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CLINICAL TRIAL REPORT

The EVO ICL for Moderate Myopia: Results from the US FDA Clinical Trial

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Purpose: To evaluate the safety and effectiveness of collamer posterior chamber phakic refractive lenses with a central port design (EVO and EVO+ Sphere and Toric implantable collamer lenses [ICLs]) for correction of moderate myopia with or without astigmatism.

Patients and Methods: Six-month results of a multicenter clinical trial were performed under United States FDA Investigational Device Exemption. Subjects 21 through 45 years of age with manifest refraction spherical equivalent ranging from −3.00 D to −6.00 D and astigmatism up to 4.00 D underwent implantation of EVO or EVO+ Sphere or Toric ICLs. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, intraocular pressure (IOP), endothelial cell density, and adverse events were evaluated over 6 months.

Results: This report includes a retrospective review of 200 eyes of 114 subjects with mean age 35.1 ± 5.1 years that completed the 6-month visit. Mean preoperative spherical equivalent (SE) measured −4.61 ± 0.87 D (range: −3.00 to −6.00 D). At 6 months, mean SE was −0.085 ± 0.26 D, with 91.5% within ± 0.50 D of target and 100.0% within ±1.00 D of target. Mean postoperative UDVA and CDVA were −0.065 ± 0.08 logMAR and −0.14 ± 0.07 logMAR, respectively. About 98.0% of eyes maintained or gained lines of CDVA, and no eye lost more than 1 line CDVA. Efficacy and safety indices were 1.03 and 1.21, respectively. No eye experienced pupillary block, required preoperative or postoperative peripheral iridotomy or iridectomy, developed anterior subcapsular cataract or had elevated IOP due to angle narrowing or pigment dispersion. Mean endothelial cell density declined by 2.2%.

Conclusion: EVO ICL lenses demonstrated accuracy, predictability and stability of refractive correction with achievement of high levels of UDVA and an excellent safety profile for patients with moderate myopia with or without astigmatism.

Keywords: phakic refractive lens, moderate myopia, astigmatism, implantable collamer lens

Introduction

Historically, implantation of phakic refractive lenses has been reserved for patients outside the range of corneal laser refractive surgery.[1] However, the EVO implantable collamer lens (EVO ICL, STAAR Surgical, Monrovia, CA, USA) has gradually gained popularity for the correction of a wide range of myopia with or without astigmatism.[2] Recently, authors have reported predictable, stable, safe, and effective results in low myopia and myopic astigmatism.[3] In the United States, over one third of subjects enrolled in the recent FDA clinical trial of the EVO/EVO+ Sphere and Toric ICL lenses demonstrated a preoperative spherical equivalent lower than −6.00 D. The purpose of this report is to provide data on the safety and effectiveness of the EVO ICL in the subpopulation of subjects with moderate myopia enrolled in the clinical trial.

Material and Methods

The EVO/EVO+ implantable collamer lens is manufactured from Collamer, a proprietary hydroxyethyl methacrylate (HEMA)/porcine collagen containing biocompatible polymer material. Investigation of implanted collamer lenses with specular microscopy and the laser flare-cell meter has demonstrated an absence of inflammatory reaction.[4] Authors have noted that "Collamer is highly biocompatible and permeable to gas and metabolites and allows maintaining a normal

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crystalline lens metabolism."[5] The lens features a 360 μ diameter central port which facilitates physiologic flow of aqueous from the posterior to the anterior chamber.

Complete details of the US Multicenter Clinical Evaluation of the EVO/EVO+ implantable collamer lens have been described in an earlier report.[6] The study was conducted with prior approval from Advarra Institutional Review Board (Columbia, MD), in accordance with HIPAA regulations, in compliance with the Declaration of Helsinki and under FDA Investigational Device Exemption (IDE) G191084. Registration information is available at https://clinicaltrials.gov/ct2/show/NCT04283149. Informed consent for the research was obtained from each subject prior to initiation of study specific activities.

Subjects were eligible for inclusion if they were 21 to 45 years of age, had spherical equivalent (SE) refraction from −3.00 D to −20.00 D with astigmatism up to 4.00 D and met endothelial cell density (ECD) requirements for age and anterior chamber depth (ACD) described in the FDA approved labeling. Subjects also had ACD ≥ 3.00 mm and Shaffer anterior chamber angle (ACA) Grade ≥ III. Investigators ordered study lenses using the STAAR ICL Calculator (www.ocos.STAAR.com) based on the ACD and corneal white-to-white (WTW) measurements. All eyes were targeted for emmetropia.

No preoperative or postoperative peripheral iridotomies or iridectomies were performed. Lenses were implanted through an incision of 3.5 mm or less following instillation of an ophthalmic viscosurgical device (OVD), hydroxypropyl methylcellulose (HPMC) 2%, in the anterior chamber. The use of prophylactic ocular hypotensive medication was not permitted. Postoperatively, an IOP check was performed 1 to 6 hours after surgery, prior to release of the subject.

