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Effect of the EVO+ Visian phakic implantable collamer lens on visual performance, quality of vision and life.

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Short title: Objective and subjective outcomes after EVO+ implantation

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INTRODUCTION

The implantation of the Visian implantable collamer lens (ICL, STAAR Surgical Co.) is a safe, effective and predictable surgical technique, which 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 6.1mm), which may result in less night vision disturbances.[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 et al.[8] have reported that the implantation of these lenses increased the overall QoL, finding better mean scores in the majority of the activities evaluated (e.g. practicing sports or traveling).[8] However, they reported the only activity which 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 1.0 million ICL devices[9] have been already implanted and 85.1% of the population (U.S. Department of Transportation) has a driving license.[10]

The implantation of the EVO model has been associated with night vision phenomena, such as glare or halos.[5,11,12] Eom et al.[12] have recently described a new visual disturbance, named ring-shaped dysphotopsia, which 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 performance, 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 five 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 2.75mm clear corneal incision after dilatation of the pupil with tropicamide 1% (Colircusí Tropicamida®; Alcon Cusí, Spain; drops administered 15 minutes apart for a total of 2 drops) under topical (two 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, 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, Tex), followed by 0.1 mL intracameral injection of acetylcholine 1% (Acetilcolina®; Alcon Cusí, Spain). At the end of the surgery, two drops of each bottled Ofloxacin (Exocin®, Allergan, Spain) and Dexamethasone (Colircusí Dexametasona®; Alcon Cusí, Spain) 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), one drop every 2 hours for 1 week and then, one drop every 4 hours for 1 week, dexamethasone 1% (Colircusí Dexametasona®; Alcon Cusí, Spain) 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, USA) twice daily for 4 weeks was administrated. Combigan® was used to avoid intraocular pressure spikes and was continued up to 4 weeks. Additionally, 250mg of oral acetazolamide (Edemox®; Chiesi, 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) 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 1m distance under mesopic conditions following ten 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 (QoV) questionnaire

The 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 four point response option and the first seven 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 quality of vision.

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 bothersome of ring-shaped dysphotopsia was evaluated using a 4-point response option scale ranging from 0 (absence) to 3 (maximum), akin to the QoV. Prior to scoring, participants were showed the illustration of a ring-shaped dysphotopsia previously published by Eom et al.[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 (QIRC) questionnaire

The 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 evaluated always after the QoV questionnaire administration due 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 et al.[21] before and after EVO implantation (pooled standard deviation: 0.076 LogMAR). A two-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 ≤1.05 log units and >1.05 log units, and halogen and xenon glare CS values were grouped into ≤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 three 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] Besides, the effect of ICL power and preoperative low mesopic pupil size (Topolyzer Vario, Alcon Laboratories, Inc., Fort Worth, TX) 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 ≤.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 females and 13 males) patients with a mean age of 31.0±6.1 years completed the study. There was one 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). Table 1 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 one line and 1 eye (2.78%) gained more than one line of BSCVA after EVO+ implantation. None of the eyes lost one or more lines 6 months after surgery.

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 1). The efficacy index (ratio of postoperative UDVA to preoperative BSCVA) was 1.15±0.22 at the 6-month postoperative visit. 100% (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 S1; Supplemental Material available at AJO.com). 17 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 (TIA) and the surgically induced astigmatism (SIA) were 1.62±1.11 D and 1.36±1.05 D, respectively (Supplemental Figure S2; 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≤.012) improved at the four postoperative visits (UDVA) in comparison with the preoperative BSCVA (Figure 1).

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≤.012) and 1-week postoperative visits (P≤.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 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 one (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 bothersome 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 three subscales was a marked improved at 1 week followed by a return to similar pre-operative levels at 1 month followed by statistically significant improvements at 3 and 6 months (Figure 3).

