

Short-Term Refractive and Safety Outcomes of Implantable Collamer Lens Implantation

Resultados Refrativos e Perfil de Segurança a Curto Prazo do Implante de *Implantable Collamer Lens*

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ABSTRACT

INTRODUCTION: To evaluate the short-term visual and refractive outcomes of V4c-V5 implantable collamer lens implantation, and its safety profile in myopia and myopic astigmatism correction.

METHODS: Retrospective unicentric observational study of patients with Implantable collamer lens implantation. Main outcome measures at 6 months were safety, efficacy, predictability, endothelial cell count loss, intraocular pressure variation and central vault. Adverse effects and complications were assessed.

RESULTS: Eighty-five eyes of 48 patients were included in the study. Postoperative uncorrected distance visual acuity was 0.05 ± 0.11 , with an efficacy index of 1.03 ± 0.22 ; the safety index was 1.10 ± 0.20 . Postoperative manifest spherical equivalent was within ± 0.50 D of intended target in 8.8% of eyes, and within ± 1.00 D in 94.5% of eyes. Mean endothelial cell density loss was $2.34\% \pm 11.43\%$. Despite being statistically significant, the increase in intraocular pressure of preoperative 12.82 to 14.3 mmHg postoperative was not clinically significant. Mean central vault was 524.06 ± 185.71 μm . Two eyes underwent lens explantation due to high vault and postoperative inflammation, and one toric lens was exchanged due to significant axis misalignment. No cases of pupillary block, chronic hypertension, cataract or lens opacity were reported.

CONCLUSION: Implantable collamer lens V4c-V5 implantation demonstrated good visual and refractive outcomes, with a favorable safety profile, for the correction of myopia and myopic astigmatism.

KEYWORDS: Lens Implantation, Intraocular; Lenses, Intraocular; Myopia/surgery; Phakic Intraocular Lenses; Refraction, Ocular.

RESUMO

INTRODUÇÃO: Analisar os resultados visuais e refrativos a curto prazo do implante de *implantable collamer lens* V4c-V5 para a correção de miopia e astigmatismo miópico, e avaliar o seu perfil de segurança.

MÉTODOS: Estudo observacional retrospectivo unicêntrico de doentes submetidos a implante de *implantable collamer lens*. Os indicadores primários aos 6 meses foram a segurança, eficácia, previsibilidade, variação da pressão intraocular, perda de contagem de células endoteliais e *vault* central. Os efeitos adversos e complicações também foram analisados.

RESULTADOS: Oitenta e cinco olhos de quarenta e oito doentes foram incluídos no estudo. A acuidade visual não corrigida à distância no pós-operatório foi de $0,05 \pm 0,11$, com um índice de eficácia de $1,03 \pm 0,22$; o índice de segurança foi de $1,10 \pm 0,20$. O equivalente esférico manifesto pós-operatório encontrou-se entre $\pm 0,50$ D da refração alvo em 81,8% dos olhos, e entre $\pm 1,00$ D em 94,5%. A perda média de densidade de células endoteliais foi de $2,34\% \pm 11,43\%$. O aumento da pressão intraocular de 12,84 mmHg no pré-operatório para 14,13 mmHg no pós-operatório, apesar de estatisticamente significativo, não foi clinicamente relevante. O *vault* central médio foi de $524,06 \pm 185,71$ μm . Dois olhos foram submetidos a explante da lente devido a um *vault* alto num caso, e inflamação intraocular no outro. Uma lente tórica foi substituída devido a um desalinamento significativo do eixo. Não foi reportado nenhum caso de bloqueio pupilar, hipertensão crónica, opacidade do cristalino ou catarata.

CONCLUSÃO: O implante de *implantable collamer lens* V4c-V5 para correção de miopia e astigmatismo miópico demonstrou excelentes resultados visuais e refrativos, com um ótimo perfil de segurança.

