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AU 4: Change by: In some cases, depending on the angle-to angle distance and crystalline lens rise, we performed fits in the ICL size recommended by the manufacturer's calculator.

AU 5: Change by: Hence, we cannot ensure that those patients who did not complete the entire follow-up did not develop complications after their last visit.

ARTICLE

Ten-year follow-up of posterior chamber phakic intraocular lens with central port design in patients with low and normal vault

AU1

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

Purpose: To assess the clinical outcomes and postoperative complications of the implantable collamer lens (ICL) with a central port throughout 10 years of follow-up in patients with low and normal vault.

Setting: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

Design: Retrospective and comparative case series.

Methods: This study included eyes that underwent a V4c ICL implantation with 10 years of follow-up. The eyes were divided into 2 groups according to the vault at 1 year postoperatively: vault <250 μm and between 250 μm and 800 μm. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure (IOP), endothelial cell density (ECD), vault, complications, and secondary surgeries were analyzed.

Results: 37 and 90 eyes were enrolled in the low and normal-vault groups, respectively. No differences in UDVA, CDVA, and refraction were found between the groups over 10 years of follow-up. No cases developed ICL-induced anterior subcapsular opacity over the follow-up period. 2 (5.4%) and 8 (8.9%) eyes in the low and normal-vault groups, respectively, required ICL exchange. 1 (2.8%) and 2 (2.2%) eyes in the low and normal-vault groups, respectively, required excimer laser to correct residual refractive error. The IOP remained stable throughout the 10-year follow-up. The loss in ECD from that preoperatively to 10 years postoperatively was 3.8% and 4.5% in the low and normal-vault groups, respectively (P = .4). No pigment dispersion glaucoma or other vision-threatening complications were reported.

Conclusions: This study shows good long-term outcomes of the V4c ICL, supporting that the central hole provides safety to the procedure and prevents the potential risk associated with low vault.

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The design enhancement in the Visian Implantable Collamer Lens (ICL) V4c model (STAAR Surgical AG), incorporating the central hole, invented by Shimizu et al., has significantly decreased ICL-related complications compared with the preceding models while maintaining excellent refractive and visual outcomes.[1–4]

With the previous ICL models, longer postoperative time and low vault were risk factors of developing ICL-related complications.[5–13] The studies that reached a follow-up of 10 years or more showed that the complication rate increased over time.[9–13] The ICL V4c version was first available in the market in 2011. The longest follow-up reported so far has been 8 years after implantation, and no previous study has been published spanning 10 years or more.[14] Currently, we are already at the moment of starting to report studies that collect outcomes over 10 years of follow-up. Considering the complications reported in the earlier long-term studies (spanning between 5 years and 8 years) with the hole-equipped ICL version, a significant decrease in the cumulative complications with time should be expected compared with the previous ICL models.[14–20] However, it is of clinical importance to evaluate whether, similar to previous models, longer postoperative time is a risk factor of increasing ICL-related complications or, by contrast, the flow of the aqueous fluid through the ICL prevents complications over a long time, discarding time as a risk factor of this procedure.

The central port also seems to significantly reduce the risk of developing cataracts in eyes with low vault.[2,20] Notably, with non-equipped central-hole ICL models, the risk of anterior subcapsular opacity development in eyes with low vault also increased with time.[9,10,21] Therefore,

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From the Fernández-Vega Ophthalmological Institute, Oviedo, Spain (Alfonso-Bartolozzi, Fernández-Vega-Cueto, Lisa, Palacios, Alfonso); Clinical and Experimental Eye Reseach Group, Faculty of Optics and Optometry, Universidad Complutense de Madrid, Madrid, Spain (Madrid-Costa).

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Corresponding author: 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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evaluating patients exposed to both potential risk factors, low vault over long time, would help confirm the benefit of the central port even for those cases with a low vault.