Results

A total of 200 eyes of 114 subjects with moderate myopia with spherical equivalent from −3.00 to −6.00 D completed the 6-month visit. Table 1 provides the preoperative characteristics of these subjects and eyes.

Table 1 Preoperative Characteristics

	Subjects (N=114)
Gender, n (%)	
Male	41 (36.0)
Female	73 (64.0)
Race, n (%)	
White	96 (84.2)
African American/Black	4 (3.5)
Asian	12 (10.5)
Native Hawaiian or Other Pacific Islander	2 (1.8)
Ethnicity, n (%)	
Hispanic or Latino	18 (15.8)
Not Hispanic or Latino	96 (84.2)
Age, years	
Mean (SD)	35.1 (5.1)
Median	36.0
Minimum, maximum	25, 45

(*Continued*)

Table 1 (Continued).

	Subjects (N=114)
	Eyes (N=200)
Manifest Refraction Sphere (D)	
Mean (SD)	−4.19 (0.94)
Median	−4.25
Min, Max	−6.00, −1.75
Manifest Refraction Cylinder[1] (D)	
Mean (SD)	−0.84 (0.86)
Median	−0.50
Min, Max	−4.00, −0.00
Manifest Refraction Spherical Equivalent (D)	
Mean (SD)	−4.61 (0.87)
Median	−4.50
Min, Max	−6.00, −3.00
Endothelial Cell Density (cells/mm^2)	
Mean (SD)	2965.3 (251.9)
Median	2965.5
Min, Max	2349, 3797
Intraocular Pressure (mmHg)	
Mean (SD)	16.1 (3.0)
Median	16.0
Min, Max	10, 22

Predictability

Figure 1 provides a scatterplot of the attempted versus achieved spherical equivalent (SE) correction (R^2 = 90.7%). Six months after surgery, 91.5% of eyes were within ± 0.50 D of the targeted SE refraction, and 100.0% of eyes were within ± 1.00 D (Figure 2).

Stability

Figure 3 provides the change in the mean SE and stability of refraction over time. The mean SE was −4.61 ± 0.87 D preoperatively and −0.13 ± 0.23 D at 1 month, −0.06 ± 0.25 D at 3 months and −0.09 ± 0.26 D at 6 months.

Efficacy

Figure 4 provides the distribution of postoperative UDVA at 6 months. 57.5% of eyes achieved 20/16 or better, 94.5% of eyes achieved 20/20 or better and 100.0% of eyes achieved 20/32 or better postoperative UDVA. The mean postoperative UDVA was −0.059 ± 0.09 logMAR, −0.071 ± 0.81 logMAR and −0.065 ± 0.08 logMAR at 1, 3 and 6 months,