PALAVRAS-CHAVE: Implante de Lente Intraocular; Lentes Intraoculares; Lentes Intraoculares Fácicas; Miopia/cirurgia; Refração Ocular.

INTRODUCTION

Phakic intraocular lenses (pIOLs) with different designs and materials have been widely used to correct myopia and myopic astigmatism. It has been broadly accepted as safe, effective, and predictable,¹⁻⁴ with several relevant advantages compared to other techniques: preservation of corneal integrity, shape and biomechanics, reversibility, and production of a lower quantity of aberrations with superior contrast sensitivity.^{1,5} Moreover, pIOLs preserve accommodation, which is a significant advantage compared to a lens-based surgical approach.

The V4c-V5 Visian ICL has a central 0.36 mm port (V4c/V5), that allows the physiological flow of aqueous through the lens. Compared to the previous ICL models, it has significantly fewer reported complications, such as the incidence of cataracts and IOP rise.^{6,8,9} ICL V4c/V5 provides great and stable visual and refractive outcomes, with low adverse event rates.¹⁰⁻¹³ ICLs are size-dependent and require meticulous eye measurements to avoid over or under-sizing, and their related complications (pIOL rotation, endothelial cell density (ECD) loss, pupillary block, among others).

The current study aims to analyze the short-term visual and refractive outcomes of central-hole ICL implantation for myopia and myopic astigmatism, and to assess adverse effects and complications.

METHODS

A retrospective observational study was conducted, designed to identify patients who had phakic ICL implantation

for myopia and myopic astigmatism, at the Ophthalmology Department of Central Lisbon Hospital and University Centre, Lisbon, Portugal, between September 2015 and September 2022. Since the study involved the retrospective collection of anonymized data, ethics approval was waived.

The inclusion criteria were as follows: age ranged from 20 to 50 years, refractive error remaining stable for at least 2 years (change of < 0.5 diopters, D), anterior chamber depth (ACD) ≥ 2.8 mm, myopia ≥ 2 D, endothelial cell density (ECD) by age: 2800 cells/mm² from 20 to 25 years old, 2650 cells/mm² from 26 to 30 years old, 2400 cells/mm² from 31 to 35 years old, 2200 cells/mm² from 36 to 45 years old, and 2000 cells/mm² for patients older than 45 years^{19,20}; intraocular pressure (IOP) < 21 mmHg, post-operative follow-up of at least 1 month. The exclusion criteria were as follows: history of ocular surgery, ectatic diseases such as keratoconus, corneal opacities, retinal detachment, maculopathy, glaucoma, iridocorneal anomalies, or ocular inflammation.

All patients underwent a thorough preoperative ophthalmological examination. Pre-operative data included the steepest keratometry (K1), flattest keratometry (K2), ACD measured from the corneal endothelium to the anterior lens capsule, and central corneal thickness measured by Scheimpflug corneal topography (Pentacam HR; Oculus Optikgeräte GmbH); IOP, using a non-contact tonometer (Topcon CT-80 NCT®; Topcon Medical Systems); the horizontal white to white distance (WTW) assessed with a combined Slit-scanning Placid System (Orbscan III; Bausch and Lomb Rochester, New York, USA). Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were measured using a Snellen decimal chart, posteriorly converted to logMAR scale, and spherical and

cylindrical manifest refraction were recorded. The central corneal ECD was determined using a non-contact specular microscope (SP-3000P Topcom; Tokyo, Japan), as the mean value of three reliable consecutive measurements.

All patients had a Visian ICL with a central port design (V4c and V5 models) implanted, targeting emmetropia. Appropriate lens sizing and power calculation of the ICL was performed using the manufacturer's modified vertex formula. A toric ICL was implanted in eyes with a manifest cylinder greater than 1.00 D. All surgeries were performed under general anesthesia by experienced refractive surgeons, following the surgical procedure previously described in the literature.¹⁴ For the toric cases, the horizontal meridian limbal reference was marked preoperatively, with a pendulum marker in an upright position; and the proper implantation axis intraoperatively with a Mendez gauge. All ICLs were inserted through a temporal limbal incision and positioned into the ciliary sulcus. Corneal 3 mm incisions were closed with corneal stromal hydration, without sutures.

