Clinical and Aberrometric Outcomes of a New Implantable Collamer Lens for Myopia and Presbyopia Correction in Phakic Patients

José F. Alfonso, MD, PhD; Luis Fernández-Vega-Cueto, MD, PhD; Carlos Lisa, MD, PhD; Belén Alfonso-Bartolozzi, MD, PhD; Ana Palacios, OD; David Madrid-Costa, PhD

ABSTRACT

PURPOSE: To assess the clinical and aberrometric outcomes of a new Implantable Collamer Lens (EVO Viva ICL; STAAR Surgical) to correct moderate to high myopia and presbyopia.

METHODS: The study included 80 eyes of 40 patients who had bilateral EVO Viva ICL implantation. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, presbyopic add power, binocular through-focus visual acuity, total ocular spherical aberration (SA), coma aberration, and root mean square of ocular higher order aberrations (RMS HOAs) (i-Trace Aberrometer; Tracey Technologies) for a 4.5-mm pupil size were evaluated.

RESULTS: The mean binocular postoperative UDVA and CDVA were 0.09 ± 0.19 and 0.02 ± 0.03 logMAR, respectively. The postoperative spherical equivalent was -0.61 ± 0.54 diopters (D). The presbyopic add power reduced from +1.31 ± 0.74 D preoperatively to +0.44 ± 0.58 D after surgery ($P < .0001$). The mean visual acuity was 0.1 logMAR or better (20/25 or better) across the vergence range from +0.50 to -1.50 D, better than 0.2 logMAR (20/32 or better) up to the vergence of -2.00 D, and remained better than 0.3 logMAR (20/40 or better) up to the vergence of -2.50 D. The total ocular aberrations induced by EVO Viva ICL were -0.34 ± 0.09 µm of SA, 0.24 ± 0.18 µm of coma, and 0.26 ± 0.12 µm of RMS HOAs.

CONCLUSIONS: The outcomes support that the new ICL might be a good alternative for myopia and presbyopia correction in patients aged between 45 and 55 years. Further studies are needed to evaluate the threshold lens misalignment from which the patient´s visual quality would be affected.

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The coexistence of moderate to high myopia and presbyopia represents a challenge in patients younger than 50 to 55 years. The age (younger than 55 years) and long axial length dramatically increase the risk for retinal detachment regardless of whether a refractive lens exchange with presbyopia-correcting intraocular lens (IOL) implantation is performed.[1,2] On the other hand, presbyopia onset and hence the consequent progressive decline in focusing ability may exacerbate spectacle or contact lens intolerance.

The Visian Implantable Collamer Lens with a central hole design (ICL V4c model; STAAR Surgical) is an effective and safe surgical procedure for myopia correction, providing outstanding visual outcomes with a high rate of refractive accuracy and few complications or adverse events,[3] even over an extended follow-up.[4-12] The clinical results reported with the ICL V4c support using this lens in older patients for myopia correction[13-15]; however, the ICL V4c is a monofocal lens. Consequently, the procedure does not address presbyopia management. Earlier studies attempted myopia and presbyopia correction with the ICL V4c in individuals with early presbyopia through monovision or an intended slight undercorrection.[16-18]

Recently, the manufacturer has launched a new ICL model with an aspheric optic design aiming to increase the depth of focus compared to the ICL V4c model, claiming to represent a novel approach to the surgical

From Fernández-Vega Ophthalmological Institute, Oviedo, Spain. (JFA, LF-V-C, CL, BA-B, AP); and the Optometry and Vision Department, Faculty of Optics and Optometry, Universidad Complutense de Madrid, Madrid, Spain (DM-C).

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Correspondence: José F. Alfonso, MD, PhD, Instituto Oftalmológico Fernández-Vega, Avda. Dres. Fernández-Vega 114, 33012 Oviedo, Spain. Email: j.alfonso@fernandez-vega.com

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correction of refractive error and presbyopia in phakic patients. This new lens (EVO Viva ICL; STAAR Surgical) retains the central port design. Preliminary results in a multicenter study over 6 months of follow-up[19] reported encouraging results, suggesting that this new ICL allowed correction of myopia and presbyopia, resulting in improvement of uncorrected near, intermediate, and distance visual acuity without compromising the quality of vision.

The current study aims to provide further evidence about the benefits and potential drawbacks of the EVO Viva ICL for myopia and presbyopia correction in phakic patients. To this extent, we evaluated the clinical outcomes of this new ICL design in 40 patients with myopia who had presbyopia over a follow-up ranging between 6 and 12 months. Furthermore, we analyzed the induced aberrations after EVO Viva ICL implantation (aiming to understand how this lens works to increase intermediate and near vision) and potential risk factors for losing CDVA lines.