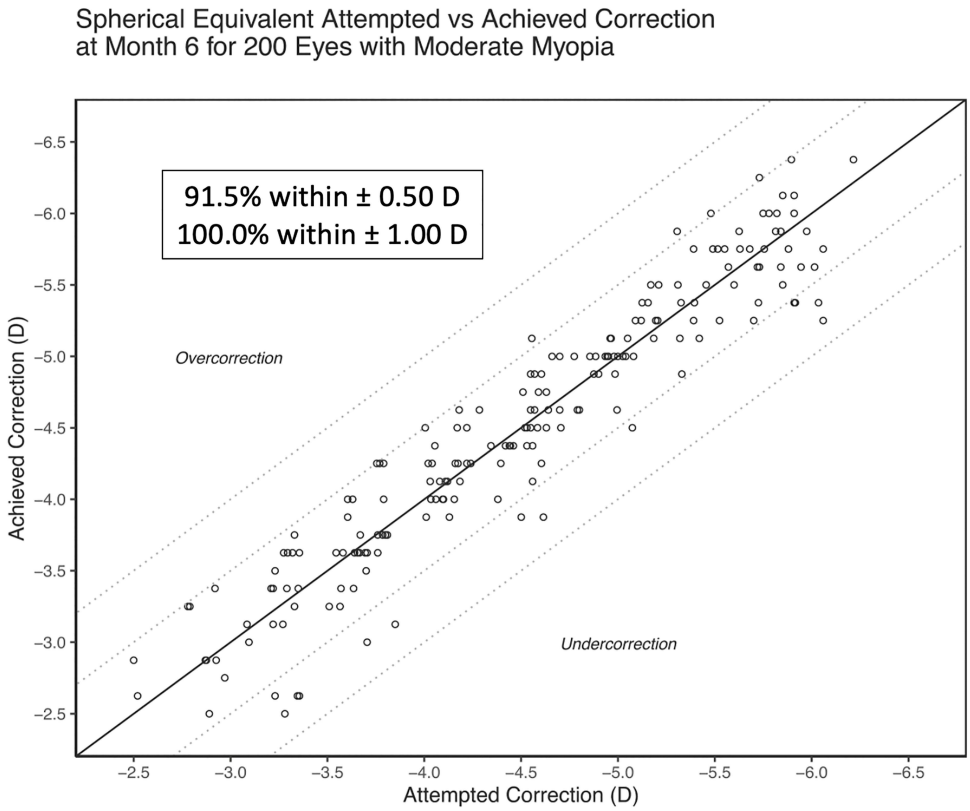


Figure 1 Scatter plot of attempted versus achieved correction of manifest refraction spherical equivalent. 91.5% of eyes were within ± 0.50 D of the targeted SE refraction, and 100.0% of eyes were within ± 1.00 D.

respectively. The efficacy index, which is the ratio of postoperative uncorrected visual acuity to preoperative corrected visual acuity, was 1.03 at 6 months.

Safety

Mean preoperative CDVA was −0.053 ± 0.068 logMAR; postoperative CDVA measured -0.13 ± 0.071 logMAR, −0.13 ± 0.070 logMAR and −0.14 ± 0.07 logMAR at 1, 3 and 6 months, respectively. Figure 5 provides the change in lines of CDVA for 200 eyes at 6 months. A total of 98.0% of eyes reported CDVA at 6 months that was equal to or better than preoperative CDVA. Overall, 56.0% of eyes gained lines of CDVA: 33.5% gained 1 line and 12.5% gained 2 lines. 52.0% of eyes experienced no change in CDVA, and 2.0% lost 1 line. No eye lost more than 1 line CDVA at 1, 3 or 6 months. The safety index, which is the ratio of postoperative to preoperative corrected visual acuity, was 1.21 at 6 months.

Intraocular Pressure, Endothelial Cell Density and Vault

Figure 6 provides the mean IOP over time. The IOP remained stable from 1 day to 6 months postoperative.

Mean endothelial cell density declined 2.2% from preoperative to 6 months.

Figure 7 provides the mean vault of the EVO ICL lens over time. The vault is the distance measured between the posterior surface of the ICL and the anterior capsule of the crystalline lens. Mean vault measured 502 ± 192 μ, 495 ± 197 μ, and 480 ± 197 μ at 1, 3 and 6 months, respectively.

Adverse Events and Secondary Surgery

There was no pupillary block, angle closure glaucoma, pigment dispersion or anterior subcapsular cataract. Thirty-six eyes (18.0%) experienced transient elevated IOP at the 1 to 6 hour postoperative visit due to residual OVD. Of note, the

