surgeons and is not really comparable between studies. Also, we
339 can note in our study that the loss rate of one line of CDVA for the NDE (22%) is much
340 higher than for the DE (7%). This is explained by the fact that the NDE present, as expected,
341 a corneal asphericity much more marked compared to the DE postoperatively. This corneal
342 asphericity degrades the quality of vision which cannot be compensated by glasses which
343 explains this difference of CDVA between the 2 eyes.

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

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

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

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

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

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

379

380

381 **What was known?**

382 • Q-factor modulation, including increased negativity of the Q factor
383 (hyperprolateness), improves depth of focus, which is useful for near vision.

384 • Presbyopia management with Q-factor modulation (F-CAT) with moderate additive
385 monovision (around 0.50-1.0 D) provides good results for distance and near vision,
386 with high rates of spectacle independence for presbyopic hyperopic patients.

387

388 **What does this paper add?**

389 • We evaluated Q-factor modulation (F-CAT) without additive monovision.

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

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Figure legends

535 **Figure 1:** Cumulative histogram of Snellen UDVA values before and one year after bilateral
536 hyperopic LASIK. The graph presents visual outcomes for: A: non-dominant eyes undergoing
537 surgery with an aspherical ablation profile; B: dominant eyes corrected for distance vision; C:
538 binocular vision. 93% of patients achieved a binocular UDVA of Snellen 20/20 or better one
539 year after surgery. *VA: visual acuity; UDVA: uncorrected distance visual acuity*

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

543 *VA: visual acuity; UNVA: uncorrected near visual acuity*

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

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

550 **Figure 5:** A: Corneal asphericity values (corneal Q factor) at a pupil size of 6 mm, before and
551 12 months after surgery, for the NDE and the DE. The NDE corneal Q factor changed from -
552 0.19 ± 0.12 before surgery to -0.77 ± 0.16 12 months after surgery. The DE corneal Q factor
553 changed from -0.18 ± 0.11 before surgery to -0.49 ± 0.13 at 12 months after surgery. B:
554 Change in corneal asphericity values (ΔQ factor for a pupil size of 6 mm) from the
555 presurgical value to the value 12 months after surgery for the NDE and the DE. Twelve
556 months after surgery, the change in Q achieved at 12 months was significantly greater for the
557 NDE than for the DE (-0.58 ± 0.22 vs. -0.31 ± 0.17 , $P < 0.0001$). *M12: 12 months after*
558 *surgery; D: diopters; SD: standard deviation; NDE: non-dominant eye; DE: dominant eye*

559 **Figure 6:** A: Zernike corneal spherical aberration coefficient (C_4^0) at a pupil size of 6 mm
560 before and 12 months after surgery, for the NDE and the DE. The NDE C_4^0 changed from 0.2
561 ± 0.12 μm before surgery to -0.24 ± 0.12 μm 12 months after surgery. The DE C_4^0 changed
562 from 0.21 ± 0.13 μm before surgery to -0.06 ± 0.17 μm 12 months after surgery. B: Change in
563 Zernike corneal spherical aberration coefficient (ΔC_4^0) from the value before surgery to that
564 12 months after surgery, for the NDE and the DE. Twelve months after surgery, the change in
565 C_4^0 RMS value was significantly greater for the NDE than for the DE (-0.43 ± 0.17 vs. -0.26
566 ± 0.15 μm , respectively; $P=0.002$). *M12: 12 months after surgery; SD: standard deviation;*
567 *RMS: root mean square; NDE: non-dominant eye; DE: dominant eye*

568 **Figure 7:** Stability of spherical equivalent refraction over the 12 months after surgery for: A:
569 the dominant eye. B: the non-dominant eye. The DE SEQ was stable over the 12 months of
570 postoperative follow-up, with a non-significant mean change from -0.3 ± 0.3 D at 1 month to
571 -0.22 ± 0.35 D ($P=0.1$) at 1 year. A progressive shift in myopia toward emmetropia was
572 observed for the NDE SEQ, with a significant mean change from -1.07 ± 0.45 D at 1 month to
573 -0.83 ± 0.5 D ($P=0.04$) at 1 year.
574 *D: diopters; SD: standard deviation; NDE: non-dominant eye; DE: dominant eye; SEQ:*
575 *spherical equivalent.*

