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CLINICAL TRIAL REPORT

Three Year Results from the United States FDA Prospective Multicenter Clinical Study of the EVO/EVO+ Implantable Collamer Lens

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Background: Continued safety and effectiveness of collamer EVO ICL posterior chamber phakic lenses with a central port design for the correction of myopia with or without astigmatism.

Patients and Methods: Subjects aged 21 to 45 years with moderate to high myopia and astigmatism up to 4.00 D underwent EVO or EVO+ Sphere or Toric ICL (collectively referred to as EVO ICL) surgery. Uncorrected and corrected distance visual acuity (UDVA, CDVA), manifest refraction, intraocular pressure (IOP), endothelial cell density (ECD), and adverse events were assessed over 3 years.

Results: This prospective multicenter study included 629 eyes (327 subjects), with a mean age of 35.6 ± 5.1 years. Mean spherical equivalent (SE) was −7.62 ± 2.75 D (range: −3.00 to −15.62 D) preoperatively, and −0.12 ± 0.30 D at 3 years with 90.7% of eyes within ± 0.50 D and 99.0% within ±1.00 D of target. Mean postoperative UDVA and CDVA were −0.053 ± 0.12 logMAR and −0.13 ± 0.08 logMAR, respectively. Additionally, 48.9% of eyes gained 1 or more lines of CDVA. Efficacy and safety indices were 1.07 and 1.25, respectively. Two eyes (0.32%) underwent lens exchange for high vault; neither of these demonstrated increased IOP. One eye (0.16%) developed an anterior subcapsular cataract (ASC) at 2 years. No eyes experienced pupillary block requiring peripheral iridotomy or iridectomy (PI), elevated IOP due to angle narrowing, or pigment dispersion. Mean ECD decreased by 3.0% from baseline at 1 year and by 6.7% at 3 years.

Conclusion: This 3-year study confirmed the central port design of the EVO ICL functions effectively to allow physiologic flow of aqueous humor, thus eliminating the requirement for preoperative PI and reducing the incidence of ASC and pupillary block. EVO ICL lenses demonstrated accuracy and stability of refractive correction and achievement of high levels of UDVA.

Keywords: phakic refractive lens, myopia, astigmatism, implantable collamer lens, EVO ICL

Background

The STAAR Surgical Implantable Collamer Lens (ICL, STAAR Surgical, Monrovia, CA, USA) has been shown to provide predictable, stable refractive correction across a wide range of myopia and myopic astigmatism.[1] It is associated with high efficacy and safety indices,[2] as well as improvements in both visual quality[3] and quality of life.[4] Multiple long-term studies have demonstrated an excellent safety profile with low rates of adverse events.[5–7] The ICL is a single piece posterior chamber phakic intraocular lens implanted between the cornea and the natural crystalline lens for correction of

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refractive error. It is manufactured from Collamer, a proprietary hydroxyethyl methacrylate (HEMA)/porcine collagen containing biocompatible polymer material. Earlier models approved in the US for the correction of myopia (Visian MICL) and myopia with astigmatism (Visian TICL) required an additional visit to perform a preoperative peripheral iridotomy (PI) to prevent postoperative complications such as pupillary block and cataract formation.

The central port design of the EVO and EVO+ sphere and toric ICL lens models (collectively referred to as EVO ICL) was introduced by STAAR Surgical in 2011 and 2015, respectively. The central port facilitates physiologic aqueous humor flow, thereby removing the need for preoperative PI required in the parent non-central hole Visian parent models. This innovation has reduced the number of required office visits and preoperative procedures, without introducing new adverse events or increasing the occurrence of known complications. Notably, "Safety data suggest lower rates of anterior subcapsular cataract and pupillary block compared to earlier models".[8]

A clinical study was conducted to support US FDA approval by assessing the safety and effectiveness of the EVO ICL models with the central port design. The FDA approved these models in March 2022, based on six-month data,[9] and the outcomes have been previously published.[10,11] This article reports on outcomes of the FDA study cohort through 3 years after surgery.

Methods

The FDA Clinical Study of the EVO Implantable Collamer Lens (ICL) was a prospective, 3-year, multicenter study designed to assess the safety and effectiveness of the EVO ICL (EVO and EVO+ sphere and toric models) for the correction of myopia and myopia with astigmatism. Inclusion criteria were 21 to 45 years of age, myopia ranging from −3.00 D to −20.00 D spherical equivalent (SE) in the spectacle plane with astigmatism up to 4.00 D, with stable manifest refraction spherical equivalent (MRSE) for one year prior to implantation within 0.50 D, and minimum endothelial cell density (ECD) requirements for age and anterior chamber depth (ACD) consistent with FDA approved labeling.[9] Potential subjects with ACD < 3.00 mm, anterior chamber angle (ACA) Grade < III, ocular hypertension or glaucoma, pseudoexfoliation, pigment dispersion, history or signs of uveitis, diabetes, previous ocular surgery, cataract, or progressive, sight-threatening disease were excluded from enrollment.

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

Examinations and Procedures

All enrolled subjects underwent a comprehensive preoperative ophthalmic examination to confirm eligibility and collect necessary preoperative data. As previously described,[10,11] investigators performed lens power and size calculations using the STAAR ICL Calculator (www.ocos.STAAR.com), and were required to select the lens size recommended by the calculator based on ACD and white-to-white (WTW) measurements obtained according to each investigator's standard methods for ICL surgery. According to the study protocol, postoperative emmetropia for all enrolled eyes with an acceptable variation of ± 0.50 D SE was to be targeted.