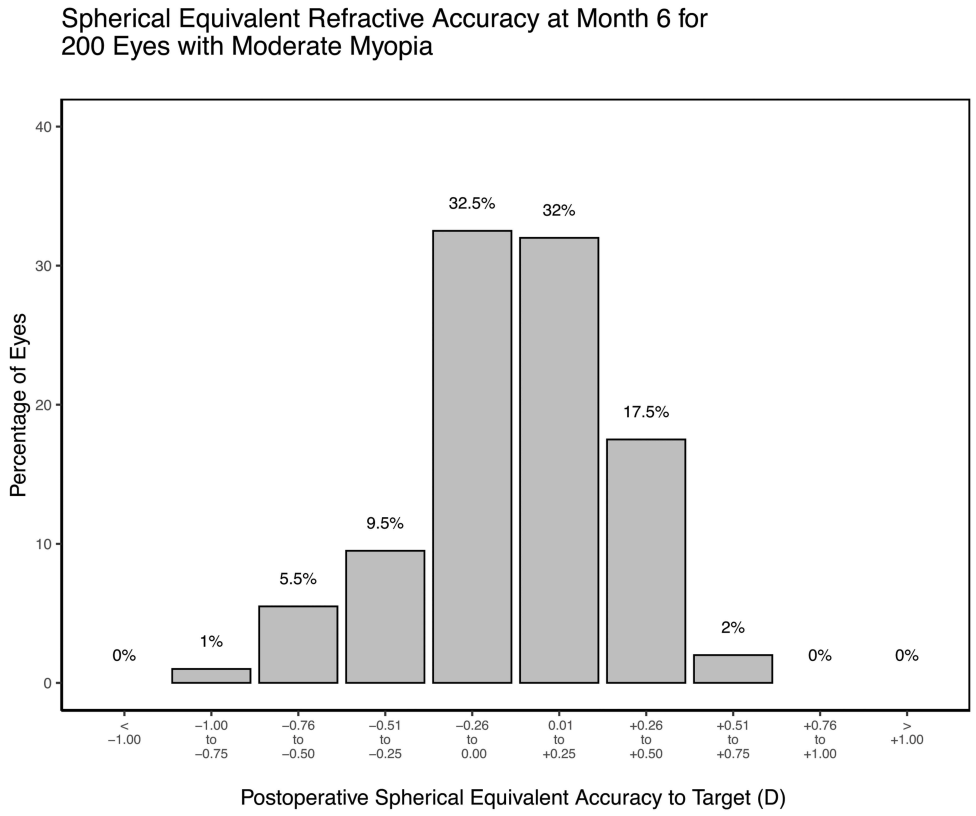
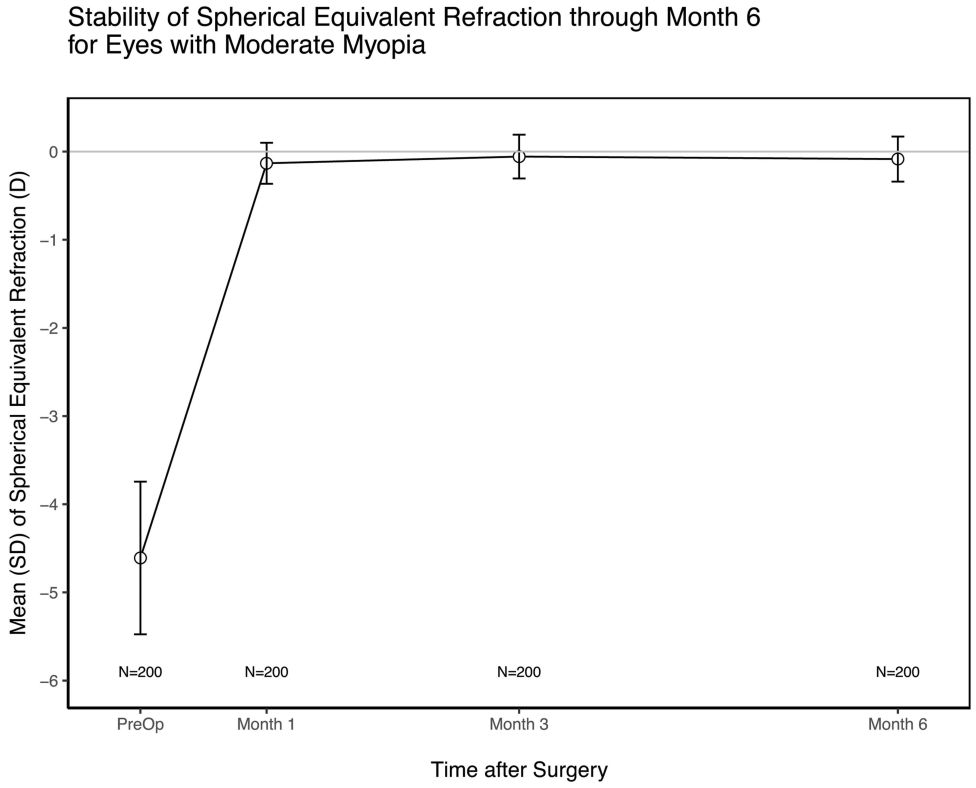


Figure 2 Accuracy of spherical equivalent refractive correction at Month 6.



Note: Consistent cohort of subjects with all visits are used.

Figure 3 The stability of the spherical equivalent refraction from Month 1 to Month 6.