The three 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 three scales, ring-shaped dysphotopsia was initially high at 1 week postoperatively which 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 three 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 ones (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 recovery time (95.10%), xenon recovery time (86.30%), QoV frequency (99.60%), QoV severity (99.90%), QoV bothersome (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 disturbances in mesopic conditions. Thus, we aimed to assess the effect on the mesopic visual performance, and 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 later 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+.[28,5,29] 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 seven 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 due 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 et al.[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 due to reduced night time 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 three 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 three categories were always equal 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 haloes and glare are clinically negligible for a global QoV perception. Alternatively, the larger optical zone of the EVO+ may be the responsible for the good QoV reached in our study. This hypothesis is in agreement with Kojima et al.,[5] who have implanted subjects with an EVO in one eye and an EVO+ in the fellow one. They have reported that all subjects who noticed differences between eyes declared better night vision in the EVO+ implanted eye.

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 dysphotopia 6 months after EVO+ implantation. The present study results are in concordance with Eom et al.[12] who have described and assessed this phenomenon. They reported that the mean duration of this visual disturbance was 2.9 months (range, from 1 to 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 et al.[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 three 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 onwards 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 their 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 evaluated 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 bothersome 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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All authors attest that they meet the current ICMJE criteria for authorship.

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FIGURE CAPTIONS.

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. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

Figure 2. Contrast sensitivity (CS) values for the three 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. Pr: preoperative. w: week. m: month. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

Figure 3. The quality of vision (QoV) questionnaire outcomes for the three categories at each visit.

Lower values indicate better quality of vision. Mean and standard deviation values are reported as circles and vertical lines, respectively. Pr: preoperative. w: week. m: month. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

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. w: week. m: month. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

Figure 5. The Quality of life impact of refractive correction (QIRC) questionnaire outcomes at each visit.

Higher values indicate higher quality of life. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

Table 1. 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	46.98±7.17	50.20±5.03	51.59±5.64	54.77±4.82	55.18±5.36

Data are presented as mean±standard deviation for continuous variables, median (interquartile range) for ordinal variables or frequency percentages for dichotomous variables. 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: The quality of life impact of refractive correction; QoV: The quality of vision questionnaire; RSD: ring-shaped dysphotopsia; UDVA: uncorrected distance visual acuity; XGCS: xenon glare contrast sensitivity.