In accordance with the study protocol[10] and approved labeling,[9] study lenses were implanted through a corneal incision of 3.5 mm or less following instillation of an ophthalmic viscosurgical device (OVD), hydroxypropylmethylcellulose (HPMC) 2%, in the anterior chamber. No PIs were performed prior to or during surgery. 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. In subjects with both eyes included in the study, fellow eye implantation occurred between 7 days and 14 days after uneventful surgery in the first eye.

Treated subjects were scheduled for 8 postoperative study visits per eye over a 3 year period after surgery (Day 1, Week 1, Month 1, Month 3, Month 6, Year 1, Year 2, and Year 3). Assessments included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), MRSE, gonioscopy, slit lamp examination, crystalline lens status per the lens opacity classification system (LOCS III),[12] specular microscopy (with corneal ECD measurements performed by an independent reading center), intraocular pressure (IOP), dilated fundus examination, optical coherence tomography (OCT; lens vault), and reporting of adverse events.

Statistical Analysis

A sample size of at least 300 primary eyes was planned to provide 95% confidence of observing at least one AE if the true event rate was 1%, based on the binomial distribution. The safety analysis population included all eyes implanted with an EVO or EVO+ ICL lens. Missing data were not imputed. Binary outcomes were summarized by counts and percentages at each visit, with exact 95% binomial confidence intervals provided where appropriate. Continuous outcomes were summarized using descriptive statistics, including N, mean, standard deviation, median, minimum, maximum, and first and third quartiles.

Results

The study enrolled 629 eyes of 327 subjects at 14 clinical sites in the US. The first subject had ICL surgery in the primary eye in January 2020, and the last eye was treated in December 2020. A total of 579 eyes (92.1%) of 300 subjects were available for analysis at the final 3-year study visit. Preoperative characteristics of subjects and eyes enrolled are provided in Table 1.

Predictability

A scatterplot of the intended versus achieved SE correction (R^2 = 0.99) is provided in Figure 1. Three years after surgery, 90.7% of eyes were within ± 0.50 D of the targeted SE refraction, and 99.0% of eyes were within ± 1.00 D (Figure 2).

Table 1 Preoperative Characteristics

	Subjects (N=327)
Gender, n (%)	
Male	114 (34.9)
Female	213 (65.1)
Race, n (%)	
Caucasian	274 (83.8)
African American/Black	11 (3.4)
Asian	38 (11.6)
Native Hawaiian or Other Pacific Islander	3 (0.9)
American Indian or Alaska Native	1 (0.3)
Ethnicity, n (%)	
Hispanic or Latino	34 (10.4)
Not Hispanic or Latino	293 (89.6)
Age, years	
Mean (SD)	35.6 (5.09)
Median	36.0
Minimum, maximum	22, 45

(*Continued*)

Table 1 (Continued).

	Eyes (N=629)
Manifest Refraction Sphere (D)	
Mean (SD)	−7.128 (2.7435)
Median	−6.750
Min, Max	−15.00, −1.75
Manifest Refraction Cylinder[1] (D)	
N	547
Mean (SD)	−1.139 (0.8929)
Median	−0.750
Min, Max	−4.00, −0.25
Manifest Refraction Spherical Equivalent (D)	
Mean (SD)	−7.623 (2.7580)
Median	−7.380
Min, Max	−15.62, −3.00
Endothelial Cell Density (cells/mm^2)	
Mean (SD)	2948.0 (268.10)
Median	2959.7
Min, Max	2119, 3797
Intraocular Pressure (mmHg)	
Mean (SD)	15.9 (2.83)
Median	16.0
Min, Max	9, 22

Notes: All cylinder measurements are reported in the negative scale; subjects with a reported cylinder value of 0.00 D are not included in summary statistics.

Stability

The mean SE and stability of refraction over time are provided in Figure 3. The mean SE was −7.62 ± 2.76 D preoperatively (range: −3.00 to −15.62 D) and −0.10 ± 0.34 D at 1 year, −0.11 ± 0.29 D at 2 years and −0.12 ± 0.30 D at 3 years. At 3 years, 94.8% of eyes were within ± 0.50 D of the corresponding SE at 6-months postoperative.

Efficacy

The distribution of postoperative UDVA at 2 and 3 years compared with preoperative CDVA for a consistent cohort is provided in Figure 4. At 3 years, 54.9% of eyes achieved 20/16 or better, 85.8% of eyes achieved 20/20 or better and 99.5% of eyes achieved 20/40 or better postoperative UDVA. Three eyes (0.5%) of 3 subjects exhibited UDVA worse than 20/40; all demonstrated CDVA 20/26 or better. The mean postoperative UDVA was −0.053 ± 0.12 logMAR. The efficacy index at 3 years was 1.07.

