ARTICLE

Visual outcomes of combined use of implantable collamer lens implantation and laser corneal visual correction for myopia over −18.00 diopters

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Purpose: To explore visual outcomes in patients with extreme myopia receiving an implantable collamer lens (ICL) at −18.00 diopters (D), with central port, followed by bioptics by laser vision correction (laser in situ keratomileusis [LASIK] or photorefractive keratectomy [PRK]) to address residual myopia or myopic astigmatism.

Setting: Clínica Baviera (Aier Eye Hospital Group), Bilbao, Spain.

Design: Retrospective analysis of cases.

Methods: The study assessed uncorrected distance visual acuity, corrected distance visual acuity (CDVA), predictability, safety, efficacy, and patient satisfaction after implantation of the ICL and bioptics. The model implanted was V4c and EVO, with a correction of −18.00 D. Bioptics were performed at least 3 months after implantation, and patients were followed up for at least 3 months after LASIK or PRK.

Results: The analysis included 125 eyes from 90 patients. Of these, 51.2% underwent LASIK and 48.8% PRK. Mean time from implantation to bioptics was 5.9 ± 9.4 months. Patients were followed up for a mean of 40.2 ± 37.9 months after bioptics. Median manifest refractive spherical equivalent was −2.89 D before bioptics and −0.49 D after. Median CDVA was 0.18 logMAR before bioptics and 0.17 after. The mean safety and efficacy indices were 2.22 ± 1.88 and 2.06 ± 1.85, respectively.

Conclusions: Visual outcomes and safety indices after ICL implantation and subsequent LASIK or PRK in patients with extreme myopia are excellent.

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High myopia is now a pressing global health concern, with projections indicating a progressive increase in incidence during the coming decades.[1] Surgical correction of moderate-to-high myopia in pre-presbyopic patients has been performed using various techniques, with phakic intraocular lens (pIOL) implantation and corneal laser vision correction (LVC) being major options. While both techniques have been used, the pIOL, particularly the widely adopted Visian Implantable Collamer Lens (ICL, STAAR Surgical Co.), which is inserted in the posterior chamber of the anterior segment of the eye, has demonstrated advantages in effectiveness and predictability, more stable refractive outcomes, and superior visual quality.[2,3]

The latest models of Visian ICL, such as V4c, EVO, and EVO plus, feature a central port designed to enhance procedural safety by addressing concerns over intraocular pressure and minimizing the risk of cataract formation.[4–6]

However, correcting very high ametropia poses a refractive challenge, as the highest available Visian ICL power is −18.00 diopters (D), correcting up to approximately −17.00 D in the spectacle plane. Consequently, patients with higher myopia may require a subsequent LVC procedure to address residual refractive errors, thus obviating the need for external optical correction methods such as spectacles and/or contact lenses. This combination of extra and intraocular refractive techniques was first described in 1999 by Zaldivar et al., who coined the term "bioptics."[7]

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This study aims to assess visual and refractive outcomes associated with the correction of high myopia using the highest power Visian ICL with a central port (−18.00 D), followed by an LVC procedure, either laser in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK).

METHODS

This multicenter, multisurgeon, single-protocol, retrospective, case series study enrolled very highly myopic eyes that had undergone implantation of a spherical posterior chamber pIOL with a power of −18.00 D and a secondary bioptics procedure by LASIK or PRK for enhancement of refractive residual ametropia.

Data were recorded from the central computerized clinical records system at Clinica Baviera, Spain. The sample comprised 125 consecutive eyes treated between January 2011 and January 2023. Forty-two surgeons and 21 clinics from the Baviera Group participated in the study, which was approved by the institutional legal and ethics committee and adhered to the tenets of the Declaration of Helsinki. All patients received detailed information preoperatively and gave their written informed consent to receive an ICL and undergo enhancement with LASIK or PRK and for the use of their anonymous and aggregated medical data for clinical research.

The study included eyes that received a Visian ICL (V4c or EVO) after January 2011 that underwent LASIK or PRK for correction of residual refractive ametropia at least 3 months after implantation. Patients were followed for a minimum of 3 months after LVC.

The exclusion criteria comprised anterior chamber depth (ACD) less than 2.8 mm, endothelial cell density less than 2000 cells/mm^2, cataract, abnormal corneal tomography, corneal pachymetry lower than 480 microns, or any corneal disease contraindicating the performance of LVC. In addition, patients with a history of corneal or intraocular surgery, glaucoma, retinal detachment, macular degeneration, retinopathy, or ocular inflammation were excluded.