A methodical postoperative examination was performed. The following outcome measures were evaluated at 6 months after surgery: UDVA; CDVA; spherical and cylindrical manifest refraction; spherical equivalent (SE); central corneal ECD; IOP and central vault - the central distance between the ICL and the crystalline lens, measured perpendicular to the lens apex or at the narrowest point, using anterior chamber optical coherence tomography (Visante, Carl Zeiss Meditec AG, Jena, Germany). Under pharmacological mydriasis, postoperative lens position was assessed for possible lens rotation or misalignment. Any adverse events and secondary surgeries were reported. The safety index was calculated as the ratio between postoperative and preoperative CDVA, and the efficacy index as the ratio between postoperative UDVA and preoperative CDVA. Predictability, IOP changes, ECD changes, and postoperative mean central vault were calculated. Regarding adverse effects and potential complications, the follow-up considered was the longest available for each eye.

Data analysis was made using Statistical Package for the Social Sciences (SPSS) software version 16.0 (SPSS, Inc., Chicago, USA). Kolmogorov-Smirnov test was used to check for variables' normality. The Wilcoxon test was used to compare preoperative and postoperative data. A *p* value less than 0.05 was considered statistically significant.

RESULTS

Eighty-five eyes of 48 patients who had ICL implanted were included in the study. Mean age was 33.25±7.23 (20-49) and 70.8% were female. Preoperative manifest spherical equivalent (SE) was -9.74±3.61 D (-3.00 to -19.13 D), and cylinder was -2.04±1.16 D (-0.25 to -6.00 D). The mean preoperative CDVA was 0.06±0.11 logMAR. **Table 1** shows patients' demographics and preoperative visual parameters. Twenty-three (27%) cases implanted an ICL V4c/V5 and 62 (73%) a Toric-ICL model. The distribution of the lens sizes implanted were: 13.7 mm in 2 eyes (2.4%), 13.2 mm in 54 eyes (63.5%),

Parameter	
Eyes/patients	85/48
Age (years), mean ± SD (range)	33.25 ± 7.23 (20 to 49)
Gender n(%)	
Female	34 (70.8)
Male	14 (29.2)
Manifest spherical equivalent (D), mean ± SD (range)	-9.74 ± 3.61 (-3.00 to -19.13)
Manifest sphere (D), mean ± SD (range)	-8.81 ± 3.57 (-2.00 to -19.00)
Manifest cylinder (D), mean ± SD (range)	-2.04 ± 1.16 (-0.25 to -6.00)
CDVA (logMAR), mean ± SD (range)	0.06 ± 0.11 (0.00 to 0.70)
Endothelial cell density (cells/mm ²), mean ± SD (range)	2575.92 ± 296.85 (2000 to 3200)
Intraocular pressure (mmHg), mean ± SD (range)	12.82 ± 1.59 (10 to 16)
Anterior chamber depth (mm), mean ± SD (range)	3.22 ± 0.18 (2.82 to 3.63)
White-to-White distance (mm), mean ± SD (range)	11.85 ± 0.35 (11.10-12.50)
K1 (D), mean ± SD (range)	42.46 ± 1.19 (40.40 to 45.50)
K2 (D), mean ± SD (range)	44.12 ± 1.23 (41.20 to 46.30)
Keratometric cylinder (D), mean ± SD (range)	1.64 ± 0.90 (0.00 to 4.50)

CDVA - corrected distance visual acuity

12.6 mm in 25 eyes (29.4%) and 12.1 mm in 4 eyes (4.7%). The mean follow-up time was 3.15±2.18 years (0.17-7.08 years). Eighteen eyes had a follow-up longer than 5 years.