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

580 **Figure 9:** Difference between one-year postoperative UDVA and preoperative CDVA for: A:
581 the dominant eye; B: the non-dominant eye; C: both eyes. Postoperative UDVA was within
582 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*

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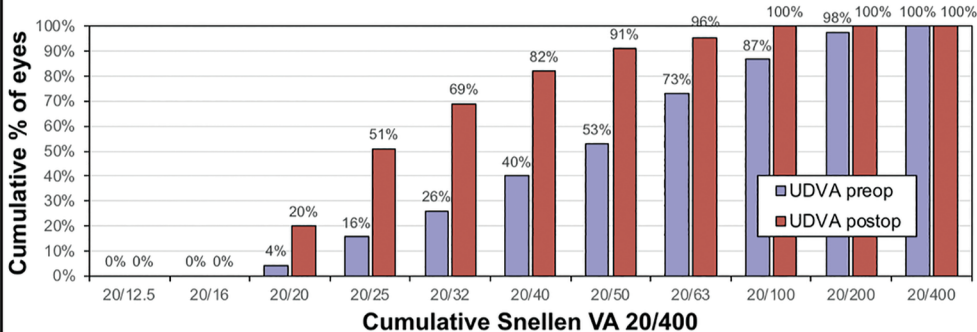
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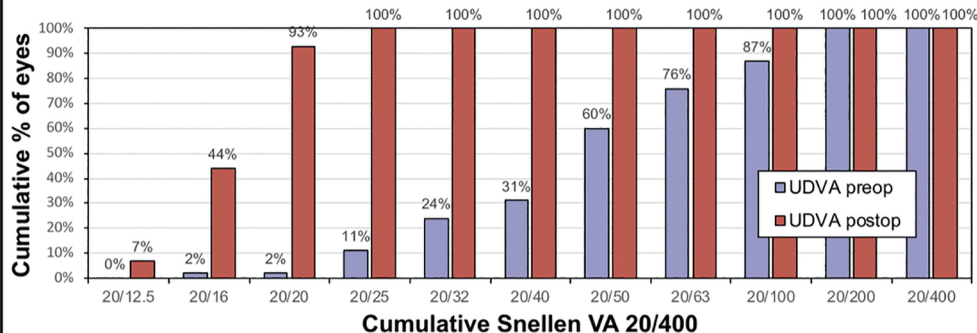
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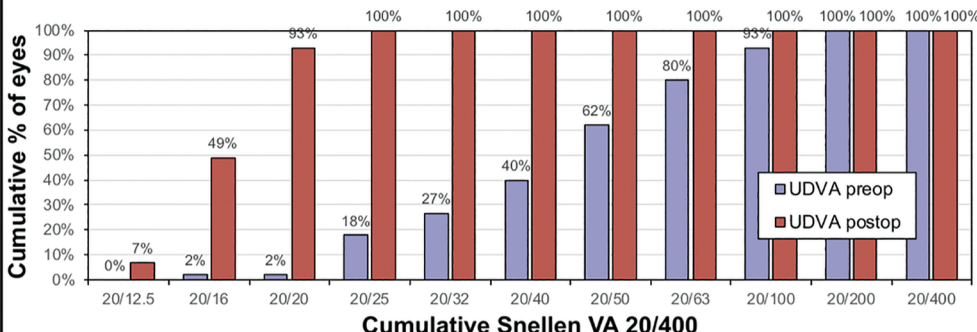
A