Phakic Lens

All the eyes in the study were implanted with a Visian ICL (available in models V4c/EVO). The Visian ICL is a flexible single-piece plate-haptic lens designed for implantation in the posterior chamber of the eye. It is supported by the structures of the ciliary sulcus. Constructed from collamer, a biocompatible hydrophilic polymer combining hydroxyethyl methacrylate and porcine collagen (STAAR Surgical Co. patent), the −18.00-D ICL features a 4.9-mm optical zone (6.17-mm effective optical zone at the corneal plane). It is available in 4 sizes corresponding to the longitudinal dimension (12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm). At this lens power, thickness is approximately 270 microns at the center of the optic and 850 microns at the edge of the optical zone. All the models included in this study had a central 360-micron hole at the center of the optic (see Supplementary Material Figure 1, available at http://links.lww.com/JRS/B125).

The ICL size was selected in accordance with the manufacturer's recommendations, based on 2 measurements: the horizontal white-to-white distance, which was measured using a tomograph, that is, Orbscan II (Bausch & Lomb, Inc.) or Pentacam (Oculus Optikgeräte GmbH), and the ACD value. The ACD value was calculated using the IOLMaster 500 (Carl Zeiss Meditec AG) after subtracting the central corneal pachymetry value obtained using the tomograph.

Surgical Technique

Intraocular Surgery Procedures were conducted by experienced surgeons at Clinica Baviera, Spain, using a 3.2-mm clear corneal tunnel incision in the steepest meridian. Topical and intracameral anesthesia were administered for patient comfort and procedural efficacy. The specific details of the implantation technique have been addressed in full elsewhere.[8]

Table 1. Preoperative data

Sphere (D)	
Range	−30.00, −15.50
Mean (SD)	−21.33 (2.54)
Median (Q1, Q3)	−21.00 (−23.50, −19.75)
Cylinder (D)	
Range	−7.50, 0.00
Mean (SD)	−1.86 (1.19)
Median (Q1, Q3)	−1.75 (−2.50, −1.00)
MRSE (D)	
Range	−30.25, −16.88
Mean (SD)	−22.26 (2.43)
Median (Q1, Q3)	−22.00 (−24.12, −20.50)
UDVA (logMAR)	
Mean (SD)	1.67 (0.14)
Median (Q1, Q3)	1.70 (1.70, 1.70)
CDVA (logMAR)	
Mean (SD)	0.44 (0.27)
Median (Q1, Q3)	0.40 (0.27, 0.52)

MRSE = manifest refractive spherical equivalent; Q = quartile

Secondary Corneal Refractive Surgery Secondary corneal refractive surgery by LASIK was performed using 2 microkeratomes with nasal hinges: Moria LSKONE and Moria One-Use-Plus-SBK (Microtech Inc., Moria Ophthalmic Instruments).

The Excimer laser models used for LVC ablation were Technolas 217C and 217-Z-100 (Bausch & Lomb, Inc.), Teneo (Bausch & Lomb, Inc.), Mel 80 and MEL 90 (Carl Zeiss Meditec AG), Schwind Amaris 500 (Schwind Eye-tech-solutions GmbH & Co. KG), and WaveLight-Allegretto Wave-Eye-Q (Alcon Laboratories, Inc.).

Statistical Analysis

The differences between the independent groups (LASIK, PRK) were analyzed using the Mann-Whitney test or an independent *t* test, depending on whether the assumptions of the parametric *t* test were satisfied. The assumption of normality was assessed using the Shapiro-Wilk test; the presence of outliers was assessed using the box plot method. The inferential results are reported as statistical value, effect size, and *P* value. The Fisher exact test was applied to evaluate differences in factor variables.

RESULTS

A total of 125 eyes were included in the study (64 right eyes [51.2%] and 61 left eyes). These eyes were from a cohort of 90 patients, including 50 women (55.6%). The mean age of patients undergoing ICL surgery was 33.3 ± 7.5 years (range, 21 to 51 years). The mean preoperative manifest refractive spherical equivalent (MRSE) was −22.26 ± 2.43 D (range, −30.25 to −16.88 D). The preoperative corrected distance visual acuity (CDVA) measured 0.44 ± 0.27 logMAR (Table 1).

