

EVO+ implantable collamer lens KS-aquaPORT location, stability and impact on quality of vision and life.

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1 ABSTRACT

2 **Purpose:** To determine the longitudinal variation in the KS-aquaPORT central hole
3 location of the phakic EVO+ implantable collamer lens (ICL) and analyze its
4 influence on visual performance, quality of vision (QoV) and quality of life (QoL).

5 **Methods:** A prospective study was performed including 36 EVO+ ICL patients. KS-
6 aquaPORT central hole location (cartesian and polar coordinates) was determined
7 with respect to the pupil center and visual axis. The effect of time (6-months follow-
8 up) on central hole location was analyzed using linear mixed models. The effect of
9 KS-aquaPORT location on visual and QoV and QoL parameters was assessed with
10 multivariate regression models.

11 **Results:** With respect to the visual axis, no significant changes in KS-aquaPORT
12 location were found during follow-up. With respect to the pupil center, X-coordinate
13 and *radius* of KS-aquaPORT location showed modest, but significant ($P \leq 0.05$)
14 differences between 1-week and 3-month postoperative visits, and between 1-week
15 and 6-months. X-coordinate variation was significant ($P = 0.022$) between 1-month
16 and 6-month visits. With respect to the visual axis, greater KS-aquaPORT
17 decentration was associated with lower visual acuity (X-coordinate: $P = 0.004$; radius:
18 $P = 0.006$), and inferior decentration with longer xenon-type glare photostress
19 recovery time ($P = 0.021$). With respect to the pupil center, lower radius was
20 associated with better QoV scores ($P \leq 0.01$) and temporal decentration produced
21 higher ring-shaped dysphotopsia ($P = 0.007$).

22 **Conclusions:** EVO+ ICL KS-aquaPORT location appears to be clinically stable up
23 to 6 months postoperatively. A central location of the EVO+ ICL KS-aquaPORT hole
24 is preferred because allows reduced perception of dysphotopic phenomena that can
25 result in better QoV.

26 INTRODUCTION

27 Adequate intraocular lens (IOL) centration is desirable to maximize visual outcomes.
28 This is particularly of relevance when it comes to the use of multifocal and toric IOLs.
29 Numerous authors have showed that multifocal IOL decentration can cause visual
30 disturbances.¹⁻³ In contrast, IOL decentration with a monofocal IOL is generally more
31 forgiving, with reports of less postoperative dysphotopsia.⁴ With posterior chamber
32 phakic IOLs, they are commonly monofocal, however, the EVO and EVO+
33 implantable collamer lens (ICL; STAAR Surgical Co.) integrate a hole in the center of
34 the optic (KS-aquaPORT™) to allow aqueous circulation. Visual disturbances can be
35 induced by reflections originating from the boundary surface of the central hole,⁵
36 which may be related to IOL decentration.

37 Previous studies have assessed visual, refractive and optical outcomes of ICL with
38 and without the central hole (V4c vs V4b ICL), demonstrating that both achieve
39 similar outcomes, even during a long-term follow-up.⁶⁻⁹ These findings may suggest
40 that there is no clinically relevant effect due to the presence of the EVO ICL central
41 hole. However, in these studies the exact IOL decentration was not monitored. Eom
42 et al.¹⁰ have described a new visual disturbance reported by patients with EVO ICL
43 implants, named ring-shaped dysphotopsia, related to the presence of the central
44 hole.¹⁰ However, these authors did not evaluate the degree of postoperative IOL
45 decentration. The scarce evidence reported in the scientific literature about the
46 influence of EVO ICL decentration on postoperative outcomes, shows that higher
47 order aberrations and quality of life can be negatively affected.^{11,12} Therefore, the
48 central hole of the EVO and EVO+ ICL, and in particular the location of the hole, may
49 influence visual outcomes.

50 The aim of the present study was, first, to determine whether there are changes in
51 the exact location of the EVO+ ICL KS-aquaPORT central hole with respect to the
52 pupil center and visual axis postoperatively and, second, to assess the effect of the
53 exact location of the central hole on the visual performance, quality of vision (QoV)
54 and quality of life (QoL).

55 **METHODS**

56 The present work is a prospective interventional case series study. It was
57 prospectively approved by the East Valladolid Health Area Ethics Committee
58 (Valladolid, Spain) and performed at Instituto de Oftalmobiología Aplicada (IOBA;
59 University of Valladolid, Spain). The study complied with the Tenets of the
60 Declaration of Helsinki and all participants provided a signed written informed
61 consent.