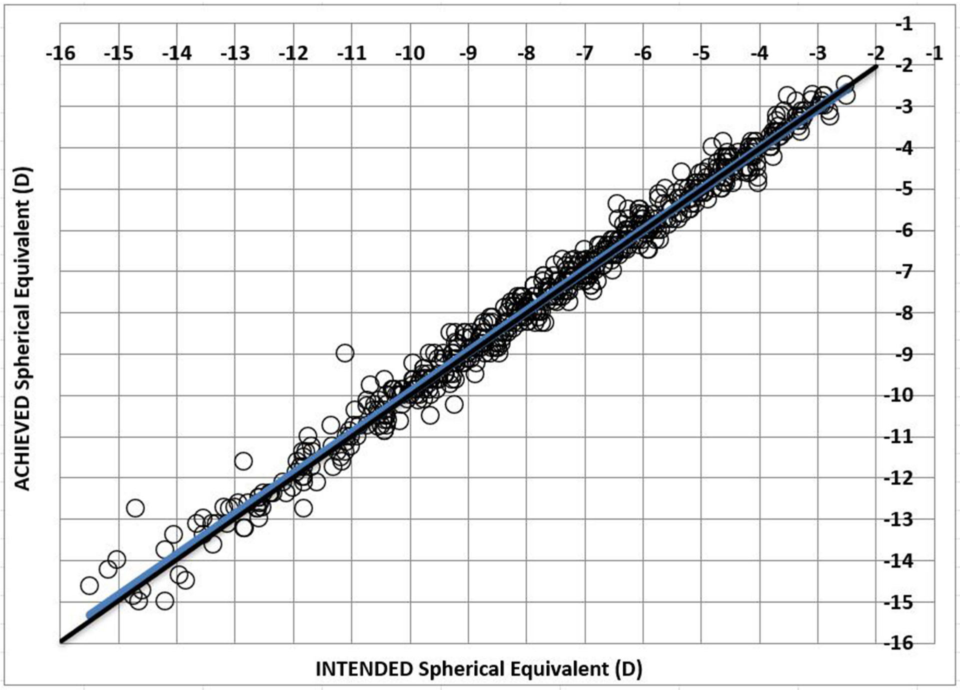

Figure 1 Scatter plot of attempted versus achieved correction of manifest refraction at 3 years (N=579 eyes).

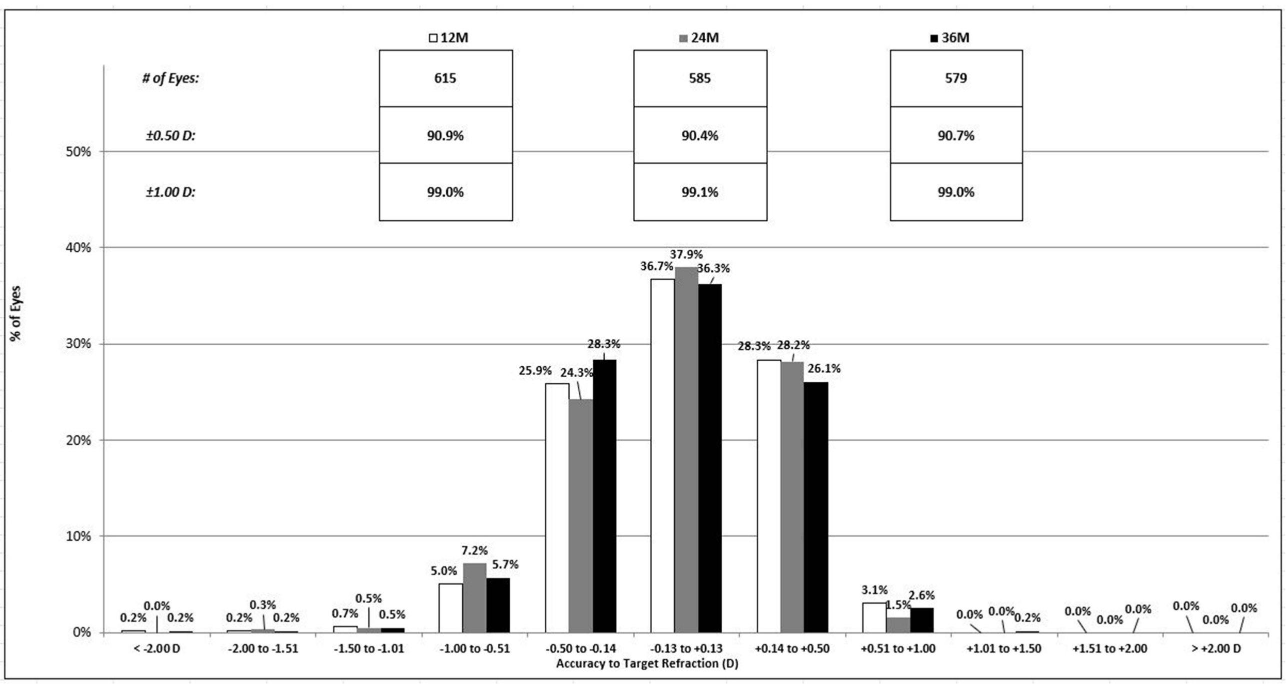

Figure 2 Accuracy of spherical equivalent refractive correction through 3 years.

Safety

Mean preoperative CDVA was −0.036 ± 0.07 logMAR; postoperative CDVA measured -0.13 ± 0.08 logMAR at 3 years. The change in lines of CDVA at 1, 2 and 3 years is provided in Figure 5. At 3 years, 98.1% of eyes reported CDVA at that was equal to or better than preoperative CDVA. Overall, 48.9% of eyes gained one or more lines of CDVA: 37.3% gained 1 line and