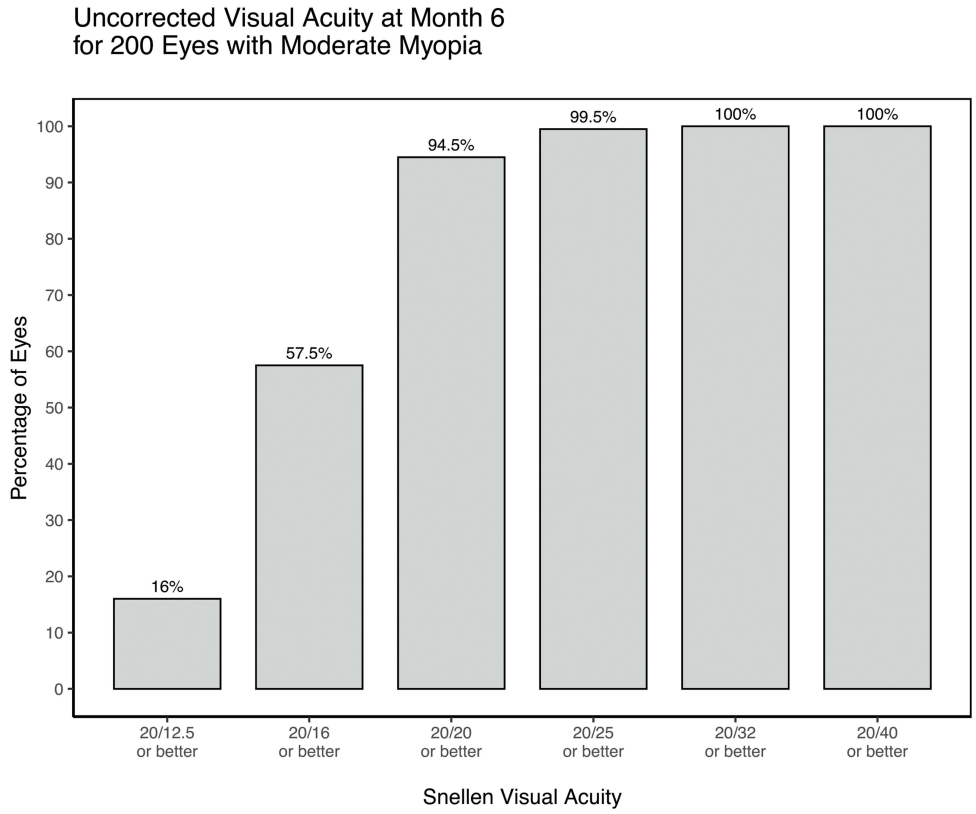


Figure 4 Frequency distribution of uncorrected visual acuity at Month 6. All visual acuity testing was performed using an ETDRS chart and values were converted from logMAR to Snellen.

use of prophylactic ocular hypotensive medications was not allowed. These eyes were treated with topical medication and/or aqueous tap, as needed. Two eyes (0.5%) experienced elevated IOP due to a steroid response. All instances of elevated IOP resolved without sequelae.

One eye (0.5%) with moderate myopia (SE −5.25 D) underwent exchange of a 13.2 mm ICL for a 12.6 mm ICL because of a narrow angle due to high vault. The IOP remained within 2 mmHg of baseline at all time points. Following lens exchange, vault of 1380 μ was reduced to 700 μ. UDVA measured 20/16 following lens exchange.

Discussion

The EVO ICL has gained popularity for the treatment of moderate myopia because it has demonstrated safety and effectiveness comparable to corneal laser refractive surgery.[7] Based on clinical outcomes from US FDA premarket approval studies enrolling subjects with similar baseline refractive errors, at 6 months postoperatively, 84.2%, 88.9%, and 82.6% of eyes undergoing small incision lenticule extraction (SMILE, VisuMax laser; Carl Zeiss Meditec AG, Jena, Germany), topography-guided LASIK (Topo-LASIK, Allegretto Wave Eye-Q laser; Alcon Laboratories, Inc., Fort Worth, TX), or wavefront-guided LASIK (WFG-LASIK, STAR S4 IR with iDesign; Johnson & Johnson Vision Care, Inc., Santa Ana, CA), respectively, had UDVA 20/20 or better (see Table 2).[8–11] In this study, 94.5% of eyes achieved UDVA 20/20 or better with the EVO ICL. Similarly, at 6 months, 93.7%, 93.0% and 68.9% of eyes undergoing SMILE, Topo-LASIK or WFG-LASIK were within ± 0.50 D of emmetropia. In this study, at 6 months, 91.5% of eyes were within ± 0.50 D of emmetropia.

Regarding safety, at 1 month, 2.5% (9/357), 0.4% (1/248) and 0.3% (1/334) of eyes exhibited a loss of 2 or more lines CDVA with SMILE, Topo-LASIK and WFG-LASIK, respectively.[8–10] At 6 months, 0.00% (0/348), 0.41% (1/244) and 0.30% (1/334) exhibited a loss of 2 or more lines CDVA with SMILE, Topo-LASIK and WFG-LASIK, respectively. In