45 eyes (Non-dominant eye)
1 year postop

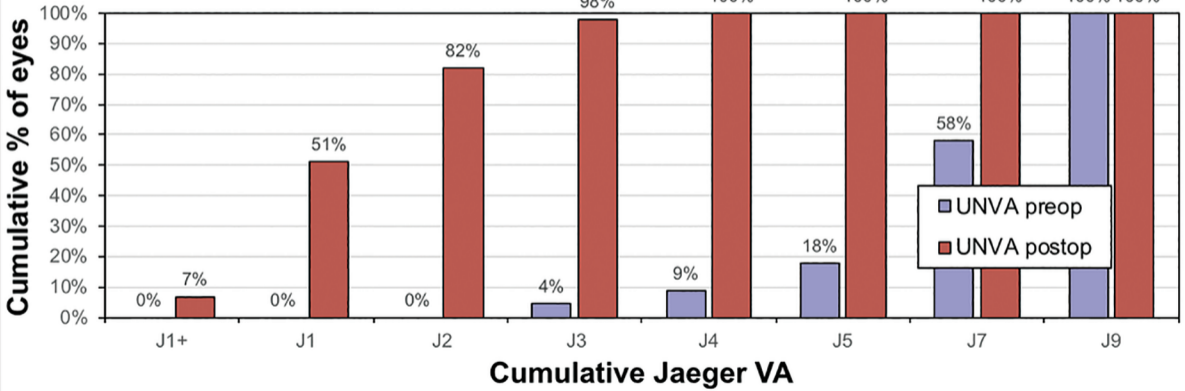
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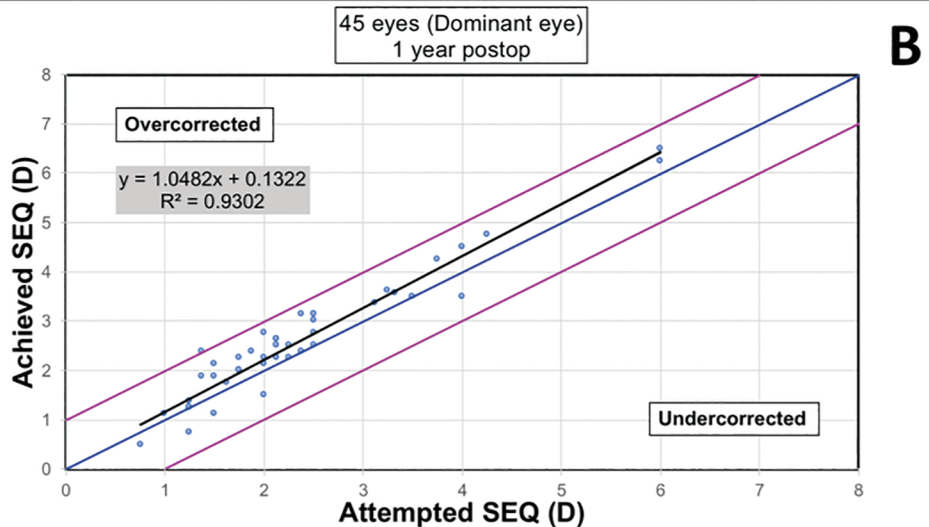
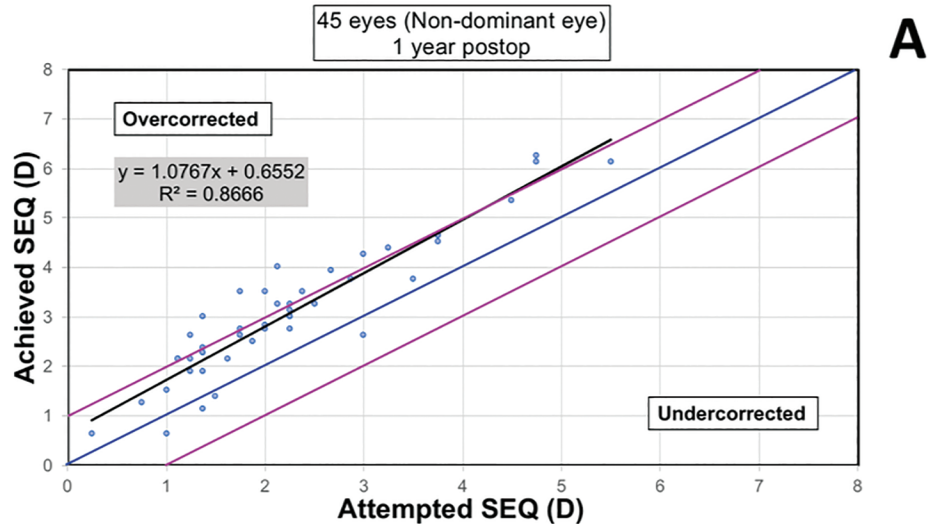
45 eyes (Dominant eye)
1 year postop