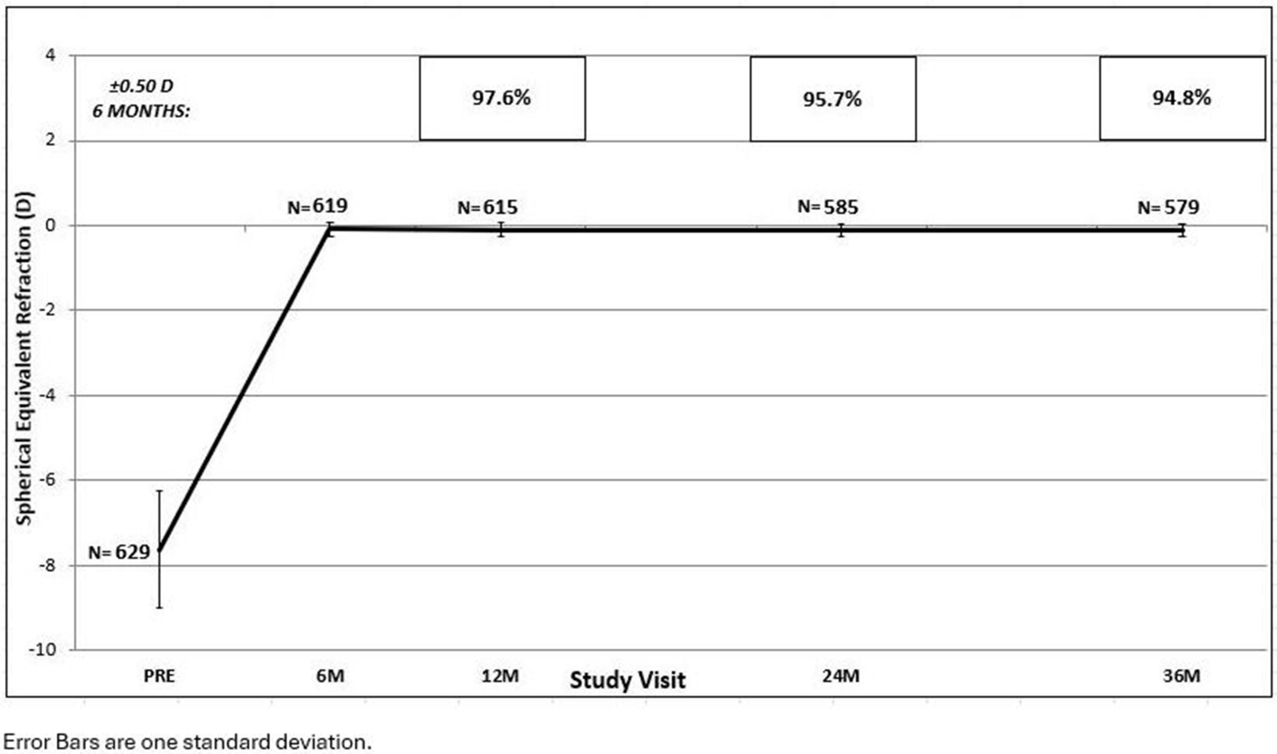

Figure 3 Stability of mean SE over time.

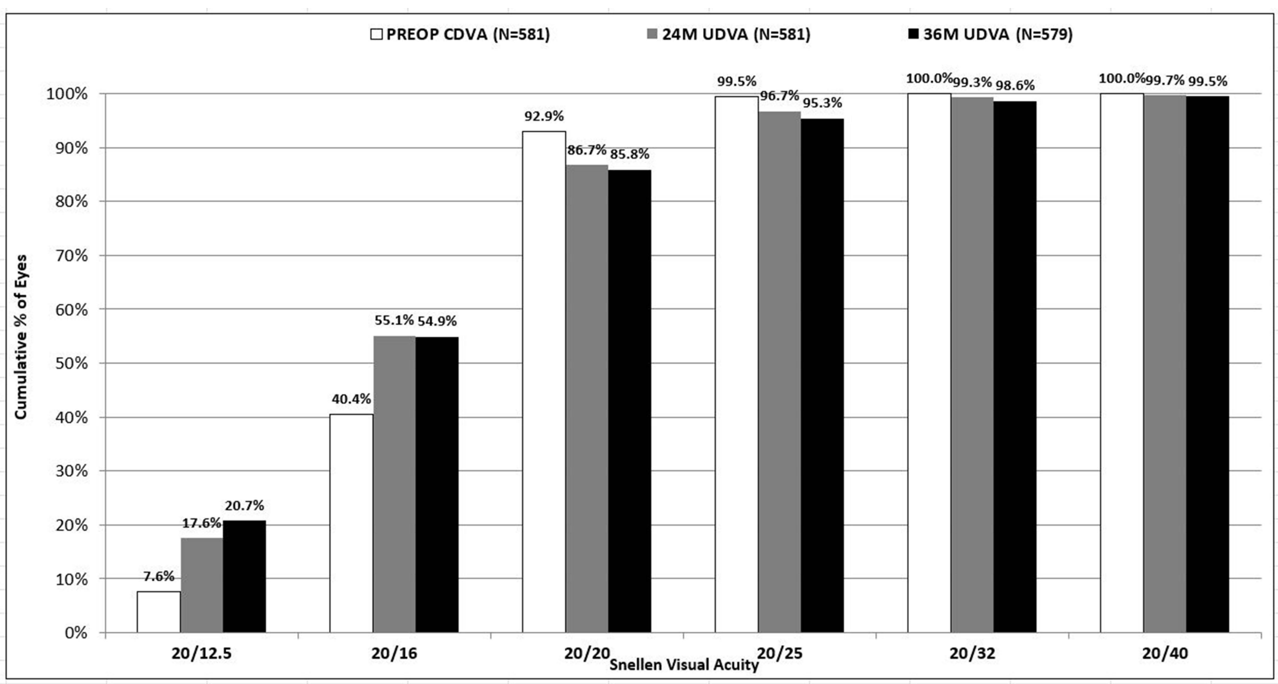

Figure 4 Postoperative UDVA compared with preoperative CDVA (consistent cohort).