Figure 1

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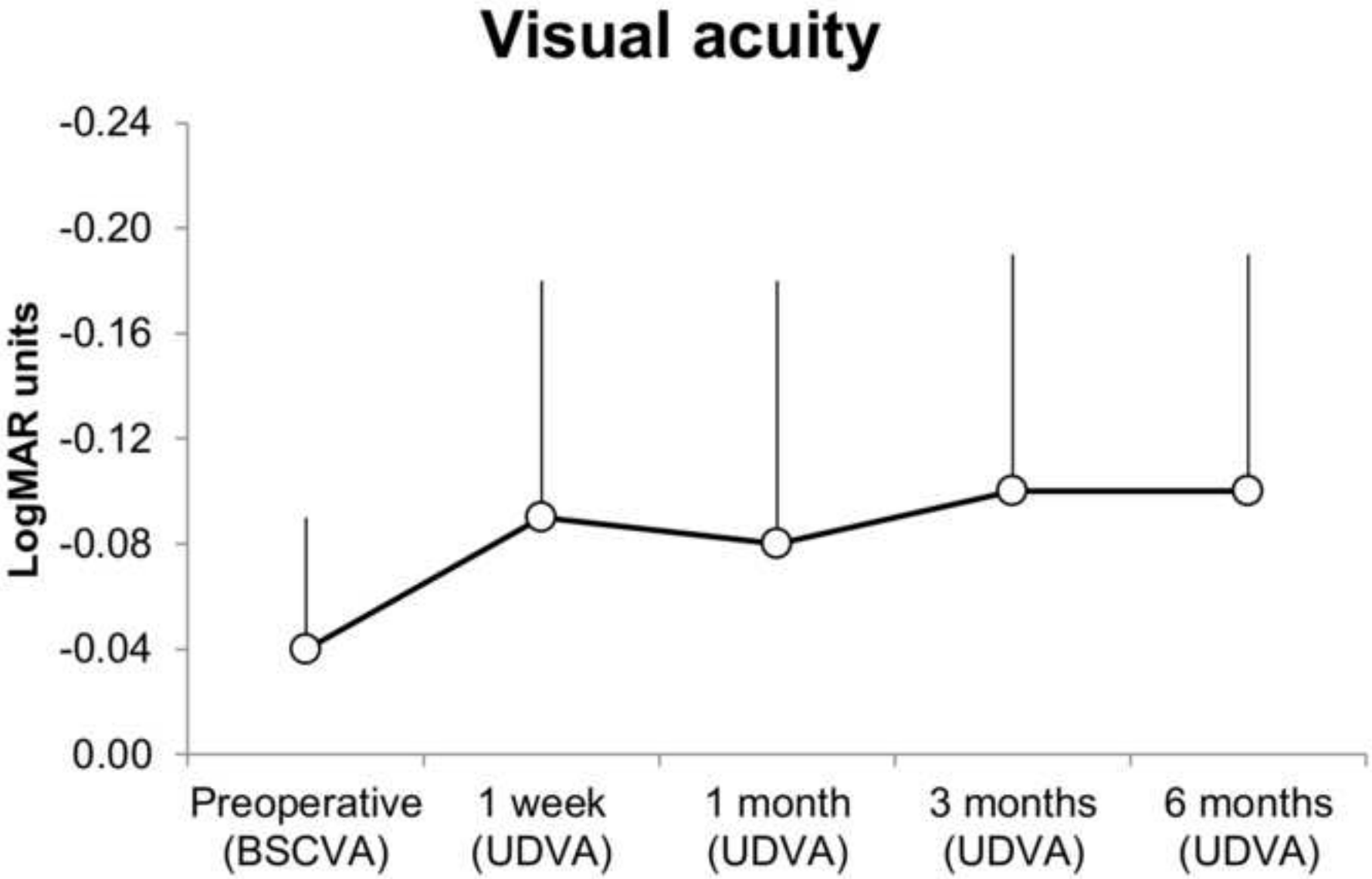

