Effect of the EVO+ Visian Phakic Implantable Collamer Lens on Visual Performance and Quality of Vision and Life

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• PURPOSE: To assess the effect of EVO+ (V5) Visian implantable collamer lens implantation on mesopic visual performance, quality of vision (QoV), and quality of life (QoL).

• DESIGN: Prospective interventional case series.

• METHODS: Thirty-six eyes of 36 participants who underwent EVO+ implantation for myopia were evaluated preoperatively and at postoperative visits at 1 week and 1, 3, and 6 months. Visual acuity (VA) and mesopic contrast sensitivity (CS) with and without halogen- and xenon-type glare sources were evaluated at each visit. Subjective QoV was assessed with the QoV questionnaire and QoL assessed with the Quality of Life Impact of Refractive Correction (QIRC) questionnaire at each visit. Ring-shaped dysphotopsia was also assessed at each postoperative visit. Linear, cumulative link and logit mixed models were fitted to analyze the effect of the EVO+.

• RESULTS: Following EVO+ implantation, VA significantly ($P \leq .012$) improved at the 4 postoperative visits. Mesopic CS progressively improved at 1, 3, and 6 months postoperatively ($P \leq .012$). Halogen glare CS decreased at 1 week and halogen and xenon glare CS improved at 6 months ($P \leq .016$). Photostress recovery time after halogen glare improved at 3 and 6 months ($P \leq .004$). QoV scores improved at 1 week and 3 and 6 months ($P \leq .001$). QIRC scores improved postoperatively ($P < .001$). Ring-shaped dysphotopsia decreased at 3 and 6 months ($P \leq .007$).

• CONCLUSIONS: EVO+ implantation provides good mesopic visual performance, QoV, and QoL during up to 6 months follow-up. Some activities performed under mesopic conditions with glare sources may be affected during the first postoperative week. Ring-shaped dysphotopsia is negligibly bothersome 6 months after surgery. (Am J Ophthalmol 2021;226: 117–125. © 2021 Elsevier Inc. All rights reserved.)

The implantation of the Visian implantable collamer lens (ICL; STAAR Surgical, Monrovia, California, USA) is a safe, effective, and predictable surgical technique that is widely used for correcting refractive errors.[1-3] The EVO+ (V5 model) is the latest model employing a central hole (also known as the KS-aquaPORT), similar to the previous model (EVO, V4c). The central hole allows aqueous flow, eliminating the requirement of iridectomy or iridotomy.[4] In comparison with the EVO, the EVO+ has a larger optical zone (up to 6.1 mm), which may result in less night vision disturbance.[5]

Visian ICL lenses provide good outcomes in terms of visual acuity (VA) and contrast sensitivity (CS).[6,7] These results can have a positive impact on quality of vision (QoV) as well as quality of life (QoL) after ICL surgery. In particular, Ieong and associates[8] have reported that the implantation of these lenses increased the overall QoL, finding better mean scores in the majority of the activities evaluated (eg, practicing sports or traveling).[8] However, they reported the only activity that was more difficult after surgery, was driving in glare conditions.[8] Therefore, the presence of night vision disturbances could be the main visual concern after ICL implantation. And it must be taken into account that more than 1 million ICL devices[9] have been already implanted and 85.1% of the population has a driving license (U.S. Department of Transportation[10]).

The implantation of the EVO model has been associated with night vision phenomena, such as glare or halos.[5,11,12] Eom and associates[12] have recently described a new visual disturbance, named ring-shaped dysphotopsia, that may be directly related to the presence of the ICL central hole. The presence of these phenomena has been reported to be higher during the first months after EVO implantation.[12,13] However, no studies have reported the longitudinal change in QoV and QoL after EVO+ implantation.

The aim of the present study is to assess the effect of the newest ICL model, the EVO+, on the mesopic visual per-

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formance, including glare conditions, as well as on subjective, patient-reported QoV and QoL.

METHODS

This prospective interventional case series study was performed at Instituto de Oftalmobiología Aplicada (IOBA; University of Valladolid, Spain). The study was conducted in compliance with the tenets of the Declaration of Helsinki and prospectively approved by the East Valladolid Health Area Ethics Committee (Valladolid, Spain). Written informed consent was obtained from all participants.