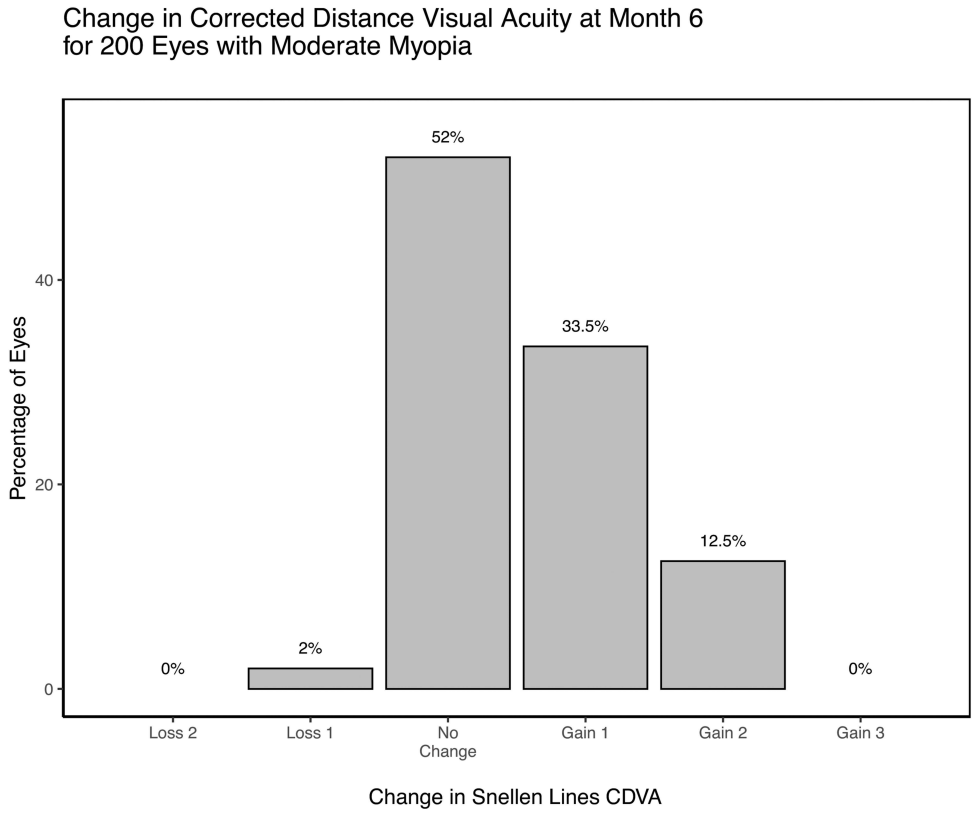


Figure 5 Lines of corrected distance visual acuity gained or lost. 56.0% of eyes gained lines of CDVA and 98.0% of eyes reported CDVA at 6 months that was equal to or better than preoperative CDVA.

this study, no eye lost more than 1 line CDVA at 1, 3 or 6 months with the EVO ICL. At 6 months, 20.4% (71/348), 36.1% (88/244) and 55.7% (186/334) of eyes demonstrated a gain of 1 or more lines CDVA with SMILE, Topo-LASIK and WFG-LASIK, respectively. In this study, 56.0% of eyes demonstrated a gain of 1 or more lines CDVA with the EVO ICL.

Corneal refractive surgery has historically been considered the "treatment of choice" for low to moderate myopia because it is considered less invasive than phakic lens surgery.[12] However, the safety profile of the EVO ICL has given surgeons reasons to reconsider this conventional approach. Enhanced safety as compared to earlier models without the central port and outstanding effectiveness across the full range of myopia make EVO an attractive option for surgeons and patients.[2] Phakic refractive surgery preserves the cornea and the crystalline lens,[7] does not induce dry eye syndrome,[13] does not pose a risk of corneal ectasia,[14] offers rapid visual recovery,[7] does not increase the complexity of IOL power calculation in future age-related cataract surgery,[15] and the phakic lens is removable.[12]

In the moderate myopia cohort described in this report, only 1 eye (1/200, 0.5%) required lens exchange, which was performed due to narrowing of the anterior chamber angle. In the full study, only this eye and 1 other (2/629, 0.3%) underwent lens exchange.[6] Narrowing of the anterior chamber angle occurred in these cases because of excessive vault of the ICL above the crystalline lens. In neither case did the IOP become elevated at any time point. However, surgeons chose to exchange these 2 lenses for the next smaller size to reduce the vault and eliminate the risk of angle closure. Variations in vault occur because of the anatomic relationship of the ICL to the ciliary sulcus; nevertheless, the low rate of lens exchange and the absence of other adverse events related to vault such as angle closure, pigment dispersion and anterior subcapsular cataract, demonstrate that variations of vault are well tolerated: 99.7% of eyes implanted in the full study exhibited satisfactory vault, and there were zero events of angle closure, pigment dispersion and anterior subcapsular cataract.