Regarding visual acuity outcomes, in terms of safety, the mean postoperative CDVA was 0.01±0.02. The CDVA was 20/20 or better in 92.1% cases, and 20/25 or better in 96.8% of eyes (**Fig. 1A**). A significant increase was found from preoperative to postoperative CDVA (*p*=0.002). Lines were gained in 35.5%, 61.1% did not change from preoperative, and 3.4% lost lines. The mean number of CDVA lines gained was 0.70±0.38. The safety index was 1.10±0.20. **Fig. 2A** shows the CDVA Snellen line changes from preoperative to postoperative. In terms of efficacy, the mean postoperative UDVA was 0.04±0.08. The efficacy index was 1.03±0.22. Sixty percent of eyes achieved UDVA of 20/20 or better (**Fig. 1B**). **Fig. 2B** shows the Snellen line differences between postoperative UDVA and preoperative CDVA. Regarding predictability, 81.8% of eyes had a postoperative manifest SE within ±0.50 D of the intended target, 94.5% within ±1.00 D of the intended target. **Fig. 3** shows the achieved versus attempted SE after surgery. Postoperative manifest sphere was -0.03±0.62 and the manifest cylinder was -0.67±1.05. **Table 2** shows the clinical evaluation data from preoperative and postoperative.

Concerning the ECD, the postoperative mean ECD was 2496.44 ± 351.70 cells/mm² (range: 1700 to 3246 cells/mm²).

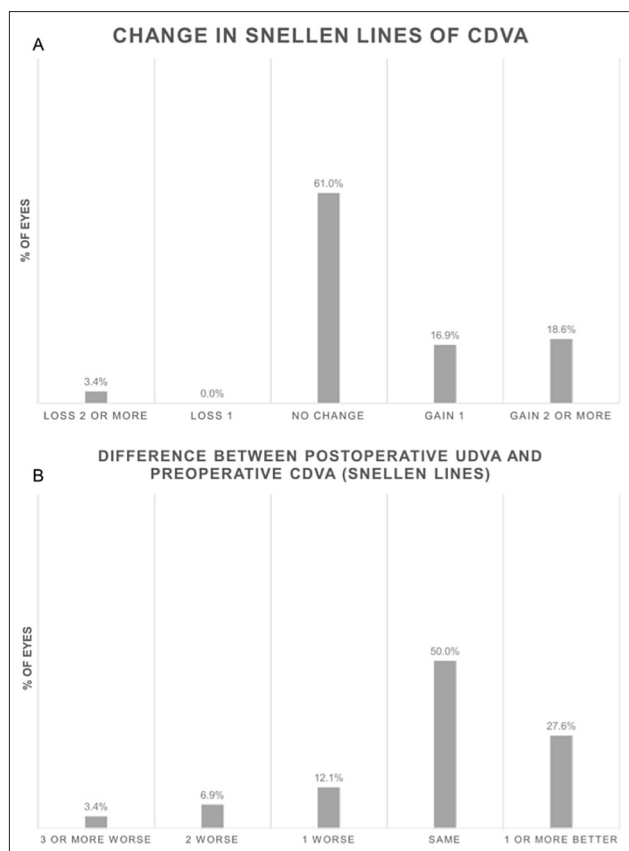


Figure 1. (A) Snellen line differences between postoperative corrected distance visual acuity (CDVA) and preoperative CDVA; (B) Snellen line differences between postoperative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA).