Figure 2

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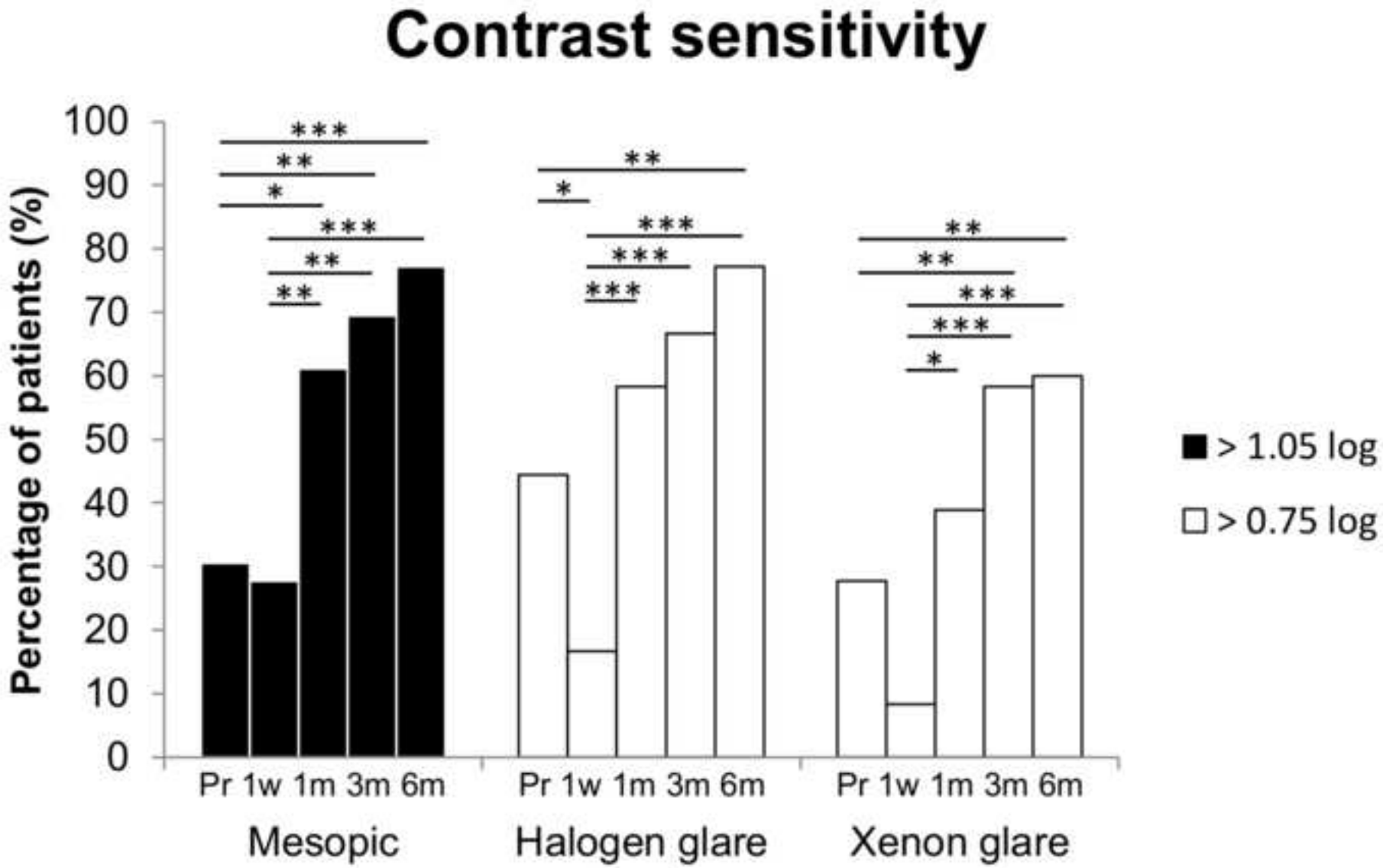