PATIENTS AND METHODS

This study comprised 80 eyes of 40 patients who underwent bilateral implantation of the EVO Viva ICL to correct myopia and presbyopia at Fernández-Vega Ophthalmological Institute, Oviedo, Spain. All patients provided written informed consent after the nature and possible consequences of the study were explained thoroughly in accordance with the tenets of the Declaration of Helsinki.

The inclusion criteria were age between 45 and 55 years, exhibiting presbyopia symptoms, a myopic error range between -2.00 and -18.00 diopters (D) of sphere, keratometric astigmatism of 2.00 D or less, a clear central cornea, anterior chamber depth (ACD) greater than 2.8 mm measured from the corneal endothelium to the anterior lens capsule, endothelial cell density (ECD) greater than 2,000 cells/mm^2, mesopic pupil smaller than 7 mm, photopic pupil greater than 2 mm, trabecular-iris angle greater than 35° (grade III by gonioscopy), crystalline lens rise less than 500 µm, and a postoperative follow-up period of at least 6 months. The exclusion criteria were cataracts, history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuro-ophthalmic disease, or any ocular inflammation history.

All included eyes in this study underwent implantation of the EVO Viva ICL model. The details of the lens have been published previously.[19] Briefly, the lens retains the most advanced elements of the ICL V4c platform, including the central hole, and incorporates an aspheric design theoretically intended to provide up to approximately 2.00 D extended depth of focus.[20]

Emmetropia was selected as the postoperative target refraction for all eyes. ICL power calculation was performed based on the manufacturer's specification. ICL size was individually determined according to the horizontal white-to-white (WTW) distance, anterior chamber depth measured by Scheimpflug tomography, and angle-to-angle distance measured with anterior segment optical Coherence tomography (AS-OCT; Casia SS-1000; Tomey Corporation). All surgeries were performed by the same experienced surgeon (JFA) following the standard procedure previously described with the ICL V4c model.[11]

Preoperatively and postoperatively, all patients had a complete ophthalmologic examination, including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refractions, presbyopic add power at 40 cm, slit-lamp examination, corneal topography and tomography (Sirius; CSO Ophtalmic), AS-OCT (Casia SS-1000), ECD measurement (SP 3000P; Topcon), and intraocular pressure (IOP) measurement by Goldmann applanation tonometry. Furthermore, the following total ocular higher order aberrations (HOAs) for a 4.5-mm pupil size were evaluated (i-Trace Aberrometer; Tracey Technologies): coma, spherical aberration (SA), and root mean square (RMS) HOAs. At the last postoperative visit, the central vault under mesopic conditions was measured (AS-OCT; Casia SS-1000), and binocular through-focus logMAR visual acuity (defocus curve; range: -4.00 to +2.00 D in 0.50-D steps) was evaluated in patients with a monocular CDVA of better than 0.1 logMAR.

Data were analyzed using SPSS for Windows software, version 14.0 (SPSS, Inc). Normality was checked with the Shapiro-Wilk test, and paired and unpaired *t* tests were used to assess statistically significant differences. Differences were considered statistically significant when the *P* value was less than .05. Visual and refractive outcomes were analyzed at the last postoperative follow-up visit. Means and standard deviations or percentages were used to report postoperative visual and refractive results. The cumulative binocular UDVA and CDVA were calculated postoperatively at the last follow-up visit. For refractive predictability, the Pearson coefficient was used to analyze the correlation between the attempted refractive sphere refraction and the achieved refractive sphere refraction.

RESULTS

This study comprised 80 eyes of 40 patients (18 men and 22 women) with a mean age of 48.05 ± 2.52 years (range: 45 to 55 years). Preoperative demographic data of the patients and ICL characteristics are summarized in **Table 1**. The distribution of the lens sizes implant-