This study aimed to retrospectively evaluate patients implanted with the ICL 4c model between July 2011 and July 2012; hence, we could collect 10 years of follow-up. In addition, as the objective was to evaluate 2 specific risk factors in particular, namely longer postoperative time and low vault, we divided the sample into 2 groups: eyes with a low vault at the 1-year follow-up visit and during the 10 years of follow-up and eyes with a normal vault at the 1-year follow-up visit.

METHODS

This retrospective observational study included patients who underwent implantation of the ICL V4c model to correct myopia or myopia and astigmatism from July 2011 to July 2012. All surgeries were performed by the same experienced surgeon (J.F.A.) at Fernández-Vega Ophthalmological Institute, Oviedo, Spain, according to the standard procedure previously described.[19] ICL power calculation was performed using a modified vertex formula provided by the manufacturer (STAAR Surgical AG). Eyes with a topographic cylinder of more than 1.50 diopters (D) were implanted with a toric ICL. In eyes with a topographic cylinder ≤1.50 D, a spherical ICL was implanted. In these cases, to reduce the topographic cylinder, clear corneal incisions (CCIs) were performed in the steep axis. In eyes with astigmatism between 0.75 D and 1.00 D, 1 CCI (3.2 mm) was performed; in eyes with astigmatism between 1.25 D and 1.50 D, 2 opposite CCIs (3.2 mm) were performed. All incisions were performed with a bevel-up steel blade (Equipsa S.A.).

The ICL size was individually determined based on the horizontal white-to-white distance, anterior chamber depth (ACD) measured by Scheimpflug photography (Sirius, Costruzione Strumenti Oftalmici), and angle-to-angle distance measured with anterior-segment optical coherence tomography (AS-OCT; Visante, Carl Zeiss Meditec AG). ICL sizing selection was performed following the manufacturer's recommendations. In some cases, based on the surgeon's experience, depending on the angle-to-angle distance and crystalline lens rise, we performed fits in the ICL size recommended by the manufacturer's calculator.

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. Data collection fulfilled Spanish legal requirements, and the Institutional Ethics Committee of Fernandez-Vega University Institute approved the study.

Patients had a complete ophthalmologic examination preoperatively and postoperatively, including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, slitlamp examination, keratometry, corneal topography, pachymetry (Sirius), endothelial cell density (ECD) measurement (SP 3000P, Topcon Europe Medical), intraocular pressure (IOP) measurement by Goldmann applanation tonometry, and AS-OCT (Visante).

The inclusion criteria were stable refraction with a myopic error in the range correctable with the V4c ICL (from −1.00 to −18.00 D of sphere), a clear central cornea, ACD greater than 3.0 mm measured from the corneal endothelium to the anterior lens capsule, ECD greater than 2000 cell/mm^2, mesopic pupil smaller than 7.0 mm, trabecular-iris angle greater than 35 degrees (grade III by gonioscopy), and crystalline lens rise less than 500 μm. The exclusion criteria were history of glaucoma or retinal detachment, previous ocular surgery, macular degeneration or retinopathy, neuro-ophthalmic disease, or any ocular inflammation history.

All eyes implanted with V4c ICL between July 2011 and July 2012 and met the inclusion criteria were evaluated. Patients not attending the 10-year follow-up visit were excluded from the complete analysis, but whether complications or adverse events occurred at their last follow-up visit were registered. That is, those cases that did not reach the 10-year follow-up were analyzed separately because it was not possible to know whether they had developed a complication if they had completed the whole follow-up. On the other hand, the eyes that required secondary surgery (cataract surgery, photorefractive corneal surgery, or ICL exchange for myopic progression over follow-up) were excluded from the visual and refractive outcomes analysis. In summary, the steps to include patients and analyze the results were as follows: (1) Patients who attended the 1-year and 10-year follow-up visits were included. (2) The eyes that required secondary surgery (cataract surgery, photorefractive corneal surgery, or ICL exchange for myopic progression over follow-up) were excluded from the visual and refractive outcomes analysis. (3) Finally, those patients who did not attend the 10-year follow-up visit were only included to register complications or adverse events at their last visit.