Figure 3

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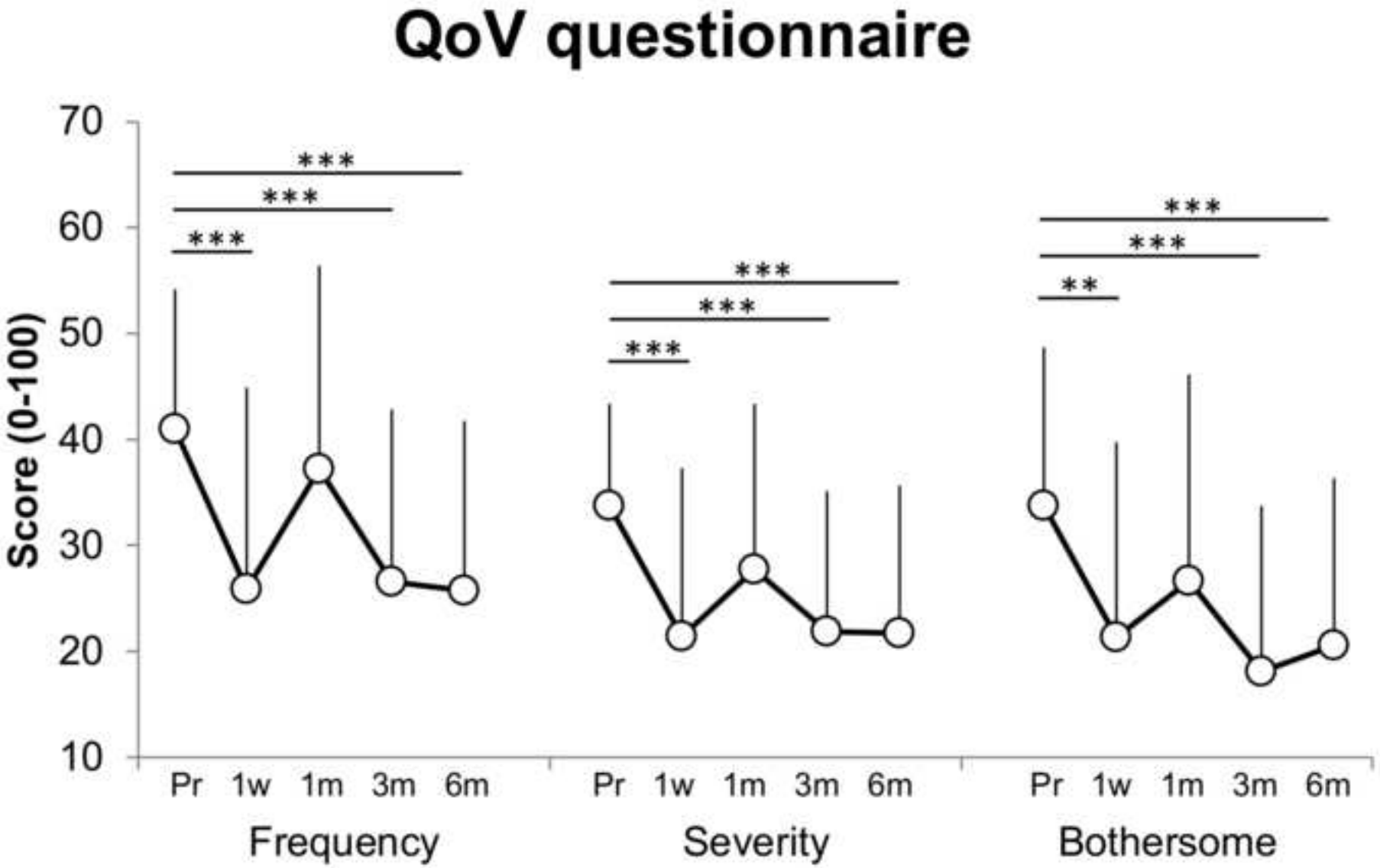