• **SAMPLE:** The present study included 36 volunteers who underwent bilateral posterior chamber (ciliary sulcus) EVO+ implantation for the correction of myopia. Inclusion criteria were subjects with a minimum age of 21 years that achieved a best spectacle-corrected visual acuity (BSCVA) $\leq +0.10$ logarithm of the minimum angle of resolution (logMAR). Exclusion criteria were the presence of cataract, glaucoma, retinal anomalies, amblyopia, macular diseases, or history of previous ocular surgery and preoperative manifest cylinder above 4.50 diopters (D).

• **STUDY DESIGN:** Patients were evaluated during 5 study visits: preoperatively, and 1 week and 1, 3, and 6 months postoperatively. Visual tests were performed in each eye at all study visits. However, the dominant eye for distance was selected for monocular tests for statistical purposes. Ocular dominance was detected by 3 successive trials using the hole-in-card test.[14]

• **SURGICAL PROCEDURE:** The EVO+ power and size were determined according to the STAAR Company online calculator (OCOS). The surgery was performed through a 2.75 mm clear corneal incision after dilation of the pupil with tropicamide 1% (Colircusí Tropicamida; Alcon Cusí, Barcelona, Spain; drops administered 15 minutes apart for a total of 2 drops) under topical (2 drops of bottled 2% unpreserved lidocaine hydrochloride) and intracameral anesthesia (0.1 mL of 1% unpreserved lidocaine hydrochloride without epinephrine injected through a paracentesis incision). The anterior chamber was filled with 1% sodium hyaluronate (Healon; Advanced Medical Optics, Santa Ana, California, USA). The EVO+ was inserted in the posterior chamber (ciliary sulcus). Then, the 1% sodium hyaluronate was completely removed by irrigation and aspiration using the coaxial stainless steel straight irrigation-aspiration tip of the Infinity vision system (Alcon Laboratories, Inc, Fort Worth, Texas, USA), followed by 0.1 mL intracameral injection of acetylcholine 1% (Acetilcolina; Alcon Cusí). At the end of the surgery, 2 drops each of bottled ofloxacin (Exocin; Allergan España SA, Madrid, Spain) and dexamethasone (Colircusí Dexametasona; Alcon Cusí) were topically applied. All implantations were performed by the same experienced surgeon (M.J.M.).

After surgery, topical medications included ofloxacin 3% (Exocin; Allergan, Spain), 1 drop every 2 hours for 1 week and then 1 drop every 4 hours for 1 week; dexamethasone 1% (Colircusí Dexametasona; Alcon Cusí) every 2 hours for 1 week, every 4 hours for 1 week, every 8 hours for 1 week, every 12 hours for 1 week, and once a day for 1 week; and brimonidine and timolol (Combigan; Allergan España SA, Madrid, Spain) twice daily for 4 weeks was administrated. Combigan was used to avoid intraocular pressure spikes and was continued up to 4 weeks. Additionally, 250 mg of oral acetazolamide (Edemox; Chiesi España SA, Barcelona, Spain) was prescribed twice daily for the first 72 hours postoperatively.

• **VISUAL PERFORMANCE TESTS:**

Visual acuity

Monocular VA was measured (logMAR) using the Early Treatment Diabetic Retinopathy Study chart at 4 meters. BSCVA was recorded at the preoperative and 6 months postoperative visit, and the uncorrected distance visual acuity (UDVA) was recorded at all postoperative visits.

Mesopic and glare contrast sensitivity

Binocular mesopic CS was assessed using the IOBA-HAXEMCST (IOBA Halogen-Xenon Mesopic Contrast Sensitivity Test) headlight glare simulation system following the methodology previously described.[7] Briefly, CS was assessed using the Pelli-Robson chart at 1 m distance under mesopic conditions following 10 minutes of dark adaptation. Then, CS was measured during 5 seconds of progressively intense glare, simulating halogen and xenon lights (random order). Photostress recovery time necessary to achieve the previous mesopic CS after halogen- and xenon-type glare was measured. Finally, discomfort glare during halogen and xenon sources was also recorded at all visits using the de Boer rating scale from 0 (unbearable) to 9 (unnoticeable).[15]

• **PATIENT-REPORTED OUTCOMES INSTRUMENTS:**

The quality of vision questionnaire

The quality of vision (QoV) questionnaire consists of a linear-scaled 10-item instrument across 3 subscales providing a QoV score in terms of symptom frequency, severity, and bothersomeness. Each item has a 4-point response option and the first 7 items have an associated picture, simulating the visual symptom to ensure patient understanding.[16,17] The QoV scores range from 0 to 100, with higher scores indicating poorer QoV.