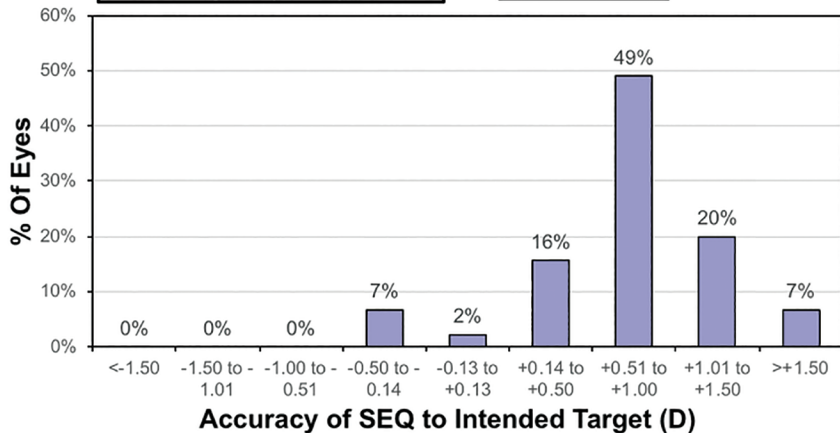
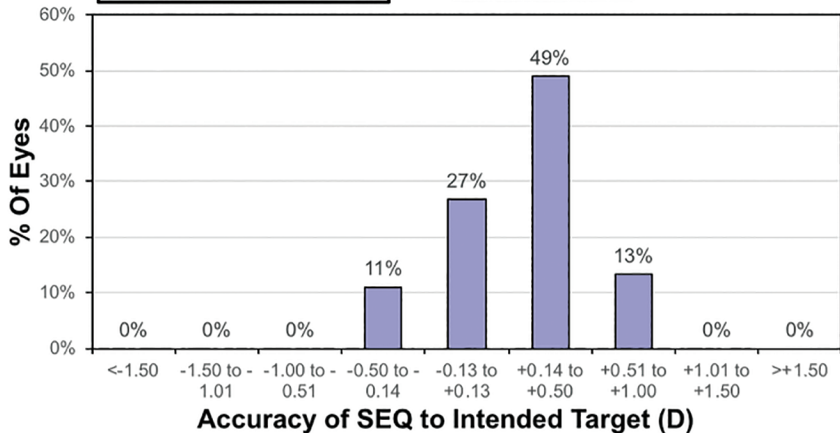
C