62 **Sample**

63 Thirty-six volunteers who underwent bilateral myopic posterior chamber EVO+ ICL
64 implantation were consecutively included. As previously reported,¹³ sample size was
65 calculated considering a two-tailed α error of 0.05/10, a β error of 0.20 (power 80%)
66 and a 10% drop-out rate to find a difference in visual acuity of 0.05 logarithm of the
67 minimum angle of resolution (logMAR) between visits using a paired t-test. Inclusion
68 and exclusion criteria were subjects with a minimum age of 21 years that achieved a
69 corrected distance visual acuity (CDVA) ≤ 0.10 logMAR. Additionally, subjects with
70 the presence of cataract, glaucoma, retinal anomalies, amblyopia, macular diseases,
71 previous ocular surgery or preoperative manifest cylinder above 4.50 Diopters (D)
72 were excluded.

73 Given that the dominant eye leads in the visual process, data from that eye was
74 selected for statistical purposes.¹⁴ Three consecutive measurements using the hole-
75 in-card test were performed to detect the dominant eye for distance.¹⁴

76 **Study schedule**

77 Surgical procedure

78 The EVO+ ICL was calculated using the OCOS calculator. The surgery was
79 performed as previously reported.¹³ In brief, a clear corneal incision of 2.75 mm was
80 performed after dilatation of the pupil with tropicamide 1% under topical and
81 intracameral anesthesia. The anterior chamber was filled with 1% sodium
82 hyaluronate and the EVO+ ICL was inserted. Then, the 1% sodium hyaluronate was
83 completely removed by aspiration and irrigation, and later acetylcholine 1% was
84 introduced. At the end of the surgery, Ofloxacin drops and Dexamethasone were
85 topically applied. All implantations were performed by the same experienced surgeon
86 (M.J.M.).

87 After surgery, topical medications included ofloxacin 3%, one drop every 2 hours for
88 1 week and then, one drop every 4 hours for 1 week, brimonidine and timolol and
89 dexamethasone 1% were administrated in tapering doses over 4 and 5 weeks,
90 respectively. Additionally, 250 mg of oral acetazolamide were prescribed twice per
91 day during the first 72 hours.

92 Follow-up evaluations

93 Participants underwent four follow-up visits: 1 week, and 1, 3 and 6 months after
94 surgery.

95

96 Central hole location assessment

97 The KS-aquaPORT central hole location was determined in the dominant eye while
98 the contralateral eye was occluded. The calculation was performed as previously
99 described by our research group.¹² Briefly, the location of the center of the KS-
100 aquaPORT was determined with respect to the pupil center using a digital image
101 obtained by slit-lamp biomicroscopy (SL- 8Z, Topcon Corp.). Then, the location of
102 the center of the hole with respect to the visual axis was determined combining the
103 data obtained from a Placido-disk dual Scheimpflug system (Galilei G4, Ziemer) and
104 the data obtained from the slit-lamp digital image (Figure 1).

105 The EVO+ ICL image obtained by slit-lamp is magnified by the refraction of the
106 anterior and posterior corneal surfaces. Consequently, the decentration data were
107 corrected (Appendix; Supplemental material). Finally, the decentration data (in
108 millimeters) were calculated in cartesian coordinates (X, Y) and polar coordinates
109 (*radius*, polar angle) from two reference systems (pupil center and visual axis).
110 Regardless of the eye analyzed, a positive and negative X value represents a nasal
111 and temporal decentration, respectively.

112 Visual assessment

113 Monocular UDVA was measured (logMAR) using the Early Treatment Diabetic
114 Retinopathy Study chart at 4m distance. Binocular contrast sensitivity (CS) was
115 assessed using the IOBA-HAXEMCST, as previously described.¹² This set allows
116 measuring CS using the Pelli-Robson chart at 1m distance. Mesopic CS was
117 assessed following 10 minutes of dark adaptation. Then, glare CS was measured

118 during 5 seconds of progressively intense glare simulating halogen and xenon lights
119 in a random order. Photostress recovery time necessary to achieve the previous
120 mesopic CS after halogen and xenon-type glare was measured. Later, discomfort
121 glare under halogen and xenon illumination was evaluated using de Boer rating scale
122 from 0 (unbearable) to 9 (unnoticeable).¹⁵

123 **Patient-reported outcomes instruments**

124 The QoV questionnaire assesses 10 visual symptoms across 3 subscales: frequency,
125 severity and bothersome of symptoms.^{16,17} The QoV scores range from 0 to 100, with
126 higher scores indicating poorer QoV.

127 The frequency, severity and bothersome perception of ring-shaped dysphotopsia was
128 also evaluated in a 0 (absence) to 3 (maximum) scale.¹⁰

129 The Quality of Life Impact of Refractive Correction (QIRC) questionnaire assess QoL
130 related to refractive correction.¹⁸ Scores range from 0 to 100, with higher values
131 indicating better QoL.