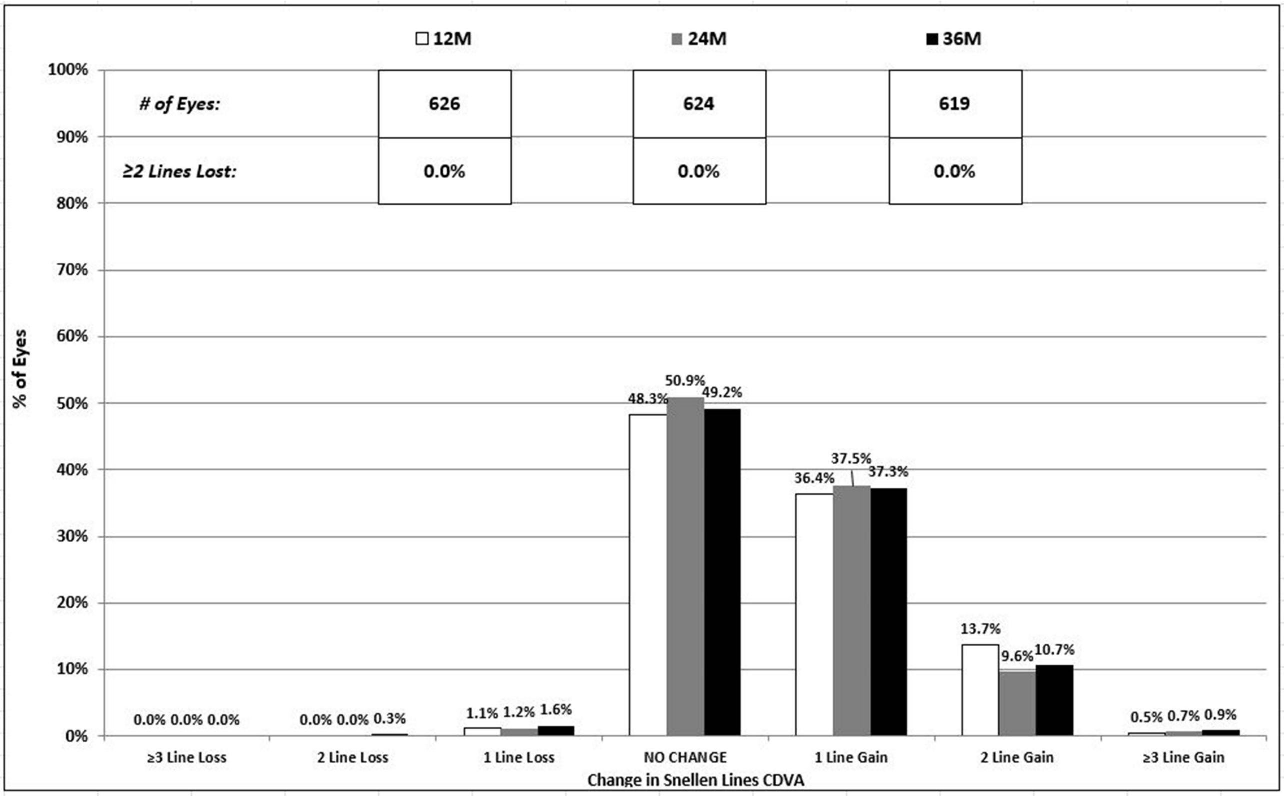

Figure 5 Change in Snellen lines CDVA.

11.6% gained 2 or more lines. 49.2% of eyes experienced no change in CDVA, and 1.6% lost 1 line. Two eyes (0.32%) lost 2 lines of CDVA, one from 20/11 to 20/17 and one from 20/12 to 20/18. The safety index at 3 years was 1.24.

Intraocular Pressure, Endothelial Cell Density, and Vault

Mean preoperative IOP was 15.9 ± 2.8 mmHg. Mean IOP was similar across the Month 6 (15.3 ± 2.4 mmHg), Year 1 (15.2 ± 2.6 mmHg), Year 2 (15.2 ± 2.6 mmHg), and Year 3 (15.5 ± 2.6 mmHg) Visits. A transient increase in IOP was reported in 19.9% (125/629) of eyes at the 1 – 6-hour postoperative visit, attributed to retained OVD (HPMC 2%) and was treated, if indicated, with topical medication and/or release of aqueous. No prophylactic systemic or topical ocular pressure-lowering medications (eg, timolol) were permitted during the study. Events of elevated IOP due to a steroid response occurred in 2.4% (15/629) of eyes from 6 to 31 days after surgery. There were no cases of elevated IOP associated with blockage of aqueous flow through the central port or with narrowing of the anterior chamber angle. Additionally, no instances of pigment dispersion or chronic intraocular inflammation were observed.

Mean ECD declined by 3.0% ± 4.0% and 6.7% ± 5.4% from preoperative to 1 and 3 years, respectively. The proportions of eyes with loss of ≥10%, ≥20% and ≥30% ECD at 3 years were 20.5% (119/579), 2.1% (12/579), and 0.5% (3/579), respectively. No eyes were reported to have ECD < 1500 cells/mm^2.

Mean vault measured 458 ± 215 µm, 422 ± 199 µm, and 412 ± 197 µm at 1, 2, and 3 years, respectively. Vault ranged from 19 µm to 1059 µm at 3 years; 120 eyes demonstrated vault < 250 µm and 11 eyes demonstrated vault > 900 µm. There were no cases of increased IOP related to narrowing of the anterior chamber angle associated with higher levels of vault.