90 Eyes (Binocular)
1 year postop

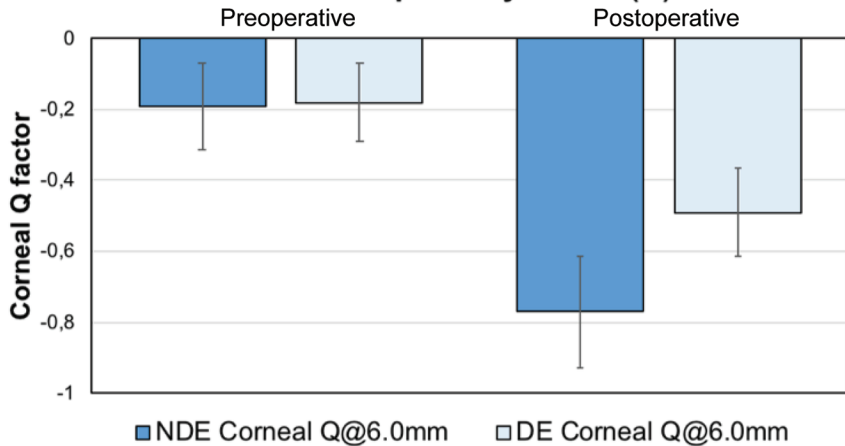
90 Eyes (Binocular)
1 year postop



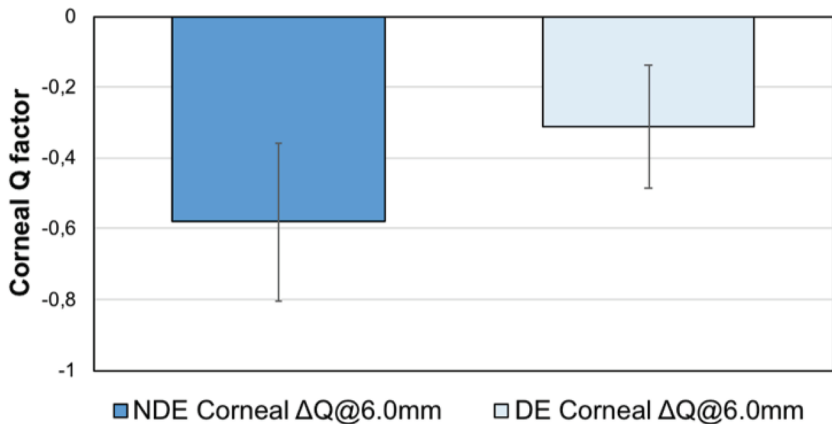


A**45 eyes (Non-dominant eye)
1 year postop****+/- 0.50 D: 25%
+/- 1.00 D: 74%****B****45 eyes (Dominant eye)
1 year postop****+/- 0.50 D: 87%
+/- 1.00 D: 100%**

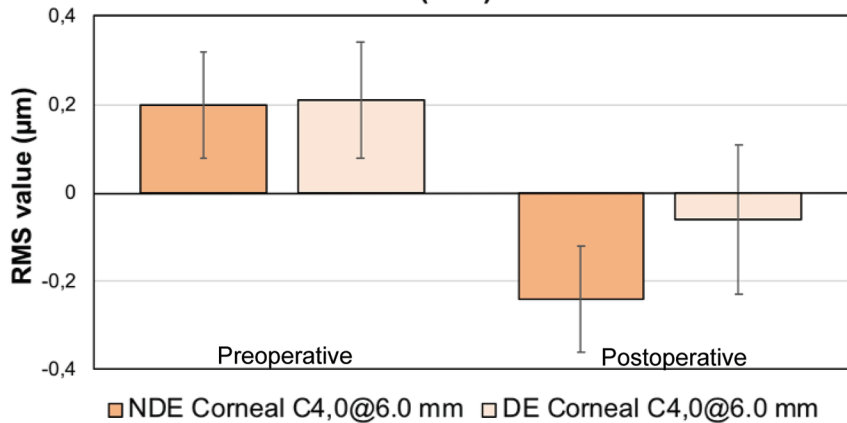
Corneal asphericity values (Q)

A

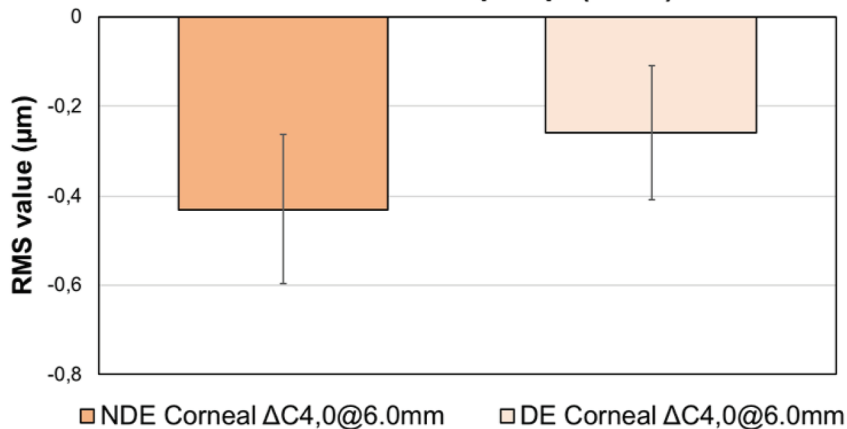
Change in corneal asphericity values M12-preop(ΔQ)