132 **Vault**

133 Vault refers to the distance between the ICL and the anterior lens capsule. Central
134 vault assessment was performed using a spectral domain optical coherence
135 tomographer (OCT; Topcon 3D-2000, Topcon Corp) at the 6-month postoperative
136 visit.

137 **Statistical analysis**

138 Statistical analyses were performed using the R statistical package version 4.0.0. by
139 a professional statistician (I.F.). The effect of time on EVO+ ICL decentration

140 parameters was analyzed using linear mixed models with random effect for subjects.
141 Significant models were followed by multiple comparisons using the Tukey method.
142 The assumptions of linearity, normality, homoscedasticity and lack of outliers were
143 checked. When normality could not be assumed, a robust model was fitted.

144 The effect of the central hole location (considering the 6-month postoperative values)
145 on the study parameters was analyzed using multivariate regression models. The
146 influence of cartesian (X, Y) and polar (*radius*, polar angle) coordinates on study
147 variables were determined using the Pillai test. When the outcome for Pillai test was
148 significant, the multivariate models were fitted including the dependent variable with
149 four dimensions (one per visit) and the cartesian or polar coordinates as independent
150 variables. The required model assumptions were multivariate normality, linearity and
151 lack of outliers, which were checked using the residuals of the fitted models. In case
152 the model did not comply with these assumptions and data transformation was not
153 sufficient to satisfy them, the model was not considered valid.

154 The effect of central vault on KS-aquaPORT decentration parameters were analyzed
155 using simple linear regression models. When normality could not be assumed, a
156 robust model was fitted.

157 Two-sided P-values ≤ 0.05 were considered statistically significant.

158 **RESULTS**

159 **Study population**

160 Thirty-six patients who underwent EVO+ ICL implantation (23 females and 13 males)
161 with a mean (\pm SD) age of 31.0 ± 6.1 years finished the study. Table 1 shows the

162 preoperative descriptive data. Table S1 (Supplemental material) shows the results of
163 the study parameters at each follow-up visit.

164 **KS-aquaPORT hole location during the follow-up**

165 EVO+ KS-aquaPORT location in relation to the pupil center and visual axis during
166 the follow-up is shown in figure 2. The mean decentration values and differences
167 between visits are presented in table 2. There were statistically significant ($P \leq 0.03$)
168 differences among visits in the KS-aquaPORT decentration for the X-coordinate and
169 for the radius, using the pupil center as a reference system. In contrast, no
170 significant ($P \geq 0.07$) differences were found among visits for the KS-aquaPORT
171 decentration with respect to the visual axis (Table 2).

172 **Effect of KS-aquaPORT hole location on visual parameters**

173 The KS-aquaPORT location had a statistically significant effect on UDVA (Pillai test:
174 X, $P=0.046$ and Y, $P=0.99$; *radius*, $P=0.034$; polar angle, $P=0.98$) using the visual axis
175 as the reference. The multivariate models showing statistically significant results are
176 shown in table 3.

177 No statistically significant effect of the KS-aquaPORT location was found on mesopic
178 CS (Pillai test: X and Y, $P \geq 0.21$; *radius* and polar angle, $P \geq 0.39$). Similarly, KS-
179 aquaPORT location in polar coordinates did not have a statistically significant effect
180 on halogen CS (Pillai test: *radius* and polar angle, $P \geq 0.13$). However, with regards
181 cartesian coordinates, it was not possible to fit a valid model for halogen CS. Likewise,
182 it was also not possible to fit any valid model for xenon CS, using any reference
183 system, in cartesian or polar coordinates. Statistical assumptions were not met, and
184 data transformations did not fix the violated assumptions.

185 No significant effect of the KS-aquaPORT location was found on photostress recovery
186 time after halogen glare (Pillai test: X and Y, $P \geq 0.44$; *radius* and polar angle, $P \geq 0.18$).
187 Likewise, the KS-aquaPORT location, using the pupil center as the reference, did not
188 have an effect on photostress recovery time after xenon glare (Pillai test: X and Y,
189 $P \geq 0.22$; *radius* and polar angle, $P \geq 0.10$). On the contrary, using the visual axis, the
190 KS-aquaPORT location in cartesian and polar coordinates showed a significant effect
191 on photostress recovery time after xenon glare (Pillai test: X, $P = 0.47$; Y, $P = 0.004$;
192 *radius*, $P = 0.77$; polar angle, $P = 0.04$); however, none of the multivariate models were
193 significant for the polar coordinates ($R^2 \leq 0.08$, $P \geq 0.14$). The statistically significant
194 multivariate models are shown in table 3.