Ring-shaped dysphotopsia

The possible perception of ring-like shapes/dysphotopsia, probably produced by stray light interaction with the central hole,[12] was also evaluated. The frequency, severity, and bothersomeness of ring-shaped dysphotopsia was evaluated using a 4-point response option scale ranging from 0 (absence) to 3 (maximum), akin to the QoV. Before scoring, participants were shown the illustration of a ring-shaped dysphotopsia previously published by Eom and associates.[12] Thus, participants were helped to distinguish this ring-like photopsia from other visual disturbances, such as halos.

The Quality of Life Impact of Refractive Correction questionnaire

The Quality of Life Impact of Refractive Correction (QIRC) questionnaire was used to measure QoL.[18] This questionnaire consists of 20 items and each question is scored on a 5-category response option scale. The responses were converted into a Rasch scale ranging from 0 (worst QoL) to 100 (best QoL). The QIRC permits the assessment of QoL of subjects with their habitual correction, spectacles or contact lenses, and it is also appropriate for refractive surgery patients.[19]

Both the QoV questionnaire and the QIRC questionnaire were administered in random order preoperatively and 1 week and 1, 3, and 6 months after surgery. The ring-shaped dysphotopsia item was always evaluated after the QoV questionnaire administration owing to their similar administration process and format.

• **STATISTICAL ANALYSIS:** Statistical analyses were performed using the R statistical package version 4.0.0.[20]

Sample size was calculated to find a difference in a paired *t* test between visits of 0.05 logMAR in VA considering the standard deviation reported by Shimizu and associates[21] before and after EVO implantation (pooled standard deviation: 0.076 logMAR). A 2-tailed α error of 0.05/10 to control for multiple comparisons and a β error of 0.20 (power 80%) were established. A sample size of 34 participants was estimated using the pwr package[22]; however, a total sample size of 37 participants was finally selected considering an estimated 10% dropout rate.

Continuous variables were presented as mean and standard deviation whereas ordinal data were presented as median and interquartile range (IQR). Because of their low frequency, CS variables were transformed into dichotomous data; thus, patients were classified into low and high CS groups, as previously performed.[7] The data transformation was as follows: the mesopic CS values were grouped into $\leq$1.05 log units and >1.05 log units, and halogen and xenon glare CS values were grouped into $\leq$0.75 log units and >0.75 log units. Consequently, CS variables were presented as percentage of patients achieving >1.05 log units for mesopic CS, or >0.75 log units for halogen and xenon glare CS.

The effect of the EVO+ implantation on the study parameters was analyzed using 3 types of mixed models, based on the dependent variable, including the visit as a fixed effect and the subject as a random effect. Continuous variables were analyzed using linear mixed models with the lme4 package.[23] The model assumptions were checked using the Kolmogorov-Smirnov test and residual plots. Some parameters (photostress recovery time after halogen and xenon glare) were inversely transformed to adjust for positive skew. Ordinal variables were analyzed using cumulative link mixed models with the ordinal package.[24] Also, the effect of ICL power and preoperative low mesopic pupil size (Topolyzer Vario; Alcon Laboratories, Inc, Fort Worth, Texas, USA) on the parameters measured was analyzed. Depending on the model, ICL power or pupil size was included as a covariate. The assumption of proportional odds ratios was checked using the likelihood ratio test. Dichotomous variables were analyzed by computing binary logit mixed models using the lme4 package.[23] Each model with a significant *P* value was followed by a multiple comparison of the estimated marginal means using the Tukey method with the emmeans package.[25] Two-sided *P* values $\leq$ .05 were considered statistically significant.