TABLE 1
Preoperative Patient Demographics and ICL Characteristics

Characteristic	Mean ± SD (Range)
Age (years)	48.05 ± 2.52 (45 to 55)
Refractive sphere (D)	-6.34 ± 3.09 (-14.50 to -2.00)
Refractive cylinder (D)	-0.70 ± 0.56 (-2.50 to 0.00)
Spherical equivalent (D)	-6.69 ± 3.09 (-14.50 to -2.00)
UDVA (logMAR)	1.45 ± 0.38 (0.7 to 2.0)
CDVA (logMAR)	0.02 ± 0.05 (0.0 to 0.3)
Minimum keratometry (D)	43.62 ± 1.50 (40.71 to 47.91)
Maximum keratometry (D)	44.44 ± 1.55 (41.32 to 47.91)
Keratometric cylinder (D)	0.81 ± 0.43 (0.09 to 2.00)
ACD (mm)	3.23 ± 0.23 (2.80 to 3.98)
WTW (mm)	12.23 ± 0.26 (11.55 to 12.84)
ATA (mm)	12.13 ± 0.29 (11.48 to 12.77)
Axial length (mm)	26.24 ± 1.41 (23.29 to 30.00)
Pupil diameter (mm)	
Photopic (85 cd/m^2)	3.38 ± 0.63 (2.18 to 4.80)
Mesopic (3 cd/m^2)	5.50 ± 0.77 (3.76 to 6.85)
ECD (cells/mm^2)	26,92 ± 268 (2,204 to 3,365)
IOP (mm Hg)	13.86 ± 2.07 (9, 18)
ICL sphere (D)	-8.13 ± 3.32 (-16.50 to -3.00)

ACD = anterior chamber depth; ATA = angle to angle distance; CDVA = corrected distance visual acuity; D = diopters; ECD = endothelial cell density; ICL = Implantable Collamer Lens (STAAR Surgical); IOP = intraocular pressure; SD = standard deviation; UDVA = uncorrected distance visual acuity; WTW = white to white distance

ed was: 12.1 mm in 28 eyes (35.0%), 12.6 mm in 51 eyes (63.7%), and 13.6 mm in 1 eye (1.3%). The mean postoperative follow-up period was 8.2 ± 2.8 months (range: 6 to 12 months).

The mean postoperative monocular and binocular UDVA were 0.14 ± 0.12 and 0.09 ± 0.09 logMAR, respectively. The efficacy index (mean postoperative UDVA/mean preoperative CDVA) was 0.78. **Figure 1A** shows the cumulative monocular and binocular UDVA at the last follow-up visit, 97.5% of the patients reached a binocular UDVA of 0.2 logMAR or better (20/32 or better), and 77.5% had a value of 0.1 logMAR or better (20/25 or better).

After surgery, the mean monocular and binocular CDVA were 0.04 ± 0.06 and 0.02 ± 0.03 logMAR, respectively. All patients achieved a binocular CDVA of 0.1 logMAR or better (20/25 or better), and 80% had a value of 0.0 logMAR (20/20) (**Figure 1B**). The safety index was 0.97. At the last follow-up visit, most of the eyes (67.5%) retained or improved the CDVA compared to preoperatively. However, 26 eyes (32.5%) experienced a loss of one line or more of CDVA after EVO Viva ICL implantation (**Figure 2**). **Table 2** compares preoperative parameters and induced total ocular aberration between the eyes that lost lines of CDVA and those that did not. Among all variables analyzed, the only one significantly higher in the eyes losing lines was induced coma.

The spherical equivalent significantly decreased from -6.69 ± 3.20 D preoperatively to -0.61 ± 0.54 D after surgery ($P < .0001$). Likewise, the add power for best near visual acuity reduced from +1.31 ± 0.74 to +0.44 ± 0.58 D ($P < .0001$). **Figure 3A** shows a scatterplot of the attempted versus achieved refractive sphere at the last visit. Forty-eight eyes (60%) were within ±0.50 D of the desired sphere refraction (emmetropia), and 70 eyes (87.5%) were within ±1.00 D (**Figure 3B**). **Table A** (available in the online version of this article) compares preoperative parameters and induced total ocular aberration between the eyes with a postoperative sphere of less than ±1.00 D and eyes with a postoperative myopic sphere of -1.00 D or greater. The group with a postoperative myopic sphere of -1.00 D or greater had a significantly lower preoperative refractive sphere, lower ICL power, and a flatter maximum and minimum keratometry.

Figure A (available in the online version of this article) plots the postoperative binocular defocus curve for the cases analyzed in patients with a monocular CDVA of better than 0.1 logMAR after the implantation of an EVO Viva ICL. The curve shows only one peak at the distance focus (0.00 D of vergence). The mean visual acuity at -0.50 and +0.50 D of defocus was 0.01 ± 0.01 and 0.06 ± 0.15 logMAR, respectively. All patients achieved a visual acuity of 0.2 logMAR or better (20/32 or better) across the vergence range from +0.50 to -1.50 D (equivalent to 66 cm from the eye), and 85% of the cases 0.1 logMAR or better (20/25 or better) in this range of vergences. At a vergence of -2.00 D (50 cm from the eye), the visual acuity was 0.15 ± 0.12 logMAR, 95% of the cases achieved visual acuity of 0.3 logMAR or better (20/40 or better), and 80% of the eyes achieved 0.2 logMAR or better. At a vergence of -2.50 D (40 cm from the eye), the visual acuity was 0.27 ± 0.14 logMAR, and 95% and 70% of the cases achieved visual acuity of 0.4 logMAR or better (20/50 or better) and 0.3 logMAR or better, respectively.