Adverse Events and Secondary Surgeries

No events of pupillary block, angle closure glaucoma or pigment dispersion occurred in this study.

Two eyes (0.32%) of 2 subjects underwent ICL repositioning and subsequent exchange due to narrowing of the anterior chamber angle in the absence of elevated IOP. Following exchange of lenses to the next smaller overall diameter, vaults decreased from 1380 µm and 1430 µm to 700 µm, and 340 µm, respectively. Angle narrowing resolved in both cases, and neither eye experienced elevated IOP. UDVA of 20/16 was achieved in both eyes following lens exchange surgery.

Toric ICL repositioning surgery was performed in one eye (0.16%) to address "blurry" UDVA of 20/32 secondary to residual astigmatism noted on the first postoperative day. The UDVA improved to 20/16 after repositioning.

One eye (0.16%) had the ICL explanted due to a subjective report of halos and glare that began the day after surgery. The fellow eye was not implanted. After explantation, the symptoms resolved and the CDVA in the affected eye returned to the preoperative level.

One eye (0.16%) developed a symptomatic anterior subcapsular (ASC) cataract first observed at 2 years post-operative. CDVA measured 20/20 and UDVA measured 20/32. Following cataract surgery, UDVA improved to 20/16 and CDVA improved to 20/12.5. Asymptomatic ASC opacities were observed in 2 eyes (0.32%). The fellow eye of the subject with the ASC cataract developed an asymptomatic ASC opacity at 2 years, which remained stable thereafter. UDVA measured 20/16 at 3 years. One additional eye developed an asymptomatic half clock-hour peripheral ASC opacity first observed at 2 years postoperative. The opacity remained stable and UDVA remained 20/16 at 3 years.

A 36-year-old subject developed a nuclear sclerotic cataract in 1 eye (0.16%), that caused myopic shift and a reduction of visual acuity. The ICL was explanted and uncomplicated cataract surgery was performed following the 6-month study visit. An asymptomatic traumatic cataract first observed at 1 year postoperative occurred in 1 eye (0.16%) following an incident during Mixed Martial Arts practice. UDVA was 20/30 and CDVA was 20/20. Unfortunately, this subject was subsequently lost to follow up.

Three eyes (0.48%) of 2 subjects with axial lengths 26.24, 27.66, and 28.49 mm underwent surgery for retinal detachment. One of these subjects exhibited UDVA 20/100 and CDVA 20/16 at 3 years in an eye which experienced a myopic shift following scleral buckle; the fellow eye demonstrated UDVA 20/20 and CDVA 20/12. At 3 years, the other subject exhibited UDVA 20/18 and CDVA 20/17 in an eye that underwent laser retinopexy and UDVA 20/21 and CDVA 20/17 in an eye that underwent pars plana vitrectomy.

Discussion

This clinical study has demonstrated the safety and effectiveness of the EVO ICL family of lenses for the correction of myopia and myopia with astigmatism and has confirmed results previously reported in the published literature. A previous review article that included data from 1905 eyes with a weighted average follow-up period of 12.5 months,[8] reported a mean efficacy index of 1.04 compared with 1.07 in this study, mean UDVA of −0.02 logMAR compared with -0.05 logMAR in this study, and 90.8% SE within ± 0.50 D and 98.7% SE within ± 1.00 D of target compared with 90.7% and 99.0%, respectively, in this study.

A transient increase in IOP due to retained OVD occurred in 19.9% of eyes (125/629) at 1 to 6 hours postoperative. These findings are consistent with results from a prospective, randomized, masked, fellow-eye comparative study, which reported that 20% of eyes in which HPMC 2% was used without prophylactic IOP-lowering medications experienced IOP elevations to > 30 mmHg (range, 33–45 mmHg) at 2-hours postoperatively.[13] As with the published study, no prophylactic systemic or topical hypotensive medications (eg, timolol) were permitted during this study. Importantly, there were no reports of increased IOP related to blockage of aqueous flow through the central port, anterior chamber angle narrowing, pigment dispersion, or intraocular inflammation.

The mean decline in ECD of 6.7% over 3 years is less than that reported for the parent MICL that did not include a central port, which was "8.4% to 9.7%, depending upon the method of analysis" at 36 months.[1] Similarly, the proportions of eyes with loss of ≥10%, ≥20%, and ≥30% ECD in the MICL IDE Clinical Study at 3 years were 33.3%, 9.1%, and 1.5%, compared with 20.5%, 2.1%, and 0.5% in this study. Nevertheless, this and other published reports suggest that the rate of endothelial cell loss after ICL implantation is higher than the physiologic rate of about 0.6% per year.[6,7,14] Mitigation for the risk of endothelial cell loss consists of preoperative specular microscopy and selection of patients with adequate ECD stratified by age.[9] Loss of ECD constitutes a risk to be weighed against the benefits of accurate, stable refractive correction and improved quality of life.[4] To the best of our knowledge, there has never been a reported case of corneal decompensation solely due to uncomplicated ICL implantation with any lens model.