A power analysis was conducted to estimate the statistical power of linear and binary logit mixed models using the simr package[26] (R software) by running 1,000 simulations per model; and the statistical power of *t* test analyses using the pwr package, which is based on Cohen notations.[27]

RESULTS

• **STUDY POPULATION:** A total of 36 (23 female and 13 male) patients with a mean age of 31.0 ± 6.1 years completed the study. There was 1 dropout because of scheduling constraints. The EVO+ implantations were uneventful, and no complications were observed during the 6-month follow-up. The mean spherical and cylindrical implanted EVO+ power was -9.47 ± 2.51 D (range: -5.00 to -14.00 D) and 0.85 ± 1.16 D (range: 4.50 to 0 D), respectively. The median implanted ICL size was 13.20 mm (IQR: 12.60-13.20 mm) (Supplemental table; Supplemental Material available at AJO.com). The Table shows the results of the parameters recorded at each study visit.

• **SAFETY, EFFICACY, PREDICTABILITY, AND ASTIGMATISM:** The mean BSCVA was -0.04 ± 0.05 and -0.11 ± 0.08 at preoperative and 6-month postoperative visit, respectively. The safety index (ratio of postoperative BSCVA to preoperative BSCVA) was 1.20 ± 0.20 at the 6-month postoperative visit. Twenty-two eyes (61.11%) showed no change in BSCVA. Further, 13 eyes (36.11%) gained 1 line and 1 eye (2.78%) gained more than 1 line of BSCVA after EVO+ implantation. None of the eyes lost 1 or more lines 6 months after surgery.

TABLE. Descriptive Results of the Study Parameters at Each Study Visit

Parameters	Preoperative	1 Week	1 Month	3 Months	6 Months
BSCVA (logMAR)	-0.04±0.05	NM	NM	NM	-0.11 ± 0.08
UDVA (logMAR)	NM	-0.09 ± 0.09	-0.08 ± 0.10	-0.10 ± 0.09	-0.10 ± 0.09
MCS (%: ≤1.05/>1.05)	69/31	72/28	39/61	31/69	23/77
HGCS (%: ≤0.75/>0.75)	56/44	83/17	42/58	33/67	23/77
XGCS (%: ≤0.75/>0.75)	72/28	92/8	61/39	42/58	40/60
PRTHG (seconds)	4.33 ± 3.85	4.79 ± 4.44	3.57 ± 2.49	2.96 ± 1.67	2.75 ± 1.25
PRTXG (seconds)	4.80 ± 4.72	5.37 ± 3.76	4.21 ± 3.00	3.30 ± 1.73	3.28 ± 1.30
De Boer halogen	6.57 ± 1.90	5.94 ± 2.07	6.39 ± 1.92	6.44 ± 1.63	6.94 ± 1.71
De Boer xenon	5.83 ± 1.90	5.25 ± 2.05	5.69 ± 1.85	6.03 ± 1.92	5.77 ± 1.83
QoV frequency	41.00 ± 13.19	25.89 ± 19.03	37.17 ± 19.19	26.58 ± 16.23	25.69 ± 16.09
QoV severity	33.75 ± 9.63	21.36 ± 15.93	27.72 ± 15.61	21.86 ± 13.28	21.69 ± 13.95
QoV bothersome	33.75 ± 14.97	21.28 ± 18.45	26.64 ± 19.48	18.06 ± 15.67	20.58 ± 15.78
RSD frequency	NM	3 (2-3)	2 (1-3)	2 (1-2)	1 (1-1)
RSD severity	NM	2 (1-3)	2 (1-2)	1 (1-2)	1 (1-2)
RSD bothersome	NM	2 (1-2)	1 (1-2)	1 (0-2)	1 (0-1)
QIRC questionnaire	46.98 ± 7.17	50.20 ± 5.03	51.59 ± 5.64	54.77 ± 4.82	55.18 ± 5.36

BSCVA = best spectacle-corrected visual acuity; HGCS = halogen glare contrast sensitivity; LogMAR = logarithm of the minimum angle of resolution; MCS = mesopic contrast sensitivity; NM = not measured; PRTHG = photostress recovery time after halogen glare; PRTXG = photostress recovery time after xenon glare; QIRC = quality of life impact of refractive correction; QoV = quality of vision questionnaire; RSD = ring-shaped dysphotopsia; UDVA = uncorrected distance visual acuity; XGCS = xenon glare contrast sensitivity.

Data are presented as mean ± standard deviation for continuous variables, median (interquartile range) for ordinal variables, or frequency percentages for dichotomous variables.