Figure 4

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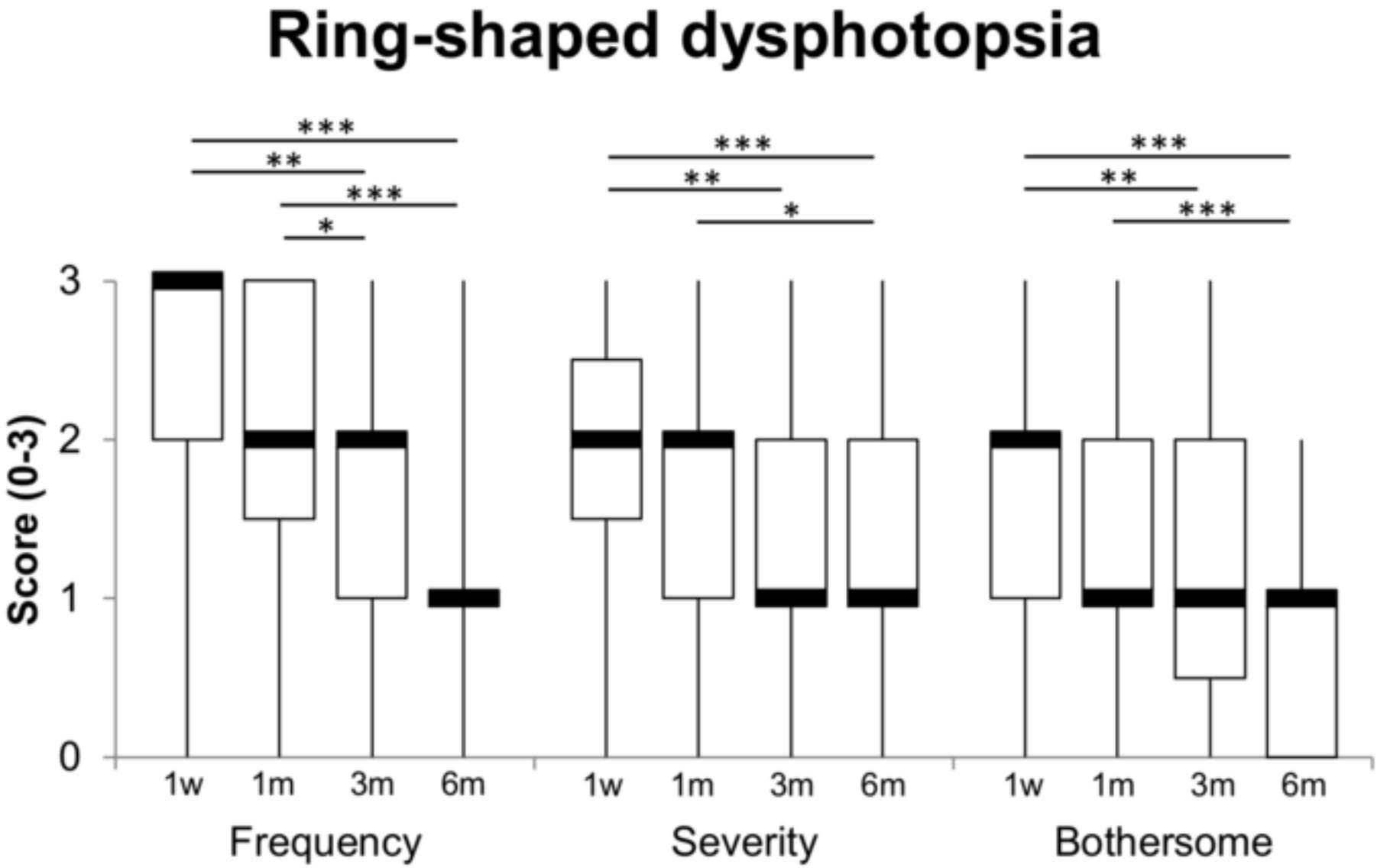