Table 2. Number of eyes with each ICL size

Size (mm)	N (%)
12.1	7 (5.60)
12.6	50 (40.00)
13.2	60 (48.00)
13.7	8 (6.40)

All ICLs have a power of −18.00 D

Table 3. Postoperative data, after ICL implantation and before enhancement

Sphere (D)	
Range	−7.25, 0.50
Mean (SD)	−2.30 (1.50)
Median (Q1, Q3)	−2.00 (−3.25, −1.25)
Cylinder (D)	
Range	−4.00, 0.00
Mean (SD)	−1.18 (0.79)
Median (Q1, Q3)	−1.25 (−1.75, −0.75)
MRSE (D)	
Range	−7.50, −0.38
Mean (SD)	−2.89 (1.48)
Median (Q1, Q3)	−2.62 (−3.75, −1.75)
UDVA (logMAR)	
Mean (SD)	0.68 (0.38)
Median (Q1, Q3)	0.61 (0.40, 0.90)
CDVA (logMAR)	
Mean (SD)	0.18 (0.17)
Median (Q1, Q3)	0.15 (0.07, 0.24)

MRSE = manifest refractive spherical equivalent; Q = quartile

Each eye received an ICL with a power of −18.00 D. The distribution of sizes of the implanted ICL (12.1 mm, 12.6 mm, 13.2 mm, and 13.6 mm) is presented in Table 2.

The mean interval between implantation and LVC was 5.9 ± 9.4 months. In the eyes treated with bioptics, 64 (51.2%) underwent LASIK while the remaining 61 (48.8%) underwent PRK. The MRSE before bioptics was −2.89 ± 1.48 D (range, −0.38 to −7.50 D). At the follow-up visit, uncorrected distance visual acuity (UDVA) was 0.68 ± 0.38 logMAR and CDVA was 0.18 ± 0.17 logMAR. Tables 3 and 4 and Supplementary Material Figure 2 (available at http://links.lww.com/JRS/B126) summarize visual and refractive data after implantation and before bioptics.

Patients were followed up for a mean of 40.2 ± 37.9 months after LVC. During the last follow-up visit, the mean MRSE was −0.49 ± 0.64 D, ranging from +0.50 to −2.88 D. Concurrently, UDVA measured 0.24 ± 0.22 logMAR, and CDVA was 0.17 ± 0.17 logMAR. Remarkably, 94 eyes (81%) exhibited residual refraction within ± 1.0 D of MRSE, and 76 eyes (67.2%) achieved within ± 0.5 D of MRSE. No statistically significant differences were observed in either the refraction treated or the refractive outcomes attained with the 2 LVC techniques used for bioptics (Table 5 and see Supplementary Material Figures 3 and 4, available at http://links.lww.com/JRS/B127 and http://links.lww.com/JRS/B128).

Safety and Efficacy

All procedures were performed without complications. No instances of cataract formation, glaucoma, or other vision-threatening conditions were detected during follow-up. Likewise, there were no complications associated with the LVC.

Mean Goldmann applanation intraocular pressure (IOP) was 16.1 mm Hg (95%CI, 15.5-16.7 mm Hg) before ICL surgery and 16.0 mm Hg (95% CI, 15.4-16.6 mm Hg) at the last follow-up before bioptics. After bioptics, the IOP decreased to 13.8 mm Hg (95% CI, 13.2-14.4 mm Hg). This decrease was attributed to the reduction in corneal thickness after LVC.

The mean central vault, measured under mesopic conditions using optical coherence tomography, was 548 ± 199 microns (n = 79).

Endothelial cell density decreased from 2730 ± 387 cells/mm^2 before implantation to 2635 ± 363 cells/mm^2 at the last follow-up visit (n = 86). The estimated difference was −95 cells/mm^2 (95% CI, −172 to −18 cells/mm^2), with an estimated relative difference of −3.53% (95% CI, −6.50% to −0.46%).

The mean efficacy index, calculated as the quotient of postoperative UDVA and preoperative CDVA after

Table 4. LASIK vs PRK as the enhancement procedure after ICL implantation. Data after ICL implantation and before enhancement

Parameter	LASIK	PRK	*P* value
Sphere (D)			.678
Range	−7.25, +0.50	−6.00, 0.00	
Mean (SD)	−2.35 (1.69)	−2.24 (1.28)	
Median (Q1, Q3)	−2.00 (−3.31, −1.19)	−2.25 (−3.00, −1.25)	
Cylinder (D)			.187
Range	−2.50, 0.00	−4.00, 0.00	
Mean (SD)	−1.09 (0.78)	−1.28 (0.80)	
Median (Q1, Q3)	−1.12 (−1.75, −0.50)	−1.25 (−1.75, −0.75)	
MRSE (D)			.945
Range	−7.50, −0.38	−6.25, −0.50	
Mean (SD)	−2.90 (1.64)	−2.88 (1.31)	
Median (Q1, Q3)	−2.62 (−3.75, −1.75)	−2.62 (−3.75, −1.75)	
UDVA (logMAR)			.610
Mean (SD)	0.05 (0.70)	0.10 (1.52)	
Median (Q1, Q3)	0.52 (0.40, 0.82)	0.70 (0.40, 0.94)	
CDVA (logMAR)			.657
Mean (SD)	0.19 (0.16)	0.17 (0.18)	
Median (Q1, Q3)	0.15 (0.06, 0.23)	0.13 (0.07, 0.24)	