The mean UDVA was -0.09 ± 0.09, -0.08 ± 0.10, -0.10 ± 0.09, and -0.10 ± 0.09 logMAR at 1 week and 1, 3, and 6 months postoperatively, respectively (Table). The efficacy index (ratio of postoperative UDVA to preoperative BSCVA) was 1.15 ± 0.22 at the 6-month postoperative visit. One hundred percent (n = 36) of eyes had a UDVA of 20/40 and 83.33% (n = 30) had 20/20 or better, 6 months after surgery.

The linear regression between the attempted and achieved myopic correction (SE) showed a coefficient value (R^2) of 0.97 (Supplemental Figure 1; Supplemental Material available at AJO.com). Seventeen eyes (47.22%) had a SE within ±0.25 D, 31 eyes (86.11%) were within ±0.5 D, and all eyes (100%) were within ±0.75 D at 6 months postoperatively.

The mean manifest SE was -7.75 ± 2.36 D (range: -3.50 to -12.38 D) preoperatively, and +0.11 ± 0.40 D (range: 0.75 to -0.50 D) at 6 months postoperatively. The target induced astigmatism and the surgically induced astigmatism were 1.62 ± 1.11 D and 1.36 ± 1.05 D, respectively (Supplemental Figure 2; Supplemental Material available at AJO.com).

• **VISUAL PERFORMANCE OUTCOMES:** The EVO+ produced a significant effect on VA ($P < .001$) over time. VA was significantly ($P \leq .012$) improved at the 4 postoperative visits (UDVA) in comparison with the preoperative BSCVA (Figure 1).

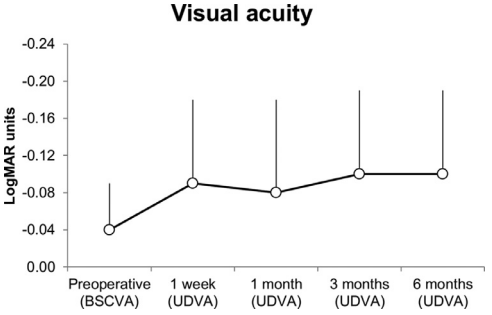

FIGURE 1. Visual acuity obtained at each visit. Best spectacle-corrected visual acuity (BSCVA) and uncorrected visual acuity (UDVA) are reported for the preoperative and postoperative visits, respectively. Mean and standard deviation values are reported as circles and vertical lines, respectively. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

The EVO+ produced a significant effect on mesopic CS ($P < .001$) and halogen and xenon glare CS (both $P < .001$). Mesopic CS showed a significant improvement at 1-, 3-, and 6-month postoperative visits in comparison to preoperative ($P \leq .012$) and 1-week postoperative visits ($P \leq .007$) (Figure 2). Halogen and xenon glare CS showed an initial deterioration at 1 week postoperatively in comparison to preoperatively, being significant ($P = .016$) for halogen glare CS (Figure 2). Both halogen and xenon glare CS

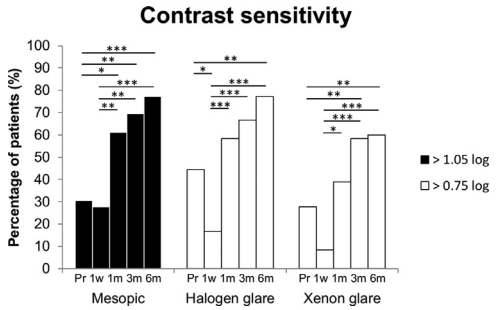

FIGURE 2. Contrast sensitivity (CS) values for the 3 scenarios (mesopic, and mesopic with halogen or xenon glare) at each visit. The mesopic CS values are presented as the percentage of patients with >1.05 log CS units. Halogen and xenon glare CS values are presented as the percentage of patients with >0.75 log CS units. m = month; Pr = preoperative; w = week. *P ≤ .05; **P ≤ .01; ***P ≤ .001.