195 Finally, the KS-aquaPORT location did not have a significant effect on the bothersome
196 after halogen or xenon glare (Pillai test: X and Y, $P \geq 0.10$; *radius* and polar angle,
197 $P \geq 0.10$).

198 **Effect of KS-aquaPORT hole location on patient-reported outcomes**

199 The KS-aquaPORT location using the pupil center as the reference axis did not have
200 a statistically significant effect in cartesian coordinates on any QoV questionnaire
201 subscale (Pillai test: X and Y, $P \geq 0.15$). However, in polar coordinates, statistically
202 significant effects were found on QoV frequency (Pillai test: *radius*, $P = 0.038$; polar
203 angle, $P = 0.59$) and QoV severity (Pillai test: *radius*, $P = 0.019$; polar angle, $P = 0.29$)
204 scales. In contrast, the QoV bothersome scale was not significantly affected by KS-
205 aquaPORT location (Pillai test: *radius*, $P = 0.06$; polar angle, $P = 0.27$). Regarding to the
206 visual axis system, neither cartesian nor polar coordinates have a statistically
207 significant effect on any QoV scale (Pillai test: X and Y, $P \geq 0.32$; *radius* and polar

208 angle, $P \geq 0.23$). The multivariate models with statistically significant results are shown
209 in table 3.

210 The KS-aquaPORT location showed a significant effect using the pupil center in
211 cartesian and polar coordinates on the ring-shaped dysphotopsia QoV severity
212 subscale (Pillai test: X, $P=0.031$; Y, $P=0.91$; *radius*, $P=0.036$; polar angle, $P=0.99$),
213 although it was not significant on the frequency and bothersome subscales of the
214 QoV (Pillai test: X and Y, $P \geq 0.22$; *radius* and polar angle, $P \geq 0.12$). The KS-
215 aquaPORT location with respect to the visual axis in cartesian coordinates, did not
216 have a statistically significant effect on any ring-shaped dysphotopsia scale (Pillai
217 test: X and Y, $P \geq 0.09$). Similarly, in polar coordinates, the KS-aquaPORT location
218 did not have any effect on the QoV severity and bothersome subscales (Pillai test:
219 *radius* and polar angle, $P \geq 0.08$). A statistically significant effect of polar coordinates
220 was found on the ring-shaped dysphotopsia QoV frequency subscale (Pillai test:
221 *radius*, $P=0.04$; polar angle, $P=0.44$); however, none of the multivariate models were
222 significant ($R^2 \leq 0.14$, $P \geq 0.06$). The statistically significant multivariate models are
223 shown in table 3.

224 The KS-aquaPORT location did not have a significant effect on QIRC scores (Pillai
225 test: X and Y, $P \geq 0.51$; *radius* and polar angle, $P \geq 0.14$).

226 **Effect of vault on decentration parameters**

227 Central vault shown a significant effect on KS-aquaPORT location using the Y-
228 coordinate with respect to the pupil center ($R^2=0.22$; $\beta=0.27 \times 10^{-3}$; $P=0.004$). The
229 central vault did not show any significant effect for any other decentration parameter
230 with respect to any reference system ($P \geq 0.10$).

231 DISCUSSION

232 In this study, EVO+ ICL decentration results obtained in terms of X-coordinate, showed
233 mostly temporal displacements of the KS-aquaPORT for both reference systems (pupil
234 center or visual axis) (Figure 2). It is likely that the KS-aquaPORT hole is located in
235 the midpoint of the sulcus to sulcus distance and, consequently, the location is
236 temporal with respect to the reference systems analyzed.^{19,20} In addition, this tendency
237 for a temporal location of the central hole might also be explained by the mydriatic
238 pupil status when the lens is positioned intraoperatively. Under pharmacological
239 mydriasis, there is a temporal shift of the pupil center in comparison to normal
240 physiological conditions.²¹ In addition, in our study the temporal displacement of the
241 central hole is larger for the visual axis than for the pupil center in agreement with
242 previous studies.^{12,22} The visual axis is usually located nasal to the pupil center,^{19,23}
243 which agrees with our study outcomes.

244 In this study, the values of the KS-aquaPORT hole decentration were highly
245 consistent during the four postoperative visits using the visual axis as reference
246 system. Similarly, the Y-coordinate and polar angle with respect to the pupil center
247 did not alter either. However, the X-coordinate and *radius* (distance) showed
248 statistically significant differences between certain postoperative visits (Table 2).
249 These differences could be the consequence of the transitory decrease of pupil
250 diameter after EVO+ ICL implantation,²⁴ in combination with the topical
251 administration of brimomidine during the first four postoperative weeks.