The total ocular aberrations induced by the EVO Viva ICL were -0.34 ± 0.09 µm of SA, 0.24 ± 0.18 µm of coma aberration, and 0.26 ± 0.12 µm of RMS HOAs.

The mean IOP was 13.86 ± 2.07 mm Hg (range: 9 to 18 mm Hg) before surgery and 13.38 ± 1.85 mm Hg (range: 10 to 18 mm Hg) at the last follow-up visit ($P = .07$). **Figure B** (available in the online version of this article) shows the changes in IOP between preopera-

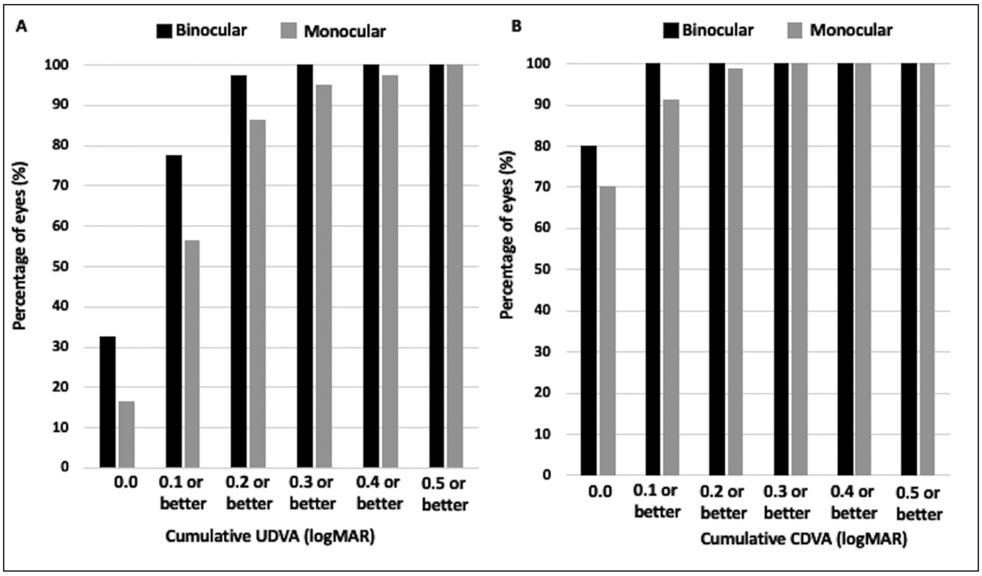

Figure 1. Cumulative monocular and binocular (A) uncorrected distance visual acuity (UDVA) and (B) corrected distance visual acuity (CDVA).

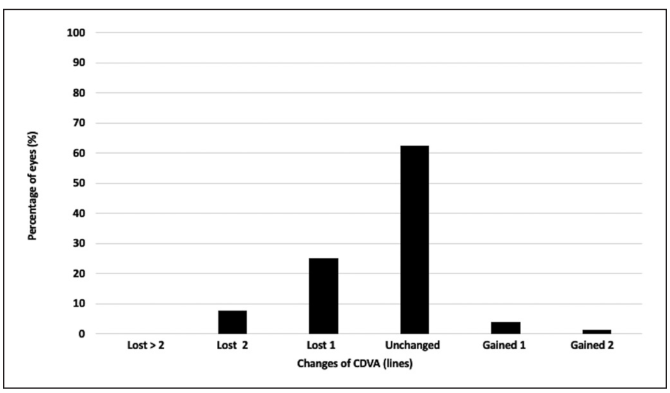

Figure 2. Variation in monocular corrected distance visual acuity (CDVA) between preoperative and the last postoperative follow-up visit.

tive and postoperative values. At the end of follow-up, the largest proportion of the eyes showed a reduction in IOP (33 eyes, 41.25%), 23 eyes (28.75%) experienced no change from the preoperative IO*P* value, 19 eyes (23.75%) increased 1 to 2 mm Hg from the preoperative IOP, and 5 eyes (6.25%) increased 3 to 4 mm Hg from the preoperative IOP. No significant increase in IOP (> 20 mm of Hg or an increase higher than 5 mm of Hg) occurred in any case during the follow-up.

There were no significant changes in the mean ECD after surgery (*P* = .23). The mean postoperative vault was 337 ± 141 µm at the last follow-up visit. **Figure C** (available in the online version of this article) shows the postoperative distribution of the vault. The most prevalent vault range was from 200 to 299 µm in 26.3% of eyes. No eyes showed a vault higher than 800 µm.