The variables analyzed included complications and adverse events over the whole follow-up, UDVA and CDVA, manifest refraction, slitlamp examination, IOP, and ECD preoperatively, at 1 year, and at 10 years and central distance between the ICL and the crystalline lens (vault) using AS-OCT at 1 year and 10 years postoperatively. The vault between the crystalline lens and the ICL was measured perpendicularly to the lens apex or at the narrowest point under mesopic conditions.

The sample analysis of the eyes which completed the whole follow-up was divided into 2 groups according to the vault distance: low-vault: eyes with a vault distance ≤250 μm at the 1-year follow-up visit and over the whole follow-up, and normal-vault: eyes with a vault distance higher than 250 and lower than 800 μm at the 1-year follow-up visit.

Data analysis was performed using SPSS for Windows, v. 14.0 (SPSS, Inc.). Normality was checked with the Kolmogorov-Smirnov test. A repeated-measures analysis of variance and Bonferroni test were performed to analyze significant differences for the variables throughout the time period. The comparison between the 2 groups was analyzed using an independent t test. Differences were considered statistically significant when the P value was <0.05.

RESULTS

A total of 262 eyes underwent a V4c ICL implantation between July 2011 and July 2012. There were no intraoperative complications in any case. From the whole sample, 135 eyes did not attend the 10-year follow-up visit, and we only registered if adverse events or complications occurred at their last visit. The mean time of the last follow-up visit in these 135 eyes was 3.81 ± 2.21 years (range 1 to 7 years). No eyes developed cataracts or any other complications at their last follow-up visit.

A total of 127 eyes completed the 10-year follow-up, of which 116 were implanted with a spherical ICL and 11 with a toric ICL. The low-vault group comprised 37 eyes, and the normal-vault group enrolled 90 eyes. Supplemental Table 1 (available at http://links.lww.com/JRS/B49) summarizes the preoperative demographic data of the patients and ICL characteristics in the 127 eyes that completed the whole follow-up.

Adverse Events and Secondary Surgeries

Of 127 eyes that attended the 10-year follow-up visits, no cases developed ICL-induced anterior subcapsular opacities. Two (5.4%) and 3 (3.3%) eyes in the low and normal-vault groups, respectively, developed cataracts during the follow-up. In the low-vault group, one of these 2

cataractous eyes had a nuclear cataract and the other a posterior subcapsular opacity. Both cases underwent uneventful simultaneous ICL extraction and phacoemulsification with IOL implantation at 10 years and 9 years of ICL implantation, respectively. In the normal-vault group, 2 cases were nuclear cataracts and 1 posterior subcapsular opacity. The 3 cases also underwent uneventful simultaneous ICL extraction and phacoemulsification with IOL implantation at 3 years, 4 years, and 9 years after ICL implantation.

In the low-vault group, 2 eyes (5.4%) required ICL exchange, one because of myopic progression and another because of toric ICL rotation. Eight eyes (8.9%) in the normal-vault group needed ICL exchange (4 at 1 day postoperatively because of a high vault and 4 because of myopic progression). One eye in the low-vault group and 2 eyes in the normal-vault group required excimer laser corneal enhancement because of myopic progression ≤1.0 D 2 years after ICL implantation.

Over the follow-up period, no pigment dispersion glaucoma, pupillary block, or other vision-threatening complications were reported.

IOP, ECD, and Vault

In the low-vault group, the preoperative, 1-year postoperative, and 10-year postoperative mean IOP values were 13.3 ± 1.7 mm Hg, 12.7 ± 2.2 mm Hg, and 13.2 ± 2.9 mm Hg, respectively (P = .07). In the normal-vault group, these were 13.2 ± 2.2 mm Hg, 12.3 ± 1.7 mm Hg, and 12.7 ± 1.6 mm Hg, respectively (P = .06). There was no significant difference in the IOP between the 2 groups at any of the 3 follow-up visits (P = .4, .3, and .11, respectively) (Figure 1). No eyes exceeded 20 mm Hg throughout the 10-year follow-up, and no medical or surgical interventions were performed to lower the IOP in any case throughout the 10 years of follow-up.