Data after ICL implantation and before enhancement

Table 5. LASIK vs PRK as the enhancement procedure after ICL implantation. Data after enhancement

Parameter	LASIK	PRK	*P* value
Sphere (D)			.954
Range	−2.00, +1.00	−2.25, +0.75	
Mean (SD)	−0.28 (0.59)	−0.29 (0.64)	
Median (Q1, Q3)	0.00 (−0.50, 0.00)	0.00 (−0.75, 0.00)	
Cylinder (D)			.553
Range	−1.75, 0.00	−1.50, 0.00	
Mean (SD)	−0.43 (0.41)	−0.39 (0.40)	
Median (Q1, Q3)	−0.50 (−0.75, 0.00)	−0.25 (−0.50, 0.00)	
MRSE (D)			.894
Range	−2.88, +0.50	−2.50, +0.50	
Mean (SD)	−0.50 (0.64)	−0.48 (0.64)	
Median (Q1, Q3)	−0.38 (−0.75, 0.00)	−0.25 (−0.91, 0.00)	
UDVA (logMAR)			.173
Mean (SD)	0.26 (0.23)	0.21 (0.21)	
Median (Q1, Q3)	0.22 (0.10, 0.40)	0.14 (0.06, 0.30)	
CDVA (logMAR)			.207
Mean (SD)	0.19 (0.17)	0.15 (0.17)	
Median (Q1, Q3)	0.15 (0.07, 0.23)	0.10 (0.04, 0.22)	

Data after enhancement

implantation and subsequent LVC, was 2.06 ± 1.85. In addition, the median efficacy index was 1.56 (interquartile range [Q1, Q3]: 1.17, 2.23). The mean post-bioptics safety index, based on the quotient of postoperative CDVA and preoperative CDVA, was 2.22 ± 1.88, with a median of 1.60 (interquartile range [Q1, Q3]: 1.26, 2.32) (see Supplementary Material Figure 2, available at http://links.lww.com/JRS/B126). When LASIK was compared with PRK as an enhancement procedure after implantation, no differences were noted in the safety and efficacy indices between both the procedures, although a trend toward more favorable outcomes was observed when the PRK technique was used for LVC (Table 6).

DISCUSSION

This study assesses the visual outcomes of 125 highly myopic eyes undergoing planned bioptic procedures. Using the highest powered Visian ICL with a central port (−18.00 D), we addressed residual refractive defects on the cornea through subsequent LASIK or PRK techniques. This dual-plane approach divided the total optical correction between the cornea and the posterior chamber.

The concept of bioptics, initially introduced by Zaldivar et al. more than 2 decades ago, has evolved beyond its origins as a secondary corneal LVC procedure after implantation of an ICL.[7] Today, the term encompasses intraocular surgeries involving various lenses combined with diverse corneal refractive techniques.[8–10] In the preliminary work by Zaldivar et al., good visual results were reported for myopia, ranging from −18.75 to −30.00 D, with 69% achieving UDVA of 20/40 or better. For this series, the authors used the earliest version of the ICL, which is no longer available. Sanchez-Galeana et al. examined 37 eyes (31 patients) implanted with similar collamer pIOL models and treated with LASIK or PRK for residual refractive errors.[11] Preoperative MRSE was −17.74 ± 4.89 D. The authors found that 97.2% of eyes were within ±1.00 D and 83.7% within ±0.50 D. Complications included subcapsular opacities in 3 eyes, macular hemorrhage in 1 eye, and corticosteroid-induced ocular hypertension in 1 eye; these complications were associated with early lens designs and surgical techniques, which were less advanced than current standards. A subsequent study by Arne et al. demonstrated favorable outcomes using the subsequently released ICL model, the V4, and similar methodology in 32 eyes with an MRSE of −18.70 D (range, −7.75 to −29.00 D).[12]

Based on updated ICL models and refined bioptics procedures, Moshirfar et al. conducted a retrospective study

Table 6. LASIK vs PRK as the enhancement procedure after ICL implantation. Safety and efficacy of corneal laser visual correction