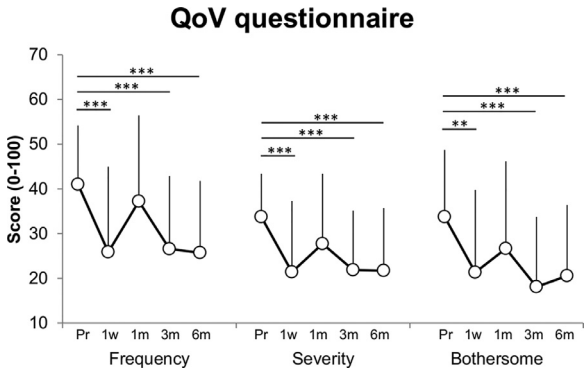

FIGURE 3. The quality of vision (QoV) questionnaire outcomes for the 3 categories at each visit. Lower values indicate better QoV. Mean and standard deviation values are reported as circles and vertical lines, respectively. m = month; Pr = preoperative; w = week. *P ≤ .05; **P ≤ .01; ***P ≤ .001.

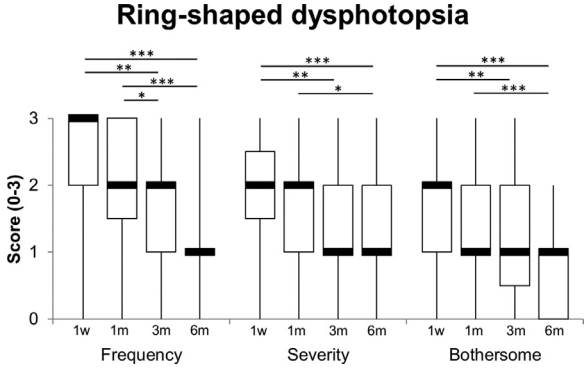

FIGURE 4. Ring-shaped dysphotopsia values obtained for each category during the postoperative follow-up period. The boxes represent the 25th to 75th percentiles, and thick black horizontal lines represent median values. The whiskers represent the minimum and maximum values. m = month; w = week. *P ≤ .05; **P ≤ .01; ***P ≤ .001.

improved significantly at the 3- and 6-month postoperative visit compared to preoperatively, with all comparisons statistically significant ($P \leq .006$) except for halogen glare CS at the 3-month visit (Figure 2). Halogen and xenon glare CS also showed a significant ($P \leq .011$) increase at the 1-, 3-, and 6-month postoperative visits in comparison with the 1-week postoperative visit (Figure 2).

Photostress recovery time after halogen and xenon glare was significantly different following EVO+ implantation ($P = .003$ and $P = .004$, respectively). Photostress recovery time after halogen glare significantly decreased 3 ($P = .02$) and 6 months ($P = .007$) after surgery compared to the preoperative time point. Photostress recovery time after xenon glare showed significantly ($P = .001$) lower values at the 6-month postoperative visit than the 1-week value. No significant effect was found for halogen and xenon glare bothersomeness using the de Boer scale at any visit ($P \geq .09$).

• **PATIENT-REPORTED OUTCOMES:** The effect of the EVO+ on the QoV questionnaire subscales (Frequency, Severity, and Bothersome) over the follow-up visits was statistically significant ($P < .001$). The trend for the 3 subscales was a marked improvement at 1 week, followed by a return to similar preoperative levels at 1 month, followed by statistically significant improvements at 3 and 6 months (Figure 3).

The 3 scales of ring-shaped dysphotopsia (Frequency, Severity, and Bothersome) showed a significant (all categories $P < .001$) effect after EVO+ implantation among the postoperative visits (Figure 4). Over the 3 scales, ring-shaped dysphotopsia was initially high at 1 week postoperatively and reduced to low levels at further postoperative visits up to 6 months. The reduction was statistically significant ($P \leq .007$) at the 3- and 6-month postoperative visits in relation to the 1-week visit. Also, the 3 scales showed a significant ($P \leq .034$) improvement (lower scores) at the 6-month postoperative visit compared to the 1-month visit. In addition, the Frequency scale was also significantly ($P = .016$) improved 3 months postoperatively compared with the 1-month visit (Figure 4). Neither ICL power ($P \geq .20$) nor preoperative pupil size ($P \geq .32$) had a significant influence on any ring-shaped dysphotopsia subscale (Frequency, Severity, or Bothersome).

The effect of the EVO+ on QIRC questionnaire scores along the follow-up period was statistically significant ($P < .001$). QIRC scores increased (improved) at each visit, obtaining statistically significant ($P \leq .009$) differences among all visits, except for the comparisons between the 1-week and 1-month postoperative visits, and between the 3- and 6-month postoperative visits (Figure 5).