Figure 2 shows the ECD preoperatively and at 10 years postoperatively. The loss in ECD from the preoperative baseline to 10 years postoperatively was 3.8% and 4.5% in the low and normal-vault groups, respectively (P = .4).

In the low-vault group, the mean postoperative vault was reduced from 185 ± 75 μm at 1 year to 144 ± 64 μm at 10 years postoperatively (P < .0001). In the normal-vault group, vault distance changed from 541 ± 133 μm at 1 year to 421 ± 128 μm at 10 years postoperatively (P < .0001). The mean reduction in the vault was statistically higher in the normal-vault group (125 ± 80 μm vs 41 ± 48 μm; P < .0001); however, the percentage of change was comparable in both groups (22.1% vs 21.8%) (P = .15). Figure 3 shows the postoperative distribution of vault in both groups at 1 year and 10 years of ICL implantation.

Visual and Refractive Outcomes

Four and 9 eyes in the low and normal-vault groups, respectively, were excluded from the visual and refractive analysis because they had cataract surgery or required photorefractive surgery or ICL exchange for myopic progression over follow-up. In the low and normal-vault groups, the mean postoperative UDVA (logMAR) at 10 years postoperatively was 0.24 ± 0.29 and 0.20 ± 0.29, respectively (P = .3). The efficacy indexes at 10 years postoperatively (mean postoperative UDVA/mean preoperative CDVA) were 0.79 and 0.82, respectively (P = .16). Figure 4 shows the cumulative UDVA and CDVA at 10 years after ICL implantation. There was no significant difference in the mean CDVA between the 2 groups at 10 years postoperatively (0.03 ± 0.02 logMAR and 0.03 ± 0.09 logMAR in the low and normal-vault groups, respectively, P = .3). Figure 5 shows the changes in CDVA between that preoperatively and 10 years after ICL implantation in both groups. No eye lost more than 1 line of CDVA in any group, and more than 30% of the eyes gained lines of CDVA. The safety indexes (ratio between the postoperative CDVA and the preoperative CDVA) were 1.05 and 1.04 at 10 years postoperatively in the low and normal-vault groups, respectively (P = .4).

Figure 6 shows the accuracy of the refractive sphere at 10 years postoperatively in both groups. In the low-vault group, the mean SE was −0.80 ± 0.73 D 10 years after ICL implantation, and in the normal-vault group, it was −0.62 ± 0.84 D (P = .12). After 10 years of the surgery, around 80% of the eyes maintained the sphere refraction within ±1.00 D of the desired refraction (emmetropia), 75% a cylinder of ≤0.5 D, and more than 75% an SE within ±1.00 D.

DISCUSSION

The studies with the preceding ICL models (without a central hole), which extended more than 5 years, found that

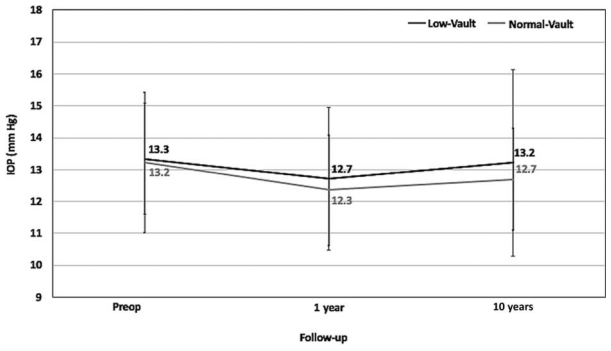

Figure 1. The time course of the mean IOP over the follow-up in each group.