Parameter	LASIK	PRK	*P* value
Safety index			.076
Mean (SD)	0.97 (0.17)	1.05 (0.24)	
Median (Q1, Q3)	1.00 (0.90, 1.06)	1.04 (0.97, 1.15)	
Efficacy index			.059
Mean (SD)	0.89 (0.28)	0.99 (0.31)	
Median (Q1, Q3)	0.96 (0.77, 1.06)	1.03 (0.83, 1.12)	

Q = quartile
Safety and efficacy of corneal laser visual correction

analyzing the results of the V4b model, packaged in balanced salt solution (not physiological saline) but still lacking the central port.[13] The authors followed up 100 myopic eyes (−3.38 to −19.88 D) that subsequently underwent PRK or LASIK, mainly to correct residual astigmatism. Of the 51 eyes presented at 12 months postoperatively, 49 (96%) achieved a target MRSE within ±1.00 D and an identical number achieved refractive astigmatism ≤1.00 D. After the bioptics procedures, the postoperative UDVA was equal to or better than the preoperative CDVA in 45 eyes (88%). Similar results demonstrating excellent long-term safety, predictability, and efficiency in addressing high myopic astigmatism were provided by Jabbour et al., who reported 3-year outcomes of spherical ICL followed by bioptics in eyes with high myopic astigmatism.[14]

A recent analysis of the results of bioptics procedures for correction of high myopia (−16.50 to −28.00 D) by Brar et al. revealed that most of the ICLs were the V4c model, which already came with a central port, and that the technique used for enhancement bioptics procedures was small-incision lenticule extraction.[10] Ten (67%) of the 15 eyes included in the study were within ± 0.50 D, whereas all eyes were within ± 1.00 D of spherical equivalent correction. A gain in CDVA ranging from 1 to 4 lines of vision was recorded in all cases.

Our series, which involved implantation of a −18.00-D ICL and subsequent bioptics with PRK or LASIK, is the longest to date of eyes treated with a central port ICL (V4c/EVO model). Waiting at least 3 months after intraocular surgery ensured the complete stabilization of refractive residual refraction before undertaking corneal laser enhancement. The final refractive results were scrutinized a mean of 42 months after bioptics, enabling comprehensive understanding of long-term outcomes. The extended analysis period may account for the percentage of eyes within ±1.00 D of MRSE (81%), which was potentially influenced by axial length growth in eyes with such high myopic ametropia.

The notable improvement in lines of CDVA in most highly myopic eyes undergoing both techniques has various explanations. First, it could be related to successful correction of residual ametropia after corneal refractive surgery. In highly myopic eyes, the accuracy of preoperative CDVA testing may be affected by factors such as phoropter decentration, fogging, poor quality of lens tests, poor compliance, and fatigue of patients or technicians in cases of eyes with poor visual acuity.[15] Correcting most of the myopic ametropia with the pIOL facilitates accurate refractive assessments, particularly within a moderate range of ametropia, leaving the abovementioned factors with little relevance in postoperative refractive tests. Furthermore, the precision of the LVC in these smaller ranges of ametropia is noteworthy, since it effectively corrects residual defects.[16,17]

Another compelling argument for the improvement in CDVA after refractive procedures is the enlargement of the retinal image in both corneal and posterior chamber plane correction. This enhancement is more pronounced when the correction is closer to the nodal point of the eye.[18] In addition, the reduction in visual aberrations with spectacles and minimized optical aberrations with lenses contribute to the improvements in CDVA observed.[19–21]

In conclusion, our extensive study of 125 highly myopic eyes treated with the Visian ICL (−18.00 D) featuring a central port, followed by bioptics with LASIK or PRK, confirm this dual-plane approach. Similar findings have been reported in previous studies of planned and unplanned bioptics, indicating that the strategy is both reliable and effective, offering patients sustained visual improvement with a favorable safety profile. Furthermore, the absence of Nd:YAG laser iridotomy or surgical iridectomy during implantation (facilitated by the central port) adds to the safety profile of the procedure. No vision-threatening complications, such as cataract formation or glaucoma, were detected during the follow-up period. A deliberate waiting period of at least 3 months after implantation of the ICL and before undertaking LVC ensured the stability of residual refraction. The extended follow-up period of at least 42 months allowed for a thorough evaluation of long-term results.

WHAT WAS KNOWN

- The combination of extra and intraocular refractive techniques, named bioptics, is a safe, effective, and predictable technique.

WHAT THIS PAPER ADDS

- Our large series of eyes with very high myopia treated by combining a −18.00 D Visian ICL with a central port and performing a correction of the residual refractive defect using corneal laser techniques (LASIK or PRK), at least 3 months later, is a safe and effective approach, without any notable complications.

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