252 The study results showed that less negative X values (equivalent to more central
253 values in our sample), as well as less *radius* (distance) with respect to the visual axis,
254 increases postoperative UDVA. Thus, a centered location of the EVO+ ICL, and

255 consequently the KS-aquaPORT, achieves good UDVA. In addition, the KS-
256 aquaPORT location of the EVO+ ICL did not affect the CS in mesopic and glare
257 conditions, although some parameters could not be statistically analyzed. In previous
258 studies, neither the presence of the KS-aquaPORT hole⁶ nor the intraocular lens
259 decentration¹² were found to affect mesopic CS. Therefore, these findings suggest
260 that the KS-aquaPORT location does not affect CS under mesopic conditions, with or
261 without glare, similar to those during nighttime. This outcome is very important
262 because it advocates that patients undergoing EVO+ ICL surgery will achieve not only
263 appropriate UDVA,^{13,25} but also adequate night vision to perform common daily
264 activities.

265 In this study, the KS-aquaPORT hole location did not have influence on bothersome
266 and photostress recovery time after halogen glare. Inferior EVO+ ICL decentration,
267 with respect to the visual axis, was associated with longer xenon glare photostress
268 recovery time at the 1-week postoperative visit. These outcomes could be related to
269 the CS decrease after glare found at the 1-week visit (Table S1; Supplemental
270 material). However, this finding is only related to the 1-week postoperative visit.

271 A lower *radius* (distance) of KS-aquaPORT decentration, using the pupil center as the
272 reference was associated with improved QoV questionnaire scores (frequency and
273 severity scales) at the 1-month postoperative visit. Similarly, previous studies reported
274 that decentrated IOLs or pupil diameters greater than the IOL optical zone can create
275 dysphotopic phenomena.^{26,27} However, these findings were only significant at the 1-
276 month postoperative visit, which could be related to the QoV decrease observed
277 during that visit (Table S1; Supplemental material). It may suggest that dysphotopic
278 phenomena and worse QoV at the 1-month postoperative visit in patients with

279 successful EVO+ ICL implantation may be transient. In addition, we found that a higher
280 *radius* (equivalent to temporal decentration in our sample) of KS-aquaPORT with
281 respect to the pupil center produces more ring-shaped dysphotopsia (severity scale)
282 at the 3-month postoperative visit. This outcome was only found at the 3-month visit
283 when the ring-shaped dysphotopsia perception has been already considerable
284 reduced in comparison with 1-week visit (Table S1; Supplemental material). Thus, it
285 suggests that most ring-shaped dysphotopsia is found at an early postoperative time
286 regardless to the central hole location.

287 In the present study, we observed different findings depending on the system used as
288 the reference axis. When the pupil center was used as a reference, QoV and ring-
289 shaped dysphotopsia were significantly affected. These parameters are used to
290 evaluate dysphotopic phenomena, which might be directly related to the pupil
291 dynamics. When visual axis was used as the reference, the parameters significantly
292 affected were UDVA and photostress recovery time after glare, which provide
293 information of the fixation point when using central fixation (fovea).

294 Higher central vaults were related to superior displacements of KS-aquaPORT in this
295 study. Specifically, for each 100 μm increase in vault, the KS-aquaPORT was
296 estimated to be located 0.027 mm superiorly, at the 6-months postoperative visit.
297 Previous studies have reported that an undersized ICL can be associated with a low
298 vault.^{28,29} Thus, patients implanted with ICLs showing low vaults may be located
299 slightly inferiorly (Y-coordinate), possibly because the lower ICL footplate may be more
300 wedged in the lower ciliary sulcus due to gravity. Nevertheless, the study outcomes
301 showed that KS-aquaPORT location (Y-coordinate) had no significant effect on QoV
302 or QoL 6-months postoperatively.

303 One limitation of the present study is that only the 6-month decentration values were
304 selected for statistical purposes to assess the effect of EVO+ ICL decentration in
305 visual performance, QoV and QoL. However, EVO+ ICL decentration parameters
306 were stable among visits and the statistically significant differences found were
307 minimal (Table 2) and they could be considered not clinically relevant. Another
308 limitation of the present study is that the outcomes obtained are related to the EVO+
309 ICL decentration values observed in our sample. Thus, these outcomes depend on
310 the EVO+ ICL location values of the patients recruited and individual surgeon, and
311 the decentration values observed are the ones expected in usual clinical settings
312 after uneventful surgeries. Finally, the sample size was calculated using a statistical
313 power of 80% and visual acuity as the main variable, thus, the power may be different
314 for other parameters evaluated in the study.