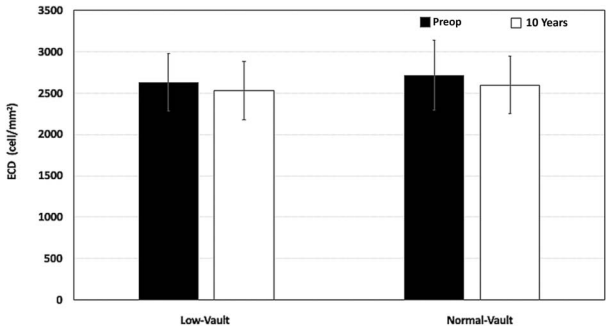

Figure 2. The mean ECD (cell/mm^2) preoperatively and at 10 years postoperatively in each group. ECD = endothelial cell density

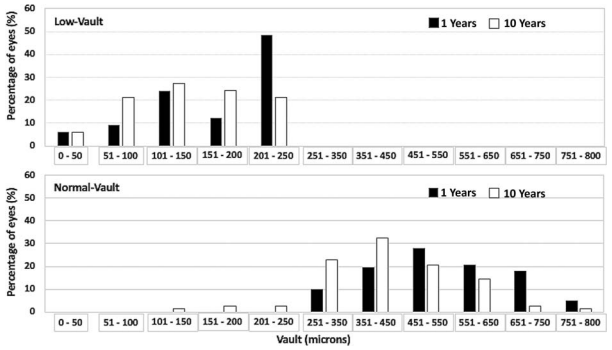

Figure 3. Distribution of eyes according to the vault in each group, measured in microns, at 1 year and 10 years postoperatively.

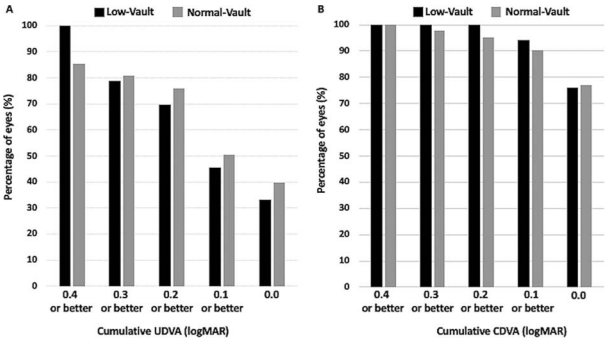

Figure 4. Cumulative UDVA (*A*) and CDVA (*B*) at 10 years postoperatively.

ICL-related complications significantly increased from 5 years of the surgery, confirming that time was a risk factor of cataract development with the previous ICL model.[8–13]

Among longest term follow-up studies published till now with the hole-equipped ICL (which spanned between 5 years and 8 years of follow-up), 4 studies reported cataracts, with an incidence rate ranging between 1.7% and 4.17%.[14–20] This study extended the follow-up to 10 years. Overall, we found cataracts in 5 eyes (3.9%), although they were nuclear or subcapsular posterior opacities. These findings seem to confirm that the central hole incorporated in the V4c model significantly decreases the risk of developing cataracts associated with long time compared with previous models.

In addition to the long term, the main predisposing factor for anterior subcapsular opacity development with the previous ICL designs was a close distance between ICL and the crystalline lens. Fernandes et al., in their review of the potential complications with the earlier models of ICL, reported that in 33.8% of ICL-induced cataracts, the vault was lower than 200 μm.[5] Our study evaluated a sample of patients exposed to these 2 cataractogenic risk factors after ICL implantation, a low vault (<250 μm; range 50 to 249 μm, under mesopic conditions) throughout 10 years. We did not find any case of anterior subcapsular opacities. Gonzalez-Lopez et al. evaluated over a follow-up of 5.82 ± 0.9 years a sample of 24 eyes implanted with central-hole ICL with a vault slightly lower than that used in our study (45 to 183 μm under scotopic light).[20] Only 1 eye (4.17%) developed anterior subcapsular opacities in that study. By contrast, with non-hole models, Maeng et al. found 30.8% of cataracts, mainly anterior subcapsular, in patients with a low vault (<250 μm) over 4 years of follow-up.[21]