Many authors regard a minimum preoperative ECD of 1800 to 2400 cells/mm^2 as sufficient for ICL implantation.[15–17] Utilizing the data from this clinical study provides a rational approach to determining the sufficient minimum preoperative cell density. Table 2 was developed using the upper boundaries of the 90% confidence intervals of the rates of endothelial cell loss observed in this clinical study with separate models for the acute (ECD loss ≤ 9 months) and chronic (ECD loss > 9 months) phases of cell loss (ACD 3.0 to < 3.2, −3.01% and −1.70%; ACD 3.2 to < 3.5, −4.04% and −1.88%; ACD ≥ 3.5, −3.27% and −1.45%, respectively) stratified by age and ACD (defined as the distance from the apex of the posterior corneal surface to the apex of the anterior crystalline lens surface). The minimum ECD criteria as functions of age and ACD provided in Table 2 would be expected to result in at least 1000 cells/mm^2 at 75 years of age.

Three eyes (0.48%) of 2 subjects in this study underwent surgical intervention for retinal detachment. In the US population, the annual risk of retinal detachment among individuals with myopia greater than −3.1 D has been reported to be 117 in 100,000, with a lifetime risk of 9.3%.[18,19] The elevated risk in myopic eyes is attributed to their distinct anatomic and physiologic characteristics.[20]

Two eyes (0.32%) of 2 subjects in this study experienced anterior chamber angle narrowing without elevated IOP, which was attributed to high vault. This event resulted in secondary surgical intervention. Neither eye developed increased IOP or other signs associated with angle closure, such as peripheral anterior synechiae, loss of pupil reactivity, or iris atrophy. In each case, the angle narrowing resolved after lens exchange. The absence of untoward events despite high vault reinforces the conclusion that "extremes of vault must be viewed as risk factors for adverse events, not as adverse events in and of themselves".[5]

The development of ASC cataract has been recognized as an infrequent complication of ICL implantation, particularly associated with reduced vault between the ICL and the crystalline lens. The published literature has shown a low rate of ASC cataract with the central port design of EVO ICL lenses: 0.49% ASC opacity and 0.00% ASC cataract at 14 months postoperative,[8] and 0.53% ASC cataract at 5 or more years.[6] In this study, at 3 years postoperative, asymptomatic ASC opacity was reported in two eyes (0.32%) and visually significant ASC cataract was reported in one eye (0.16%). These low rates of ASC opacity and cataract appear to be less than those previously reported for the MICL, which demonstrated a risk estimate for ASC opacity of 3.2% and a risk estimate for visually significant ASC cataract of 0.4% at 24 to 36 months.[9]

The zero incidence of pupillary block in this clinical study highlights the safety of the EVO ICL central port design, which maintains physiologic aqueous flow across a range of postoperative vault without the requirement for PI. The incidence of pupillary block with EVO ICL lens is notably lower than that reported in earlier clinical studies of lenses requiring preoperative PIs, including the TICL PMA study (0.5% [1/210] incidence of pupillary block) and the MICL PMA study (3.2% [17/526] incidence of pupillary block).[9] In this clinical study of the EVO ICL lenses, no cases of pupillary block occurred, and no secondary PIs were required.

Table 2 Minimum Endothelial Cell Density by Age and ACD

Age	Minimum Endothelial Cell Density		
	ACD 3.0 mm to <3.2 mm	**ACD 3.2 mm to <3.5 mm**	**ACD ≥ 3.5 mm**
21-25	3470 cells/mm^2	2447 cells/mm^2	2417 cells/mm^2
26-30	3079 cells/mm^2	2245 cells/mm^2	2220 cells/mm^2
31-35	2732 cells/mm^2	2060 cells/mm^2	2039 cells/mm^2
36-40	2423 cells/mm^2	1891 cells/mm^2	1873 cells/mm^2
41-45	2150 cells/mm^2	1735 cells/mm^2	1721 cells/mm^2
>45	1954 cells/mm^2	1619 cells/mm^2	1608 cells/mm^2

The association of extremes of vault with adverse events including angle closure glaucoma and ASC has been an ongoing topic of concern. While it has been accepted that the central port design does not change the vault characteristics of the ICL, it may mitigate the associated adverse events.[5] As shown in this study, a wide range of vault is well tolerated: 120 eyes demonstrated vault < 250 µm; however, only 1 developed a symptomatic ASC. Eleven eyes demonstrated vault > 900 µm, and none developed pupillary block or angle closure glaucoma. The indication for lens exchange in this study was based on gonioscopy rather than central vault, reflecting the investigators' understanding that central vault with the central port has a limited correlation with the functional anatomy of the anterior chamber angle and the dynamics of aqueous flow. This study has confirmed that vault of any degree should be recognized only as a risk factor for adverse events, and not as an adverse event in and of itself. Furthermore, gonioscopic angle grade should be a determining factor when considering lens repositioning or exchange. Of note, the 2 cases of lens exchange for angle narrowing in this study were performed in the absence of elevated IOP and should rightly be considered prophylactic procedures. The importance of central vault with EVO may have previously been exaggerated because of the mindset that developed over years of experience with the non-central port model ICLs.

Conclusion

EVO ICL lenses have experienced growing popularity, with over 2.5 million lenses distributed across 75 countries.[21] This prospective, multicenter 3-year follow-up clinical study provides rigorous confirmation of findings from numerous peer-reviewed publications, demonstrating excellent long-term safety and effectiveness. Key outcomes include safety and efficacy indices of 1.24 and 1.07, respectively; UDVA of 20/20 or better in 85.8% of eyes and 20/40 or better in 99.5%; and SE within ± 0.50 D and within ± 1.00 D of target in 90.7% and 99.0% of eyes, respectively. The EVO ICL also showed a reduced incidence of ASC cataracts and endothelial cell loss compared with the earlier ICL models without the central port. Notably, there were no cases of increased IOP secondary to pupillary block, angle narrowing, pigment dispersion, or intraocular inflammation; and no new or unanticipated adverse events were reported. These findings further support the long-term safety and effectiveness of the EVO ICL for the correction of myopia and myopia with astigmatism.