315 In conclusion, the results of the present study indicate that EVO+ ICL KS-aquaPORT
316 hole location appears to be clinically consistent throughout the short-term
317 postoperative course. Additionally, an accurate centration of the phakic EVO+ Visian
318 ICL allows higher QoV levels, with a low perception of dysphotopic phenomena
319 during the first 6 postoperative months. Also, the central hole location does not
320 appear to affect CS under mesopic and glare conditions when decentration values
321 are representative of the ones commonly observed after uneventful EVO+ ICL
322 surgeries. Further, KS-aquaPORT decentration does not affect QoL during the short-
323 term follow-up.

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FIGURE CAPTIONS.

Figure 1. Schematic representation of the KS-aquaPORT, pupil center and visual axis locations.

The figure is composed of an anterior segment image provided by a dual-Scheimpflug system (Galilei G4, Ziemer) and the representation of an EVO+ implantable collamer lens. The central area of the image has been magnified to allow easier comprehension of the relationship between the locations of KS-aquaPORT (H), visual axis (V) and pupil center (P).

The Galilei G4 image includes: two green concentric circles showing limbus and pupil diameter (a green cross-hair has been added for ease location of pupil center), a red cross-hair showing the Galilei G4 alignment system for image acquisition (it shows the alignment performed in this image during acquisition) and a partially superposed yellow cross-hair indicating the surface alignment (which is the appropriate alignment that should be performed during the acquisition process), based on the Purkinje images (dots) reflected from the anterior corneal surface intercepting visual axis. The EVO+ ICL representation is drawn in blue and consists of ICL boundaries, optical zone and the central KS-aquaPORT.

Figure 2. Polar plot of the EVO+ KS-aquaPORT hole location (mm) in relation to the pupil center (A) and visual axis (B).

The radius (mm) and polar angle (degrees) are shown as the distance from the center of the axis (0.2 mm per ring) and the orientation, respectively. (0°: nasal; 180°: temporal).

Table 1. Descriptive data of the preoperative visual, refractive and ICL parameters.

Parameter	Mean \pm SD or Median (IQR)	Range
CDVA (LogMAR; Snellen equivalent)	-0.04 \pm 0.05; 20/18	-0.12, 0.08; 20/24, 20/15
Refractive sphere (D)	-7.23 \pm 2.31	-12.00, -3.00
Refractive cylinder (D)	-1.00 \pm 1.06	-4.50, 0
Refractive spherical equivalent (D)	-7.75 \pm 2.36	-12.38, -3.50
ICL sphere (D)	-9.47 \pm 2.51	-14.00, -5.00
ICL cylinder (D)	0.85 \pm 1.16	0, 4.50
ICL power (spherical equivalent) (D)	-9.05 \pm 2.38	-13.50, -4.50
ICL size (mm)	13.20 (12.60, 13.20)	12.10, 13.70

CDVA: corrected distance visual acuity; D: diopters; ICL: implantable collamer lens; IQR: interquartile range; LogMAR: logarithm of the minimum angle of resolution; mm: millimeters; SD: standard deviation.

Table 2. EVO+ KS-aquaPORT hole location in relation to the pupil center and visual axis. Data is provided in cartesian (X, Y) and polar coordinates (radius and polar angle) for each postoperative visit.