There were no intraoperative complications. There were no cases of anterior subcapsular opacity, cataract, pigment dispersion glaucoma, or pupillary block over the follow-up.

DISCUSSION

The current study reports the clinical and aberrometry outcomes of the new EVO Viva ICL to correct myopia and presbyopia in phakic patients. The lens design claims to extend the depth of focus through an aspheric design. Hence, an increase in ocular HOAs is expected. Our analysis yielded that the EVO Viva ICL induced, on average, a SA -0.34 ± 0.08 µm for 4.5 mm of the pupil and generated a mean of coma aberration of 0.24 ± 0.17 µm.

The aberrometric outcomes confirmed that this ICL seeks to improve intermediate and near vision by deliberately increasing SA. Hence, this lens should be considered an increased-SA lens. However, the induced coma may be an unwanted effect of lens misalignment. In vitro optical evaluation of the monofocal ICL found that lens decentration induced coma aberration,[21] although with a magnitude that could be considered clinically negligible in affecting the visual quality of a patient (maximum increment of 0.072 µm at 4.5 mm pupil).[21,22] However, the impact of misalignments of this new ICL (an aspheric design with increased negative SA) on coma induced is expected to be significantly higher,[23-30] and, as we will discuss below, depending on the magnitude might compromise the visual quality of the patient.

Overall, our distance visual acuity outcomes were satisfactory and in line with those previously reported by Packer et al[19] in the first study on the EVO Viva ICL. The mean binocular UDVA was 0.09 ± 0.09 logMAR, with more than 97.5% of the patients reaching a binocular UDVA of 0.2 logMAR or better (20/32 or better) and 77.5% had a value of 0.1 logMAR or better (20/25 or better). In turn, the mean binocular CDVA was 0.02 ± 0.03 logMAR, with all patients achieving

TABLE 2

Comparison of Eye Parameters That Lost One or More Lines of CDVA Versus Eyes That Did Not[a]

Parameter	No Lost Lines of CDVA	Lost Line(s) of CDVA	*P*
Eyes	54	26	–
Age (years)	47.5 ± 2.24	48.9 ± 2.7	.06
Preoperative refractive sphere (D)	-6.37 ± 3.10	-6.28 ± 3.14	.45
Preoperative minimum keratometry (D)	43.60 ± 1.37	43.67 ± 1.76	.43
Preoperative maximum keratometry (D)	44.72 ± 1.45	44.37 ± 1.74	.40
Preoperative corneal SA (μm)	0.08 ± 0.03	0.07 ± 0.03	.08
Preoperative total ocular SA (μm)	0.06 ± 0.03	0.03 ± 0.03	.08
Axial length (mm)	26.20 ± 1.45	26.32 ± 1.33	.35
Pupil diameter (mm)			
Photopic (85 cd/m^2)	3.43 ± 0.65	3.28 ± 0.58	.16
Mesopic (3 cd/m^2)	5.55 ± 0.78	5.39 ± 0.74	.19
Induced total ocular SA with EVO Viva ICL (μm)	-0.34 ± 0.08	-0.36 ± 0.10	.18
Induced total ocular coma aberration with EVO Viva ICL (μm)	0.21 ± 0.17	0.35 ± 0.21	.01

D = diopters; ICL = Implantable Collamer Lens; SA = spherical aberration for 4.5-mm pupil size
[a]Values are presented as mean ± standard deviation.
The EVO Viva ICL is manufactured by STAAR Surgical.