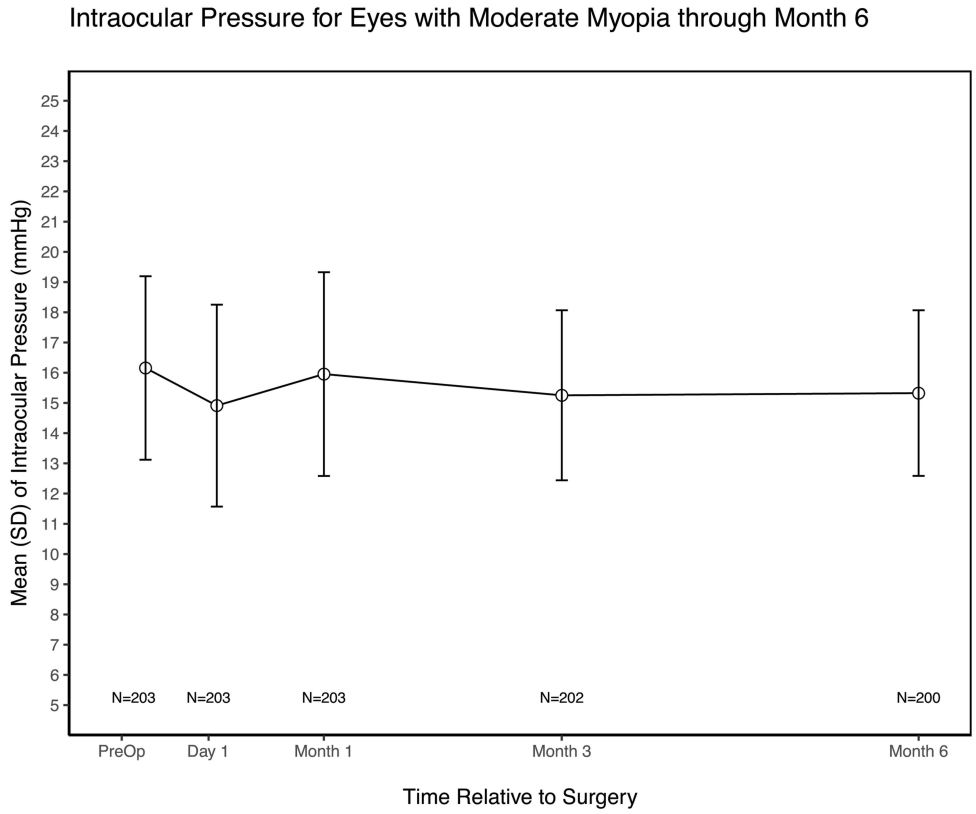


Figure 6 Mean postoperative intraocular pressure remained stable through Month 6.

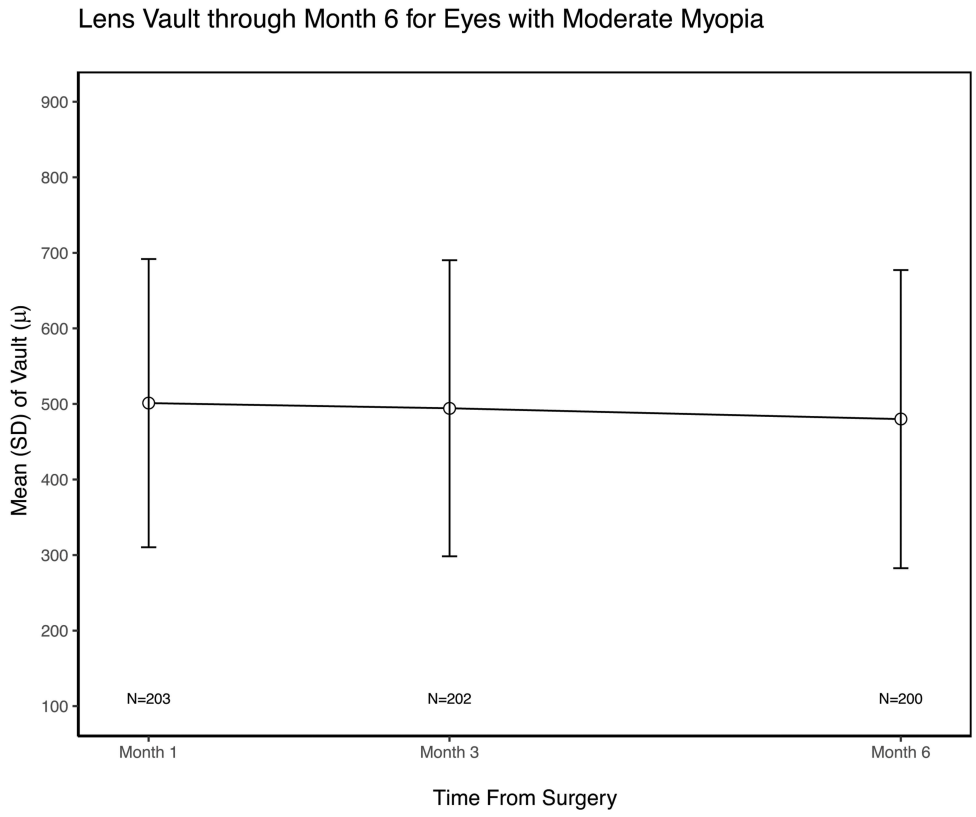


Figure 7 Vault measurements were consistent with values previously reported in the published literature.