Figure 5

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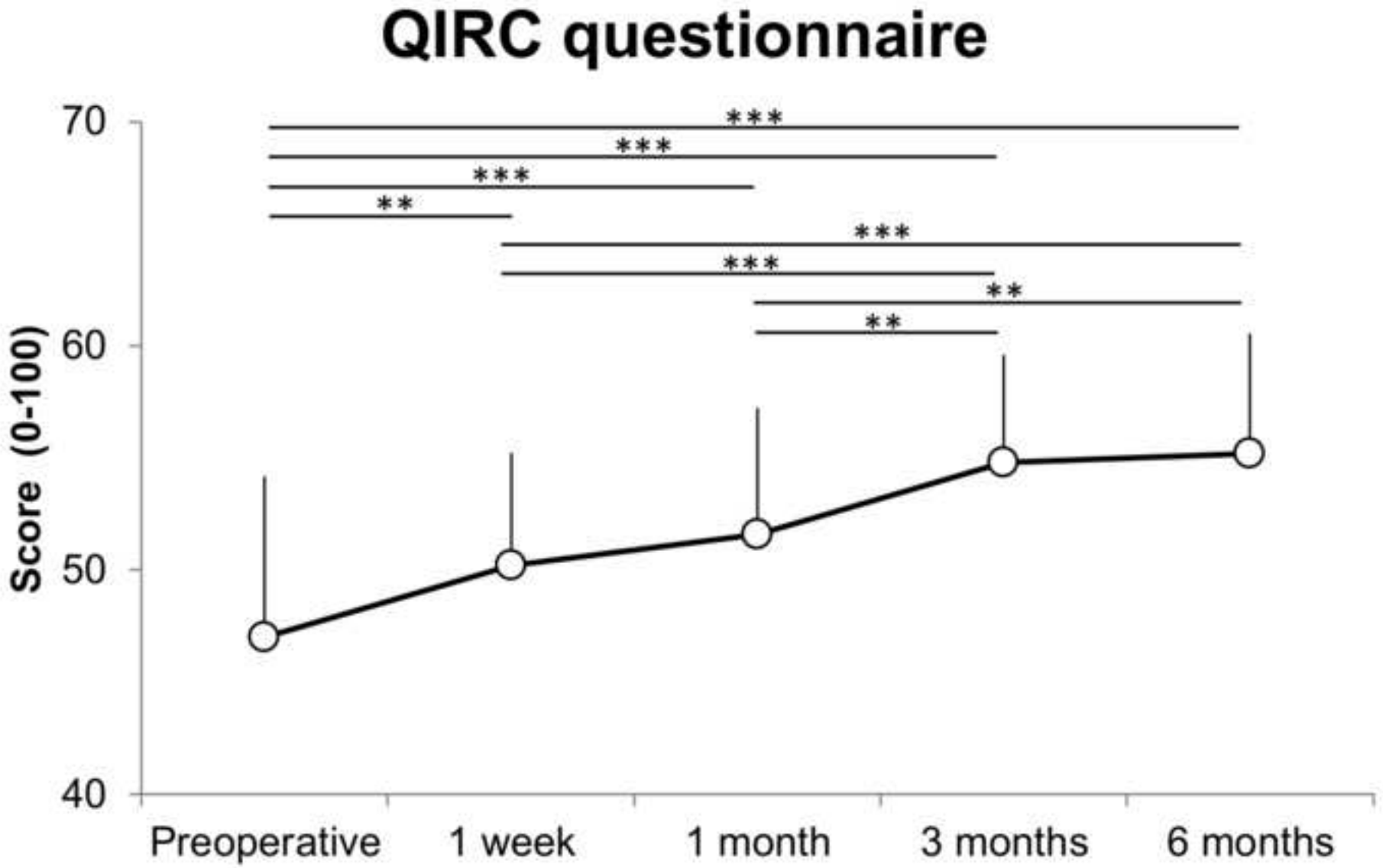

Table of content statements.

EVO+ implantation provides better mesopic visual performance, quality of vision and quality of life six months after surgery. However, some activities performed under mesopic conditions with glare sources may be affected during the first postoperative week. Ring-shaped dysphotopsia peaks during the first postoperative week and decreases up to negligible values six months after surgery.

HIGHLIGHTS

- EVO+ ICL implantation improves mesopic visual performance, quality of vision and life.
- Activities under mesopic conditions with glare can be affected during 1-week postop.
- Ring-shaped dysphotopsia decreases progressively to very low levels by 6 months.

Supplementary Material: Images, Tables, Text
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Table S1. Power and optical diameter characteristics of implanted EVO+ ICL.

Sphere	Cylinder	EVO+ Optical diameter	Participants (n)
-0.5 to -9.0	+0.5 to +6.0	6.1	20 (55.5%)
-9.5 to -10.0	+0.5 to +6.0	5.9 to 6.1	4 (11.1%)
-10.5 to -12.5	+0.5 to +6.0	5.3 to 5.8	8 (22.2%)
-13.0 to -14.0	+0.5 to +6.0	5.0 to 5.2	4 (11.1%)

Supplementary Material: Images, Tables, Text

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Figure S1. Scatter plot showing the attempted vs achieved spherical equivalent correction six months after EVO+ implantation. Grey box provides linear regression coefficients. Black line represents best fit linear regression analysis. Green and red lines indicate error margin of ±0. 50 D and ± 1.00 D, respectively.

Figure S2. Scatter plot showing the target induced astigmatism vs surgically induced astigmatism vectors. Grey box provides linear regression coefficients. Black line represents best fit linear regression analysis. Green and red lines indicate error margin of ±0.50 D and ± 1.00 D, respectively.