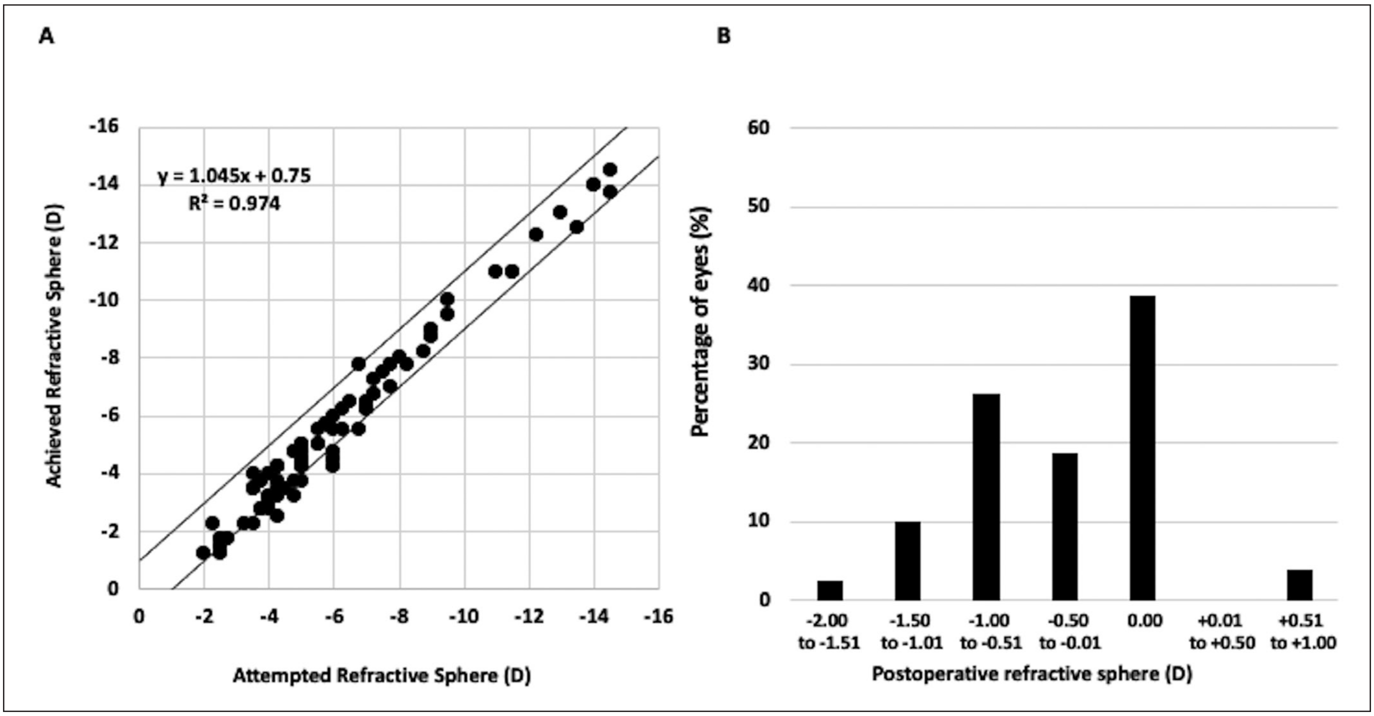

Figure 3. Plot of (A) attempted versus achieved refractive sphere at the last postoperative follow-up visit (predictability) and (B) accuracy of the manifest refractive sphere. D = diopters

a binocular CDVA of 0.1 logMAR or better (20/25 or better), and 80% had a value of 0.0 logMAR (20/20). Despite these encouraging outcomes, it is worth noting that this increased-SA ICL is new, and there is a paucity of studies, consequently limiting knowledge. Beyond showing the outcomes as a whole, we consider it interesting to discuss the areas of improvement after our retrospective evaluation. First, the efficacy index was 0.78, far from that reported with the monofocal ICL (approximately 1.0).[3] The differences in the design could partially explain it; however, as we will discuss below, in 12.5% of eyes, the residual myopic refractive error was higher than 1.00 D, which limits the UDVA and, consequently, the efficacy index. Likewise, although, in general, the CDVA outcomes were good, it is essential to note that 32.5% in our study and 36.8% in Packer et al's study[19] lost lines of CDVA after EVO Viva ICL implantation. The comparison between the eyes that experienced a loss of one or more CDVA lines with those that did not lose lines revealed that the only parameter difference between groups was a significantly higher induced coma (**Table 2**). As we previously proposed, we speculated that the increased coma aberration might be related to lens misalignment. Unfortunately, in our study, we did not register the tilt and decentration of the lens. Previous clinical studies have analyzed the misalignment of the ICL, reporting that the mean of decentration and tilt was approximately 0.25 mm and 2.5°,[31,32] respectively, with a maximum decentration of 0.50 mm and 4° of tilt. Such a magnitude of ICL misalignment did not influence the visual quality with a monofocal lens. However, the experience in pseudophakic IOL has demonstrated that in aspheric and multifocal designs the IOL tilt and decentration can induce image quality degradation with a significant impact on the visual quality of the patients.[23-30] Therefore, in this increased-SA ICL, lens displacement (mainly the maximum levels) could be responsible for the visual acuity decrease. Further studies should be conducted to properly assess the effect of increased-SA ICL decentration and tilt on coma induction and its repercussion on visual quality. If, as we speculate, the centration of this new ICL plays a crucial role in achieving good optical and visual performance, it would need to establish the tolerance to lens displacement (ie, the threshold lens misalignment from which the patient´s visual quality would be affected). In this way, for eyes that suffer from losing lines of CDVA with increased coma aberrations induced by lens misalignment, it would be interesting to assess whether the ICL rotation to the vertical meridian enhances the lens centration and might be a good approach to improve the visual results.