According to the incidence rate of cataracts reported in long-term studies with the ICL designs with and without a central hole, it seems evident that the central port prevents from developing cataracts over the long term, even for those patients with a low vault at the early follow-up visits. Gonzalez-Lopez et al. hypothesized that the dynamic bellows movement of the iris and crystalline lens provokes the continuous turnover and clearance of aqueous humor through the hole, facilitating a more physiological metabolism of the crystalline lens.[20] We agree with that, but we would add the hypothesis that the aqueous humor movement flow behind the ICL would induce a lifting of the ICL away from the crystalline lens, which would also diminish the contact at the mid-periphery. Consequently, this mechanism would minimize metabolic and mechanic factors involved in the anterior subcapsular opacification. However, we want to highlight that this is only an authors' speculation that should be confirmed in a study designed adequately with such an aim.

Concerning IOP, our study confirms the results previously reported on the effectiveness of the central hole in maintaining stable IOP over a long-term follow-up without preoperative iridotomy or intraoperative iridectomy, hence,

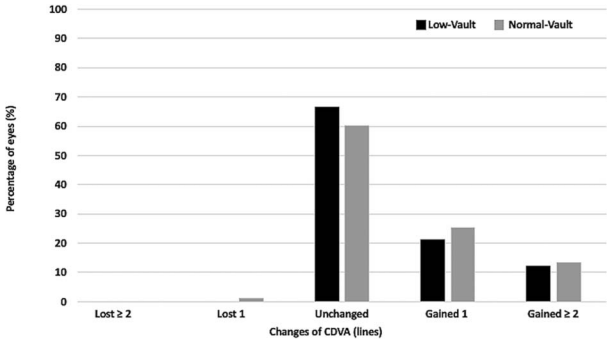

Figure 5. Variation in CDVA between that preoperatively and 10 years postoperatively in each group.

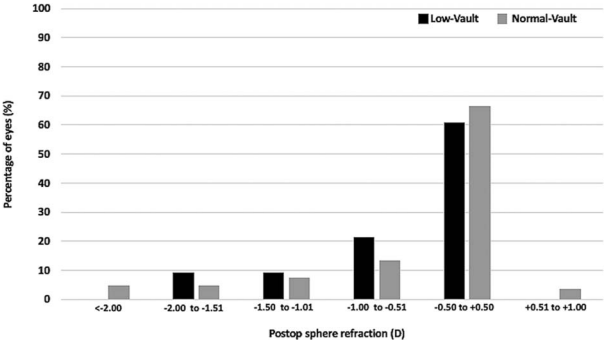

Figure 6. Accuracy of manifest spherical refraction at 10 years after ICL implantation in each group.

reducing the risk of developing ocular hypertension over long-term follow-up associated with chronic pigment dissemination.[5,13–19] Furthermore, we found no significant difference in the IOP control between the 2 groups at any of the 3 follow-up visits. However, it is noteworthy that in the normal-vault group, no eyes showed a vault higher than 800 μm at any time. In this sense, it should be noted that 4 eyes (4.4%) required ICL exchange at 1 day postoperatively because of a high vault. Our current knowledge allows us to propose 2 approaches to prevent a postoperative high vault. First, considering the central hole may prevent the risk of cataract development in the case of a low vault, we should opt for the smaller one in case of doubt between 2 ICL sizes. Second, in spherical ICL, the lens rotation to the vertical meridian is an effective maneuver that decreases the vault height.[18,22,23] Currently, intraoperative OCT allows the measurement of the vault intraoperatively. Hence, for those cases with an extreme intraoperative vault, the ICL can be rotated to the vertical meridian during the same surgical session.[24,25]

Regarding the ECD, our results were in line with previous studies showing that the ICL does not induce a significant ECD loss over long periods.[14–19] However, it is interesting to note that excessively high vault might increase the risk of ECD loss.[26] In our study, the loss in ECD from the preoperative baseline at 10 years postoperatively was 3.8% and 4.5% in the low and normal-vault groups, respectively, and we did not find a correlation between vault and ECD loss. Of note, any case showed a vault higher than 800 μm, eliminating the risk factor related to an excessively high vault. The ICL exchange performed in 4 cases because of a high vault may have also prevented the loss of ECD.