• **POWER ANALYSIS:** The following analyses reached a power of at least 80%: VA (99.60%), mesopic CS (100%), halogen CS (100%), xenon CS (99.90%), halogen recov-

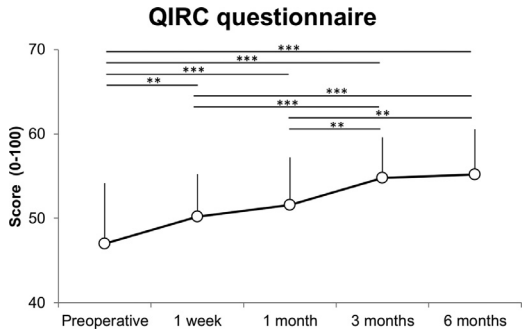

FIGURE 5. The Quality of Life Impact of Refractive Correction (QIRC) questionnaire outcomes at each visit. Higher values indicate higher quality of life. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

ery time (95.10%), xenon recovery time (86.30%), QoV frequency (99.60%), QoV severity (99.90%), QoV bothersomeness (99.90%), and QIRC questionnaire (100%). The following analyses reached a power lower than 80%: halogen de Boer scale (61.60%) and xenon de Boer scale (38.70%).

DISCUSSION

The EVO+ model has a larger optical zone than the previous model (EVO), and it may result in less postoperative vision disturbance in mesopic conditions. Thus, we aimed to assess the effect on the mesopic visual performance and the subjective, patient-reported quality of vision and life. We found that the EVO+ implantation produced an improvement in VA and mesopic CS, with and without glare sources, from the first postoperative week and month, respectively. These visual outcomes were accompanied by an improvement in QoV and QoL, which was continuous for the latter until the third postoperative month. In addition, the perception of ring-shaped dysphotopsia was continuously declined up to 6 months follow-up.

The UDVA was significantly better at all postoperative visits in comparison to preoperative BSCVA. The significant improvement at the 1-week postoperative visit indicates the rapid visual improvement that an uneventful EVO+ implantation provides, surpassing preoperative BSCVA. Excellent values for safety, efficacy, and predictability were found. Numerous authors have also described better VA values in the early postoperative time than preoperatively, showing efficacy indexes (ratio of postoperative UDVA to preoperative BSCVA) greater than 1 for EVO and EVO+.[5,28,29] In our study, we obtained similar VA results at all postoperative visits, suggesting that this visual parameter rapidly improves and remains stable during the 6-month postoperative period. Similarly, other authors have reported that the VA remains stable during the early postoperative period,[21] at least up to 7 years.[30] Other authors have shown lower efficacy indexes in longer follow-up periods, although external factors not associated with the ICL may be involved, such as aging or myopia progression.[1-3]

Contrast sensitivity was measured in mesopic conditions as well as under progressive halogen- and xenon-type intensity glare sources. Preoperative mesopic CS was similar to 1 week postoperatively, whereas halogen and xenon CS experienced a decrease at this visit, although not reaching significance for xenon glare CS ($P = .078$). The decrease of CS under glare conditions suggests that the visual performance could be reduced during the first week if patients with ICL implants are exposed to intense illuminations. This CS decrease observed at the 1-week postoperative visit may be caused by mild postoperative transient corneal edema, mild anterior segment inflammation, ocular surface irregularities owing to the healing corneal incision, and/or moderate punctate keratopathy. After the first postoperative week, mesopic and glare CS showed improvement trends along all postoperative visits. Likewise, Shimizu and associates[6] have also reported a significant improvement in mesopic and glare CS 3 months after EVO implantation. In addition, in our study we found that after halogen glare, patients showed lower photostress recovery time during the 3- and 6-month visits than before surgery. These outcomes demonstrate that the EVO+ implantation provides better CS values than preoperatively, even under mesopic conditions with glare.