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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References

1. Sanders DR, Doney K, Poco M. ICL in Treatment of Myopia Study Group. United states food and drug administration clinical study of the implantable collamer lens (ICL) for moderate to high myopia: three-year follow-up. *Ophthalmology*. 2004;111(9):1683–1692. doi:10.1016/j.ophtha.2004.03.026
2. Lisa C, Alfonso JF, Alfonso -bartolozzi B, Fernández-Vega L, Pérez-Vives C, Montés-Micó R. Collagen copolymer posterior chamber phakic intraocular lens supported by the ciliary sulcus to treat myopia: one-year follow-up. *J Cataract Refract Surg*. 2015;41(1):98–104. doi:10.1016/j.jcrs.2014.05.036
3. Sanders DR, Vukich JA. Comparison of implantable contact lens and laser assisted in situ keratomileusis for moderate to high myopia. *Cornea*. 2003;22(4):324–331. doi:10.1097/00003226-200305000-00009
4. Ieong A, Hau SC, Rubin GS, Allan BD. Quality of life in high myopia before and after implantable Collamer lens implantation. *Ophthalmology*. 2010;117(12):2295–2300. doi:10.1016/j.ophtha.2010.03.055
5. Packer M. Meta-analysis and review: effectiveness, safety, and central port design of the intraocular collamer lens. *Clin Ophthalmol*. 2016;10:1059–1077. doi:10.2147/OPTH.S111620
6. Wannapanich T, Kasetsuwan N, Reinprayoon U. Intraocular implantable collamer lens with a central hole implantation: safety, efficacy, and patient outcomes. *Clin Ophthalmol*. 2023;17:969–980. doi:10.2147/OPTH.S379856
7. Montés-Micó R, Ruiz-Mesa R, Rodríguez-Prats JL, Tañá-Rivero P. Posterior-chamber phakic implantable collamer lenses with a central port: a review. *Acta Ophthalmol*. 2021;99(3):e288–e301. doi:10.1111/aos.14599
8. Packer M. The Implantable Collamer Lens with a central port: review of the literature. *Clin Ophthalmol*. 2018;12:2427–2436. doi:10.2147/OPTH.S188785
9. Approval and Labeling For The EVO/EVO+ Visian Implantable Collamer Lens. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030016S035C.pdf. Accessed April 1, 2022.
10. Packer M. Evaluation of the EVO/EVO+ sphere and toric visian ICL: six month results from the united states food and drug administration clinical study. *Clin Ophthalmol*. 2022;16:1541–1553. doi:10.2147/OPTH.S369467
11. Packer M. The EVO ICL for Moderate Myopia: results from the US FDA Clinical Study. *Clin Ophthalmol*. 2022;16:3981–3991. doi:10.2147/OPTH.S393422
12. Chylack Jr LT, Wolfe JK, Singer DM, et al. The lens opacities classification system III. The longitudinal study of cataract study group. *Arch Ophthalmol*. 1993;111(6):831–836. doi:10.1001/archopht.1993.01090060119035
13. Ganesh S, Brar S. Comparison of surgical time and IOP spikes with two ophthalmic viscosurgical devices following Visian STAAR (ICL, V4c model) insertion in the immediate postoperative period. *Clin Ophthalmol*. 2016;10:207–211. doi:10.2147/OPTH.S89487
14. Bourne WM, Nelson LR, Hodge DO. Central corneal endothelial cell changes over a ten-year period. *Invest Ophthalmol Vis Sci*. 1997;38(3):779–782.
15. Russo A, Filini O, Mertens E, et al. Immediate sequential bilateral implantable collamer lens surgery is safe and effective. *J Refract Surg*. 2024;40(5):e313–e320. doi:10.3928/1081597X-20240326-01
16. Chung B, Choi JY, Kang DSY, Kim K, Kim BY, Kim TI. Ten-year clinical outcomes of V4c implantable collamer lens implantation: longitudinal analysis of visual acuity, endothelial cell density, and vault dynamics. *Am J Ophthalmol*. 2025;269:1–10. doi:10.1016/j.ajo.2024.08.007
17. Choi H, Lee SY, Lee BY, Cho HJ, Yoo TK. Paired-eye comparison of endothelial cell density and vault height after implantable collamer lens implantation. *Sci Rep*. 2024;14(1):27643. doi:10.1038/s41598-024-79613-7
18. Haarman AEG, Enthoven CA, Tideman JWL, Tedja MS, Verhoeven VJM, Klaver CCW. The complications of myopia: a review and meta-analysis. *Invest Ophthalmol Vis Sci*. 2020;61(4):49. doi:10.1167/iovs.61.4.49
19. Burton TC. The influence of refractive error and lattice degeneration on the incidence of retinal detachment. *Trans Am Ophthalmol Soc*. 1989;87:143–55;discussion155–7.
20. Bernheim D, Rouberol F, Palombi K, Albrieux M, Romanet JP, Chiquet C. Comparative prospective study of rhegmatogenous retinal detachments in phakic or pseudophakic patients with high myopia. *Retina*. 2013;33(10):2039–2048. doi:10.1097/IAE.0b013e31828992ac
21. Available from: https://investors.staar.com/press-releases/press-release-details/2024/STAAR-Surgical-Celebrates-Three-Million-Implantable-Collamer-Lenses/default.aspx. Accessed February 8, 2025.