In terms of visual and refractive outcomes, the outstanding safety, efficacy, predictability, and stability of ICL implantation over a long time have been demonstrated. Our results show that CDVA was maintained over the 10 years, with a safety index higher than 1.0 in both groups, which implies that the postoperative CDVA was equal to or better than preoperative CDVA (Figure 5). The accuracy rate of the sphere refraction (80% of the eyes had a sphere refraction within ±1.00 D of the desired refraction) and efficacy indexes (around 0.8) agreed with previous longer term studies. However, both indicators (efficacy index and accuracy rate refraction) were lower than those reported in shorter term studies since almost all these studies reported 100% of ±1.00 and efficacy indexes of 1.0 or higher. This slight decrease in the efficacy outcomes over time should not be associated with the ICL implantation procedure itself. This procedure is usually performed in young patients in whom an axial elongation may occur over time, leading to an increase in myopia, which affects the refractive and UDVA outcomes of the procedure and, consequently, the efficacy index.[8]

It is worth noting that 13 eyes (10.2%) were excluded from the visual and refractive analysis because they had a second surgery with visual and refractive implications (cataract surgery, laser corneal enhancement, or ICL exchange for myopic progression over follow-up). If these cases had not undergone secondary surgery, our visual and refractive outcomes would have worsened. On the other hand, these cases showed that potential adverse events, such as cataracts or myopia progression, can be safely and effectively managed with secondary surgery procedures. Interestingly, one of the 2 toric ICLs implanted in the low-vault group had to be exchanged for one with a larger size because of rotation. By contrast, the 9 toric ICLs implanted in the normal-vault group remained rotationally stable. Wei et al. recently reported that a potential factor for poor rotational stability is the placement of an undersized ICL.[27] This leads to a dilemma in the toric ICL when there is doubt between 2 ICL sizes. Choosing an undersized ICL prevents potential complications related to a high vault; furthermore, as we previously noted, the central port prevents possible complications associated with a low vault. However, an undersized ICL might have a higher rotational instability risk, leading to ICL exchange. By contrast, an oversized ICL and high vault would obligate ICL exchange, because, with toric ICL, the maneuver of rotation of the ICL to the vertical meridian to decrease vault is not possible.

Finally, it is worth highlighting that a limitation of the study was that it was conducted retrospectively, and it was impossible to collect all the data from all patients over the 10 years. Hence, we cannot assure that those patients who AU5 missed out on the follow-up had no complications despite their last visit they did not have it.

In conclusion, our results with V4c ICL during 10 years of follow-up support that the central-hole design of the V4c ICL might provide safety to the outstanding visual and refractive outcomes previously reported with the previous model, also preventing the potential risk associated with the low vault.

WHAT WAS KNOWN

- The design enhancement in the Visian ICL V4c model, incorporating the central hole, has significantly decreased the ICL-related complications compared with the preceding models while maintaining excellent refractive and visual outcomes.
- With the previous ICL models (non-equipped central-hole ICL models), the longer postoperative time and low vault were risk factors of developing ICL-related complications.

WHAT THIS PAPER ADDS

- This is the first study spanning a follow-up of 10 years after V4c model implantation, evaluating eyes with a low vault over the whole follow-up.
- The central-hole design of the V4c ICL provides safety to the procedure and prevents the potential risk associated with the low vault.

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First author:
Belén Alfonso-Bartolozzi, MD

Fernández-Vega Ophthalmological Institute, Oviedo, Spain

000 Ten-year follow-up of posterior chamber phakic intraocular lens with central port design in patients with low and normal vault

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

The V4c ICL implantation is a safe procedure over a long follow-up, even in patients with a postoperative low vault.