Our results agreed with those reported in Packer et al's study[19] regarding postoperative refraction. The postoperative spherical equivalent was -0.61 ± 0.54 D, and the add power for best near visual acuity reduced from +1.31 ± 0.74 D preoperatively to +0.44 ± 0.58 D after increased-SA ICL implantation. A good correlation between the attempted and achieved refractive sphere was obtained (**Figure 3A**), and most of the eyes (87.5%) were within ±1.00 D (**Figure 3B**). Hence, we found good predictability after EVO Viva ICL implantation. However, it is essential to note that most studies with a monofocal ICL reported a percentage of eyes within ±1.00 D of approximately 100%.[3] Therefore, the accuracy rate with the increased-SA design was significantly lower. In our study, the eyes with a postoperative sphere of -1.00 D or higher had a lower preoperative refractive sphere and ICL power. Interestingly, there were no differences in the axial length, and the differences in the preoperative sphere refraction came from a flatter keratometry reading (**Table 3**). In vitro evaluation of the optical power profile would help determine whether the increased-SA design influences the effective distance power, providing an increase for lower ICL power, which would explain these findings. On the other hand, another plausible explanation is that the formula's accuracy decreases for this profile of eyes (long axial length with flat keratometry reading). Enhancement in the power ICL estimation in these eyes would significantly improve the overall efficacy results of the procedure.

Concerning intermediate and near visual acuity results, Packer et al[19] found outstanding results, reporting uncorrected binocular intermediate (80 cm) visual acuity of -0.02 ± 0.08 logMAR and uncorrected binocular near visual acuity (40 cm) of -0.01 ± 0.05 logMAR. It is worth noting that these intermediate and near measurements were obtained without distance correction and consequently influenced by the postoperative refractive error. The postoperative spherical equivalent reported in that study ranged from -0.67 to -2.25 D. Hence, the results were likely better than if the patients had achieved the target for distance (ie, emmetropia). To avoid this potential bias and analyze the performance at intermediate and near distances generated by the increased-SA design itself, we opted to evaluate the depth of the focus curve. Furthermore, to better understand the potential performance of the lens, without considering adverse events leading to loss of lines of CDVA, we only included patients with an optimal postoperative CDVA. With these considerations in mind, our results showed that the combination of the increased-SA ICL design and the patient´s residual accommodation provided a defocus curve compatible with the criteria of extended depth of focus lenses. The mean visual acuity was 0.1 logMAR or better (20/25 or better) across the vergence range from +0.50 to -1.50 D (equivalent to 66 cm from the eye), better than 0.2 logMAR (20/32 or better) up to the vergence of -2.00 D (50 cm from the eye), and remained better than 0.3 logMAR (20/40 or better) up to the vergence of -2.50 D (40 cm from the eye). These results showed that this new increased-SA ICL provides good distance visual acuity, and optimal or functional visual acuity up to a distance between 40 and 50 cm from the eye.

There were no intraoperative complications or cases of anterior subcapsular opacity, cataracts, pigment dispersion, glaucoma, or pupillary block. The behavior of the lens in terms of the postoperative vault, IOP, and ECD did not differ from the results published with the ICL V4c model.[3] The EVO Viva ICL retains the most advanced elements of the ICL V4c platform, including the central hole. It has been widely reported that the hole design provided safety to the procedure and prevented potential ICL-related complications. However, future studies should focus on more extended follow-up periods to confirm the same safety results and absence of ICL-related complications in older patients as those reported in younger patients.

Our findings showed that in patients with myopia aged between 45 and 55 years, this new increased-SA ICL provided a good distance visual acuity and resulted an optimal or functional visual acuity up to a distance between 40 and 50 cm. Hence, this new ICL could be a good alternative for myopia and presbyopia correction. Further studies are needed to evaluate the threshold lens misalignment from which the patient´s visual quality would be affected.

AUTHOR CONTRIBUTIONS

Study concept and design (JFA, LF-V-C, CL, BA-B, AP, DM-C); data collection (BA-B, AP); analysis and interpretation of data (JFA, LF-V-C, CL, BA-B, AP, DM-C); writing the manuscript (JFA); critical revision of the manuscript (JFA, LF-V-C, CL, BA-B, AP, DM-C); supervision (JFA, DM-C)

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TABLE A

Comparison of Eye Parameters With a Postoperative Sphere < ±1.00 D and Eyes With a Postoperative Myopic Sphere of ⩾ -1.00 D[a]