Table 2 6 Month Results from US FDA Studies

	EVO ICL Full Cohort[6]	EVO ICL Moderate Myopia	SMILE[8]	Topo-LASIK[9]	WFG-LASIK[10]
Baseline MRSE	−7.62 ± 2.76 (−3.00 – −15.62)	−4.61 ± 0.87 (−3.00 – −6.00)	−5.39 ± 2.30 (−1.50 – −10.88)	−4.61 ± 2.43 (0.00 – −9.00)	−6.21 ± 2.78 (0.00 – −12.00)
Baseline Cylinder	−1.14 ± 0.89 (−0.00 – −4.00)	−0.84 ± 0.86 (−0.00 – −4.00)	−1.53 ± 0.70 (−0.75 – −3.00)	−1.19 ± 1.23 (0.00 – −6.00)	−1.77 ± 1.65 (0.00 – −8.00)
UDVA 20/20 or better	87.6%	94.5%	84.2%	88.9%	82.6%
MRSE within ± 0.50	90.5%	91.5%	93.7%	93.0%	68.9%
Lost 2 or more lines CDVA	0.00%	0.00%	0.00%	0.41%	0.30%
Gained 1 or more lines CDVA	52.3%	56.0%	20.4%	36.1%	55.7%

Mean corneal endothelial cell loss in this study measured 2.2% at 6 months. Assuming an average physiologic loss of 0.6% per year,[16] these results are closely correlated with the published literature on the EVO ICL, which has demonstrated a mean loss of 2.6% at 14.7 months.[17] Longer term follow up of ICL implantation suggests that corneal remodeling in the early postoperative period leads to stabilization of endothelial cell density.[18] As Montes-Mico et al have stated

> We consider that the largest loss occurs during the early postoperative period, and the surgical procedure is the main cause of this loss (surgeon variable-dependent), and that the loss tends to achieve a stable state (or with lower rates of loss) after that period.[19]

Long-term studies of endothelial cell density with the EVO ICL suggest very low rates of endothelial cell loss. For example, in a study of 177 eyes of 106 patients, Kamiya et al reported mean endothelial cell loss of 3.6 ± 7.9% at 8 years postoperative.[20] Chen et al reported mean endothelial cell loss of 3.66% and 3.20% at 5 years postoperative in 43 eyes of 24 patients with spherical equivalent from −6.00 to −12.00 D and 40 eyes of 22 patients with spherical equivalent greater than −12.00 D, respectively.[21] In a study of 84 eyes of 52 patients, Fernandez-Vega-Cueto et al reported mean endothelial cell loss of 2.6% at 7 years postoperative.[22] These results support the conclusion that endothelial cell loss stabilizes following the early postoperative period.

Multiple authors have reported on the safety and effectiveness of EVO ICL implantation in low myopia. For example, Kamiya et al conducted a multicenter retrospective review of 172 eyes of 111 patients with spherical equivalent −3.00 D or less.[23] At 12 months, 94% of eyes demonstrated UDVA 20/20 or better. One eye underwent lens exchange due to residual refractive error, and 4 eyes (2.3%) had repositioning of toric ICLs. No symptomatic or asymptomatic cataract, pigment dispersion, pupillary block, retinal detachment, or significant endothelial cell loss occurred. Alonso-Juarez et al recently reported on 82 eyes of 82 patients with low myopia (mean spherical equivalent −2.34 ± 0.82, range −5.50 to −1.00 D). Efficacy and safety indices were 1.07 and 1.09, respectively.[3] These authors concluded that

> Our study confirms that ICL implantation is a very good alternative to [laser vision correction] for low myopia patients while also offering the previously mentioned advantages: reversibility, corneal compliance, non-induction of dry eye and excellent visual quality.[3]

It has been 15 years since Schallhorn et al concluded, based on their prospective, randomized study, that

> The TICL performed better than PRK in all measures of safety (BSCVA), efficacy (UCVA), predictability, and stability in this comparison, supporting the TICL as a viable alternative to existing refractive surgical treatments.[24]

The subsequent innovation of the central port design, the elimination of the requirement for peripheral iridotomy and the improved safety profile of the EVO ICL serve to strengthen this conclusion.[17]

Conclusion

Approximately one third of subjects enrolled in the US FDA clinical trial of the EVO ICL had spherical equivalent refraction less than −6.00 D, demonstrating the investigators' broad acceptance of the EVO ICL as a treatment for moderate myopia. The results in this cohort of patients are comparable to the outcomes for the full population, indicating that the safety and effectiveness of the EVO ICL does not vary across the entire spectrum of myopia and myopia with astigmatism.

The ICL has gained in popularity worldwide and has recently surpassed a milestone of more than two million lenses sold globally, including more than one and a half million EVO lens with the central port design.[25] This growth demonstrates that surgeons now view the ICL as a safe and effective primary procedure for the full range of myopia.

Data Sharing Statement

No further data beyond those provided will be shared.

Ethics Approval and Informed Consent

The study was conducted with prior approval from Advarra Institutional Review Board (Columbia, MD), and in accordance with HIPAA regulations under FDA Investigational Device Exemption (IDE) G191084. Registration information is available at https://clinicaltrials.gov/ct2/show/NCT04283149. Informed consent for the research was obtained from each subject prior to initiation of study specific activities.

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Disclosure

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