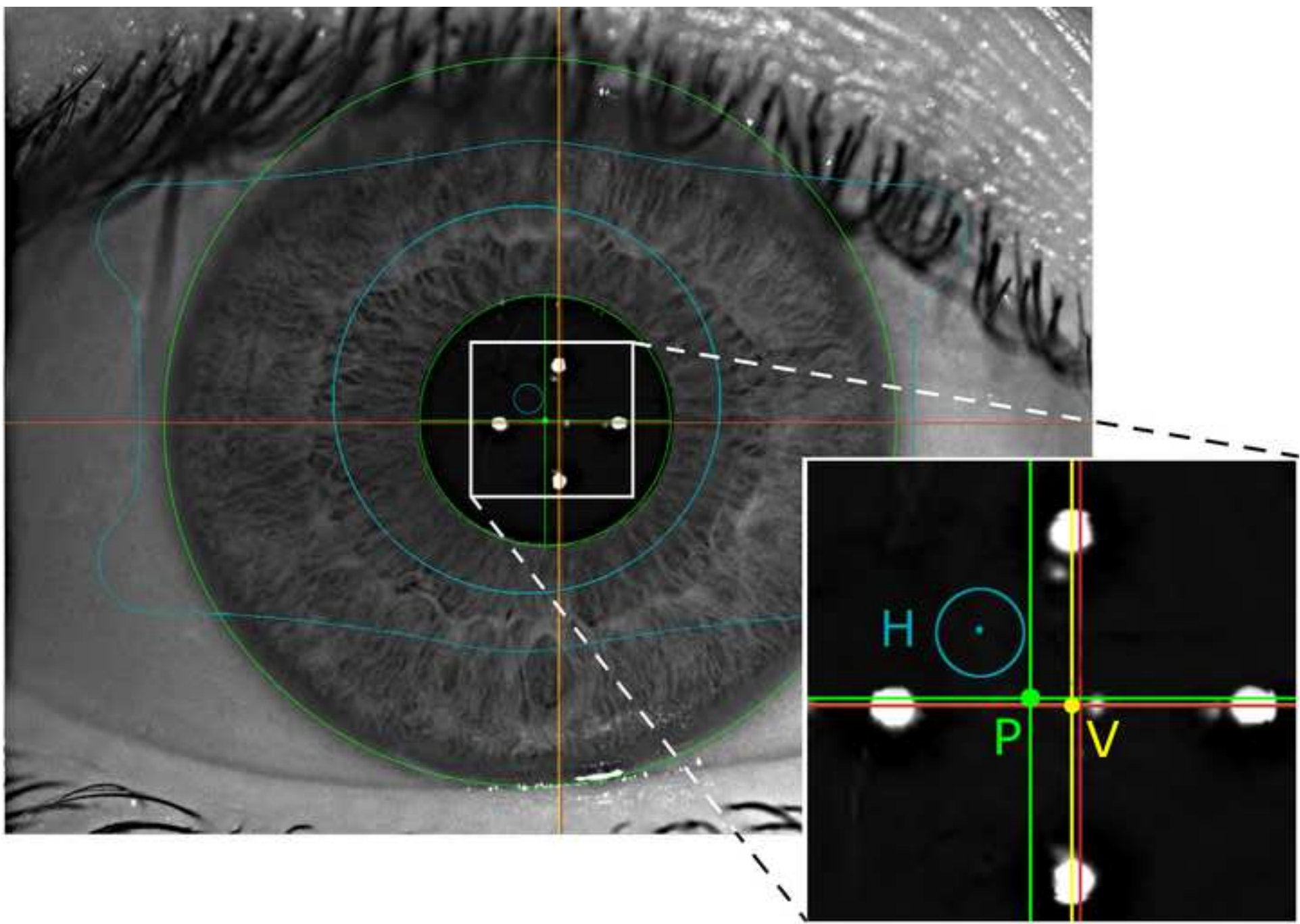
Reference system	Visit	Cartesian coordinates		Polar coordinates	
		X	Y	Radius	Polar angle
		(mm)	(mm)	(mm)	(degrees)
Pupil center	1 week	-0.27 ± 0.17 * ‡	0.07 ± 0.14	0.32 ± 0.15 * ‡	168.11 ± 39.95
	1 month	-0.27 ± 0.16 †	0.07 ± 0.13	0.32 ± 0.15	168.73 ± 34.26
	3 months	-0.25 ± 0.16 *	0.06 ± 0.13	0.30 ± 0.14 *	168.88 ± 40.51
	6 months	-0.25 ± 0.17 ‡ †	0.07 ± 0.12	0.30 ± 0.13 ‡	165.28 ± 40.49
Visual axis	1 week	-0.37 ± 0.15	0.04 ± 0.18	0.42 ± 0.13	174.49 ± 30.18
	1 month	-0.40 ± 0.14	0.03 ± 0.18	0.44 ± 0.13	176.60 ± 23.16
	3 months	-0.36 ± 0.16	0.00 ± 0.19	0.41 ± 0.14	180.16 ± 30.47
	6 months	-0.38 ± 0.14	0.04 ± 0.17	0.42 ± 0.13	174.91 ± 27.31