Parameter	< ±1.00 D	⩾ -1.00 D	*P*
Eyes	59	20	–
Age (years)	47.9 ± 2.35	47.6 ± 2.17	.30
Preoperative refractive sphere (D)	-6.86 ± 3.18	-4.88 ± 2.35	.002
Preoperative minimum keratometry (D)	43.88 ± 1.57	42.97 ± 0.92	.001
Preoperative maximum keratometry (D)	44.75 ± .58	43.65 ± 1.04	< .001
Preoperative corneal SA (μm)	0.07 ± 0.03	0.07 ± 0.03	.17
Preoperative total ocular SA (μm)	0.05 ± 0.05	0.05 ± 0.05	.42
Axial length (mm)	26.23 ± 1.49	26.26 ± 1.16	.47
ICL power (D)	-8.73 ± 3.36	-6.43 ± 2.57	.001
Pupil diameter (mm)			.06
Photopic (85 cd/m^2)	3.31 ± 0.62	3.58 ± 0.59	.08
Mesopic (3 cd/m^2)	5.40 ± 0.81	5.75 ± 0.59	.19
Induced-total ocular SA with EVO Viva ICL (μm)	-0.33 ± 0.08	-0.37 ± 0.07	.07
Induced-total ocular coma aberration with EVO Viva ICL (μm)	0.25 ± 0.17	0.32 ± 0.22	.07

D = diopters; ICL = Implantable Collamer Lens; SA = spherical aberration for 4.5-mm pupil size

[a]Values are presented as mean ± standard deviation.

The EVO Viva ICL is manufactured by STAAR Surgical.

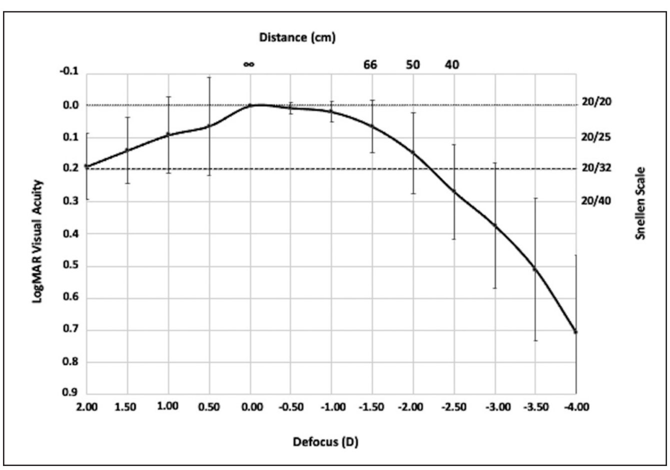

Figure 1. Mean binocular visual acuity (logMAR) with the best correction for distance as a function of the chart vergence. The Y-axis on the right shows the Snellen feet equivalent of visual acuity and the X-axis shows vergence (bottom diopters and top equivalence in cm). Error bars represent the standard deviation (SD). D = diopters

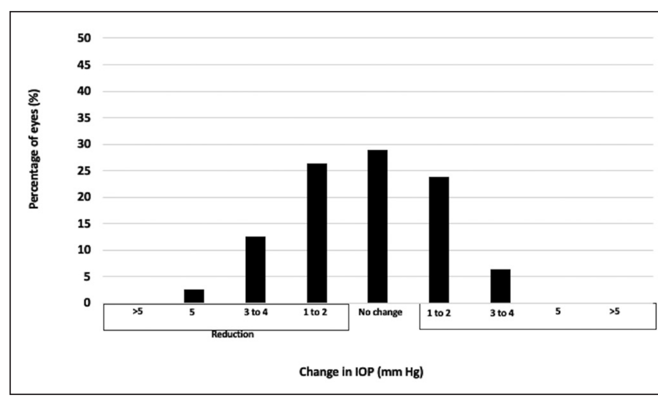

Figure 2. Intraocular pressure (IOP) variation between preoperative and at the last postoperative follow-up visit.

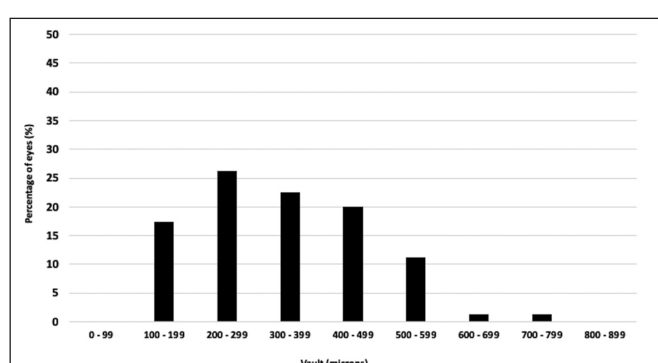

Figure 3. Distribution of eyes according to the vault, measured in microns, at the last follow-up visit.