B

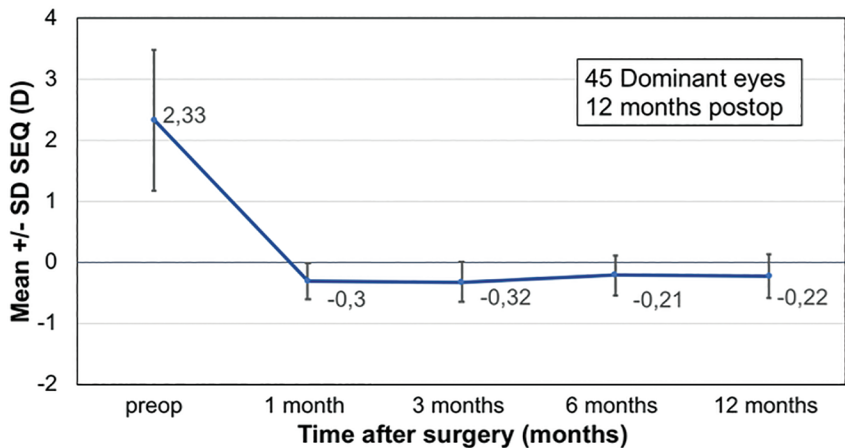
Zernike corneal spherical aberration coefficient (C40)

A

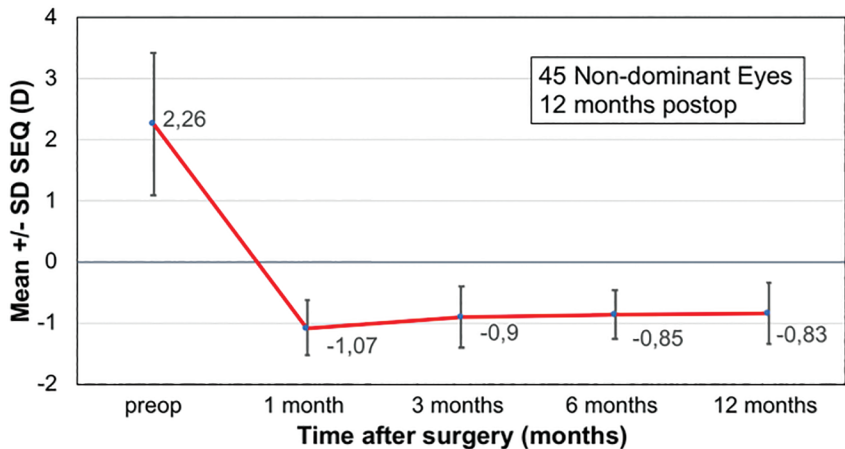
Change in Zernike corneal spherical aberration coefficient M12 - preop (ΔC40)