Subjective, patient-reported quality of vision, as measured with the QoV questionnaire, improved following EVO+ implantation. There was an initial marked improvement in QoV scores at 1 week, presumably owing to reduced nighttime activity in the immediate postoperative period, followed by a return to similar preoperative scores at 1 month (better at 1 month compared to preoperatively for all 3 subscales of the QoV, but not reaching statistical significance). This trend was followed by a marked improvement at 3 months, which was maintained at 6 months, at scores similar to the values at 1 week postoperatively. However, it must be taken into account that patients had brimonidine (and timolol) treatment for 28 days (because a considerable proportion of myopic and highly myopic eyes are steroid responders[31,32]); thus, 1-week postoperative QoV scores could be underestimated as a consequence of the pupillary constriction that brimonidine may produce. This effect tends to disappear by 24 hours after instillation[33,34]; thus, it is unlikely to cause any long-term consequences. Some studies have highlighted the incidence of glare and halos with central hole ICL models[11,12,35]; however, they gradually disappear over the postoperative follow-up.[13] These visual disturbances are comprehensively addressed in the QoV questionnaire, a tool specifically focused on measuring positive dysphotopsia. In our study, we also observed an improvement in the QoV questionnaire over time after EVO+

implantation. The postoperative QoV values in the 3 categories were always equal to or better than the preoperative ones. In fact, the decrease in all categories (QoV improvement) 3 months after surgery is already noteworthy. Thus, our outcomes may suggest that the appearance of halos and glare are clinically negligible for a global QoV perception. Alternatively, the larger optical zone of the EVO+ may be responsible for the good QoV reached in our study. This hypothesis is in agreement with Kojima and associates,[5] who have implanted subjects with an EVO in 1 eye and an EVO+ in the fellow eye. They have reported that all subjects who noticed differences between eyes declared better night vision in the eye implanted with EVO+.

Ring-shaped dysphotopsia is a visual disturbance that appears to be related to the ICL central hole (KS-aquaPORT).[12] In our study, we found that this phenomenon had a decreasing trend over the postoperative follow-up, showing its highest values at the first postoperative week and lowest 6 months after surgery. Ring-shaped dysphotopsia might be most perceived during the 1-week postoperative visit because it is a completely new phenomenon for patients, and because ocular surface alterations might exacerbate photic phenomena. In addition, based on our clinical experience patients do not usually report dissatisfaction associated with ring-shaped dysphotopsia 6 months after EVO+ implantation. The present study results are in concordance with Eom and associates,[12] who have described and assessed this phenomenon. They reported that the mean duration of this visual disturbance was 2.9 months (range, 1-12 months). These findings as well as our outcomes indicate that ring-shaped dysphotopsia is likely to diminish with time during the first postoperative months. Additionally, the ICL power or the pupil size diameter at preoperative time seems not to have an effect on ring-shaped dysphotopsia subscales.

QoL, as measured with the QIRC questionnaire, showed a significant improvement at all visits after EVO+ implantation. Ieong and associates[8] have also studied the effect of ICL (V4 model) implantation on QoL using the QIRC questionnaire. In agreement with our results, they have reported that the values of the QIRC questionnaire were significantly higher after ICL implantation in comparison with the preoperative time point. Additionally, our results showed a progressive improvement in QoL during the postoperative time, up to the 3 months, where the plateau was reached. This finding could be the consequence of several factors, such as the continuous improvement of CS (Figure 2), even under mesopic glare conditions, the progressive reduction of ring-shaped dysphotopsia or the decrease of concerns regarding the short-term postoperative complications. From 3 postoperative months onward, the QoL appears to be stable, which may indicate that patients have already adapted to their new visual status.

The present study has limitations. First, the clinical evaluation was mainly focused on performance under mesopic conditions, including glare sources. However, other parameters assessing visual quality, such as total higher-order aberrations,[36] were not available to us; therefore, we could not evaluate them before and after EVO+ ICL surgery, and it could be considered a limitation of the study. Second, we did not recruit patients implanted with the EVO model V4c, a group whose outcomes could have been compared to the EVO+ patients. However, future studies assessing the comparisons between the objective and subjective outcomes of both models are required.

In conclusion, our results show that the implantation of the phakic EVO+ model provides improved visual acuity, mesopic visual performance (CS), QoV, and QoL. However, there is transient lower ability to perform activities under mesopic conditions with glare during the first postoperative week. In addition, photostress recovery time improved postoperatively and subjective halogen and xenon glare bothersomeness using the de Boer scale was not significantly changed. It would be prudent for patients seeking ICL surgery to be counseled on the possibility of postoperative ring-shaped dysphotopsia; however, this is likely to become minimally bothersome at 6 months. The findings of the present study show that patients with EVO+ implants have superior mesopic visual function than before surgery, which may allow them to perform some common activities requiring high visual demands more comfortably.

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