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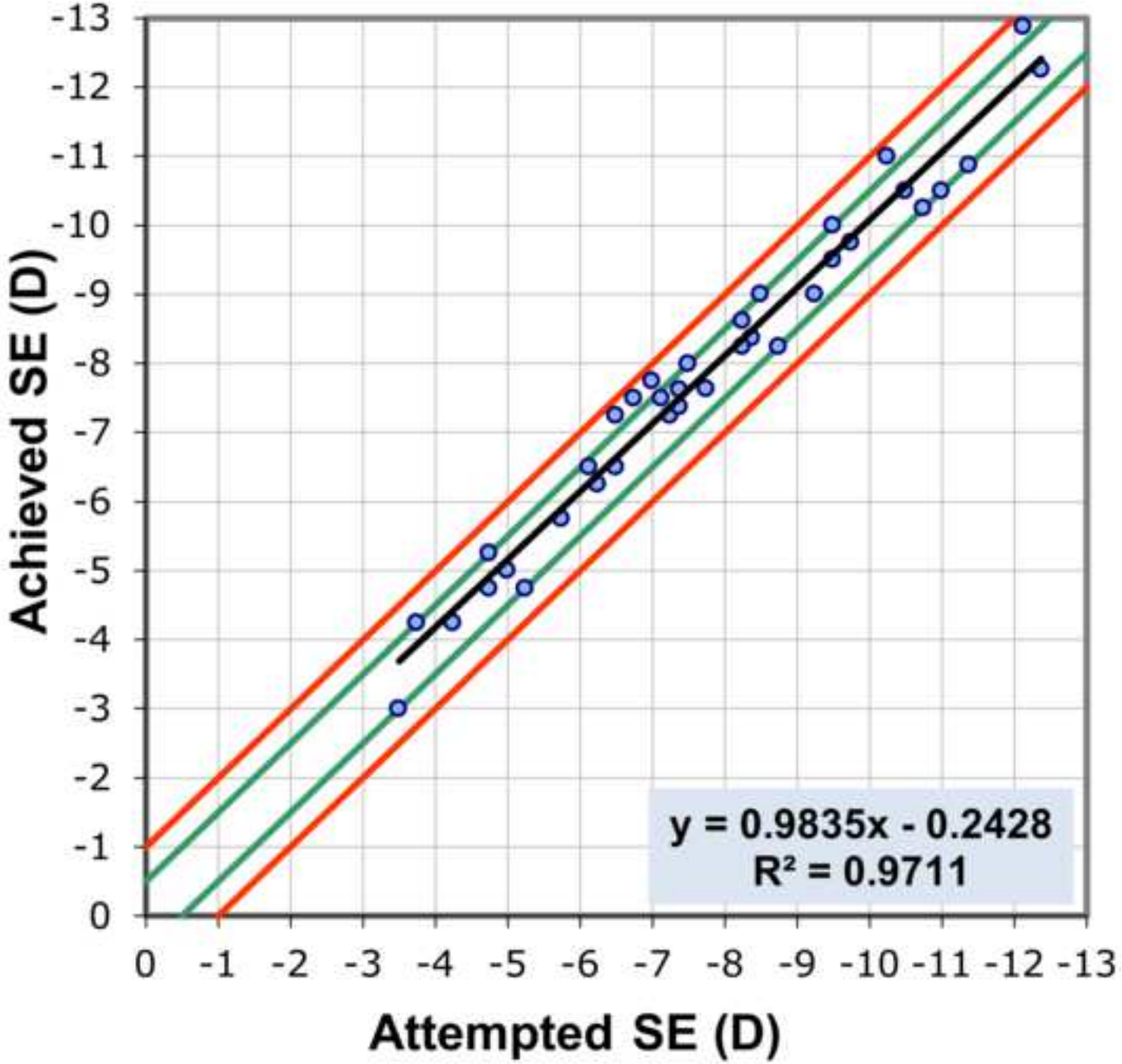

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