B

Spherical equivalent refraction stability of dominant eye

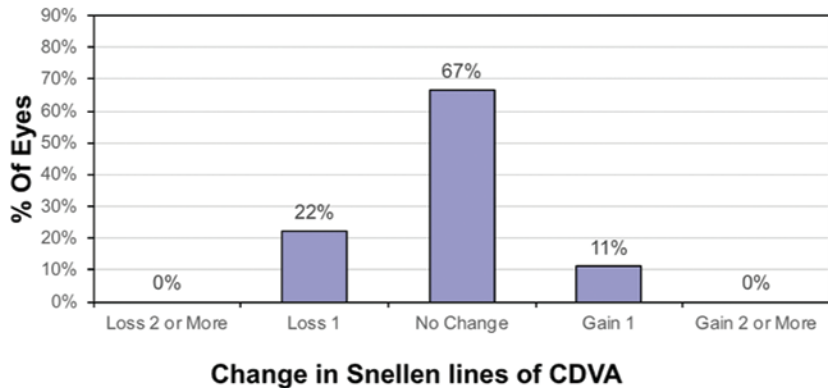
A

Spherical equivalent refraction stability of non-dominant eye

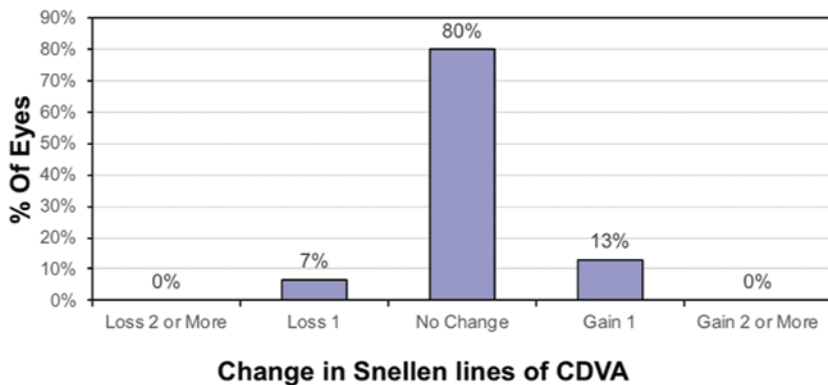
B

A

45 eyes (Non-dominant eye)
1 year postop

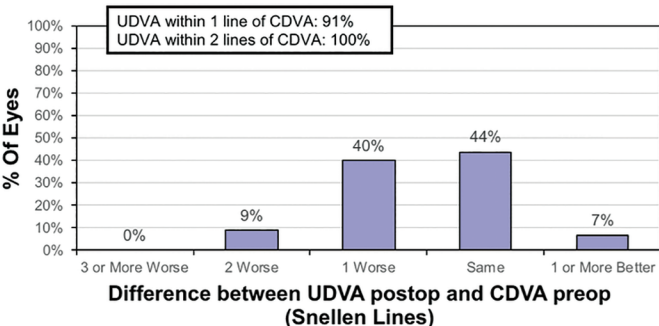
**B**

45 eyes (Dominant eye)
1 year postop

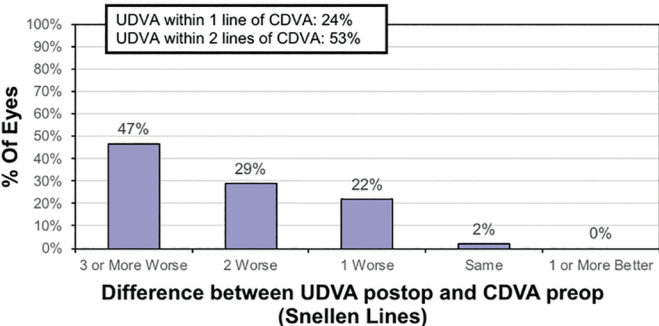


A

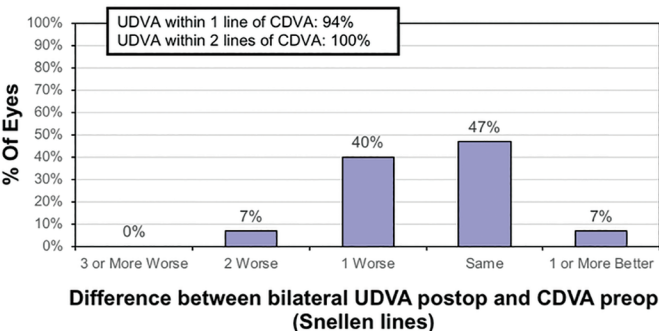
45 eyes (Dominant eye)
1 year postop

**B**

45 eyes (Non-dominant eye)
1 year postop

**C**

90 eyes (Binocular)
1 year postop



	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).