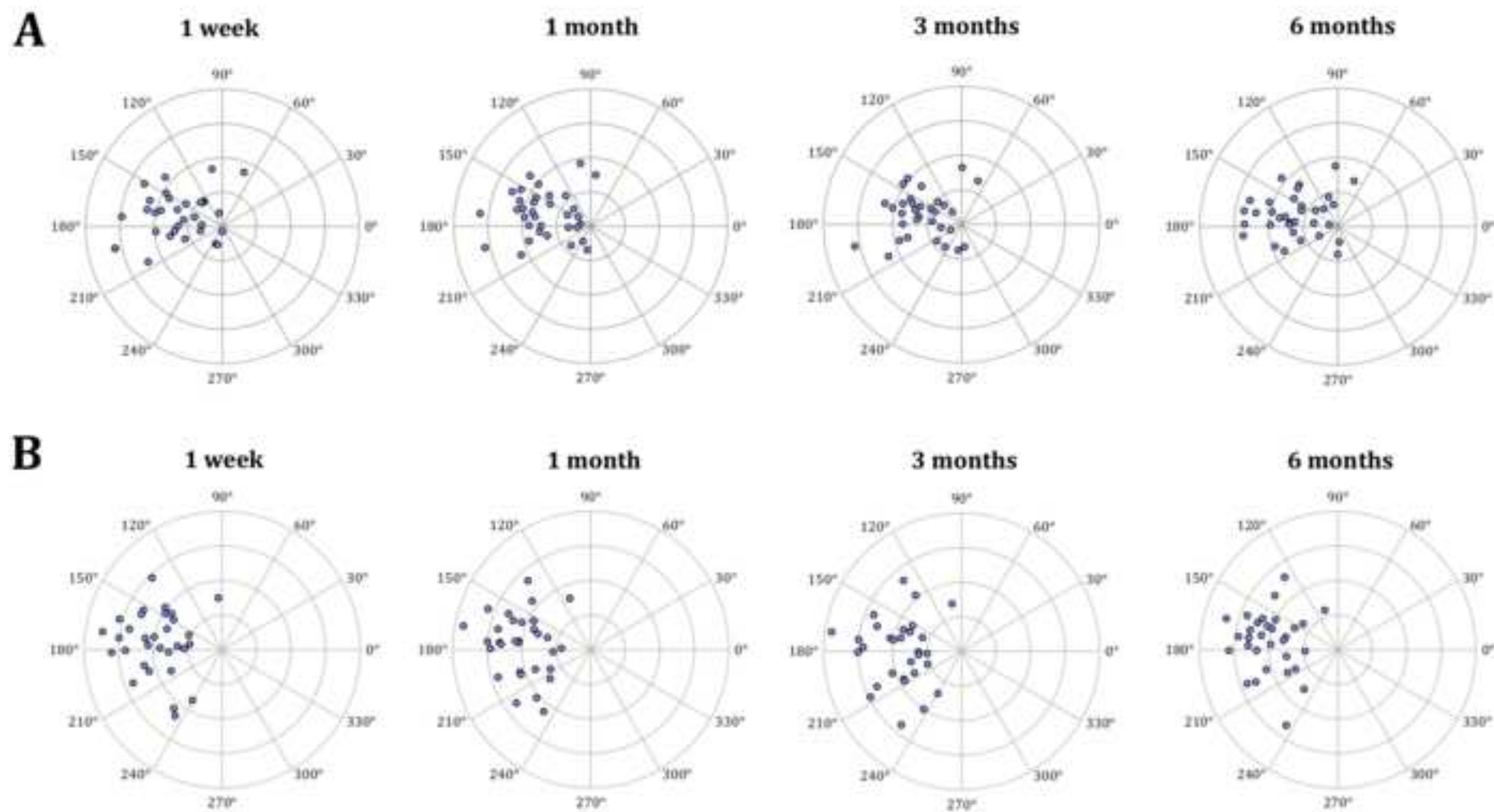
Values are shown as mean ± standard deviation. *: statistically significant difference between 1-week and 3-month visits ($p < 0.05$), ‡: statistically significant difference between 1-week and 6-month visits ($p \leq 0.01$), †: statistically significant difference between 1-month and 6-month visits ($p = 0.02$).

Table 3. Regression coefficient and P-value of Cartesian and polar coordinates for statistically significant multivariate models.

Reference system	Parameter	Visit	Model R ² (p-value)	Coefficients Coordinate: β (p-value)
Pupil center	QoV, Frequency	1 month	0.24 (0.004)	r: 70.91 (0.002) / α : -0.08 (0.28)
	QoV, Severity	1 month	0.23 (0.005)	r: 58.13 (0.002) / α : -0.05 (0.39)
	RSD, Severity	3 months	0.17 (0.021)	X: -2.02 (0.007) / Y: -0.46 (0.66)
			0.11 (0.054)	r: 2.21 (0.016) / α : 0.00 (0.82)
Visual axis	UDVA	3 months	0.22 (0.011)	X: -0.31 (0.004) / Y: 0.03 (0.68)
			0.19 (0.018)	r: 0.32 (0.006) / α : 0.00 (0.65)
	PRTXG	1 week	0.22 (0.022)	X: 2.71 (0.18) / Y: -3.83 (0.021)

α : polar angle; r: radius; X & Y are the Cartesian coordinates. PRTXG: photostress recovery time after xenon glare; QoV: quality of vision; RSD: ring-shaped dysphotopsia.

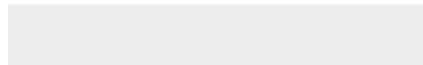






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