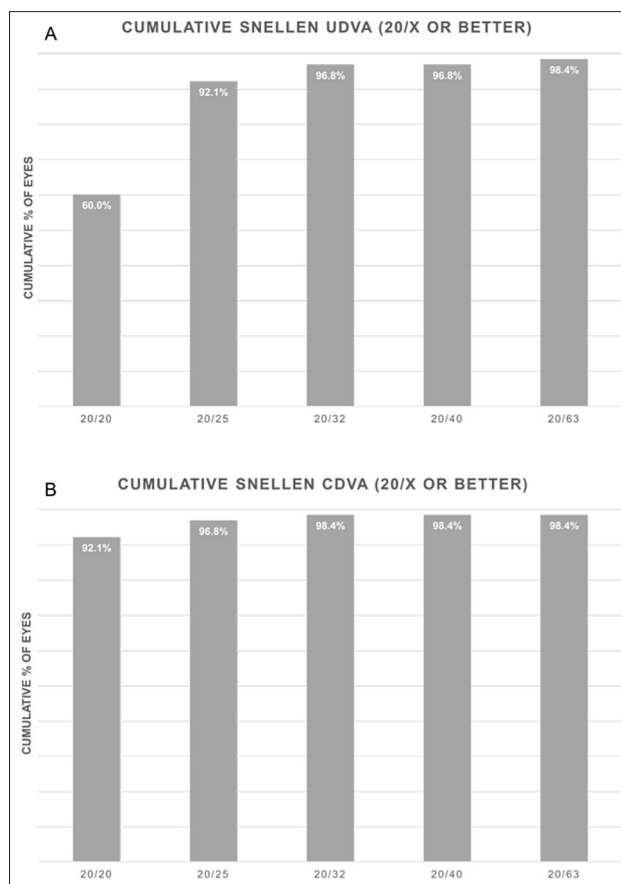


Figure 2. (A) Cumulative rates of eyes attaining 20/x or better levels of postoperative corrected distance visual acuity (CDVA); (B) Cumulative rates of eyes attaining 20/x or better levels of postoperative uncorrected distance visual acuity (CDVA).

Characteristic	Preoperative	Postoperative
UDVA (logMAR), mean \pm SD	-	0.05 \pm 0.11 (0.00 to 0.70)
CDVA (logMAR), mean \pm SD	0.05 \pm 0.11	0.01 \pm 0.02 (0.00 to 0.10)
Manifest spherical equivalent (D), mean \pm SD (range)	-9.74 \pm 3.61 (-3.00 to -19.13)	-0.19 \pm 0.46 (-1.75 to 0.75)
Manifest sphere (D), mean \pm SD (range)	-8.81 \pm 3.57 (-2.00 to -19.00)	-0.31 \pm 0.79 (-5 to 2)
Manifest cylinder (D), mean \pm SD (range)	-2.04 \pm 1.16 (-0.25 to -6.00)	-0.31 \pm 0.79 (-5 to 2)
Endothelial cell density (cells/mm ²), mean \pm SD (range)	2575.92 \pm 296.85 (2000 to 3200)	2496.44 \pm 351.70 (1700 to 3125)
Intraocular pressure (mmHg), mean \pm SD (range)	12.82 \pm 1.59 (10 to 16)	14.13 \pm 2.85 (10 to 22)

UDVA - uncorrected distance visual acuity; CDVA - corrected distance visual acuity

No significant decrease was observed from preoperative to postoperative ECD ($p=0.081$). The mean rate of ECD loss was $2.34\% \pm 11.43\%$ at 6 months. In the 4 eyes with a vault greater than $800 \mu\text{m}$, the mean ECD loss was $3.07\% \pm 2.01\%$.

During follow-up, mean IOP showed a statistically significant increase ($p < 0.001$). A reduction in IOP was observed in 13.6% of the eyes, in 29.5% the IOP did not change from the preoperative value and 27.3% experienced a 1-2 mmHg increase. A significant transient increase in IOP (> 20 mmHg or an increase higher than 5 mmHg) occurred in

18.2% at the 1 to 6-month postoperative visit, including 2 of the 4 eyes with a vault greater than $800 \mu\text{m}$.

The postoperative mean central vault was $524.06 \pm 185.71 \mu\text{m}$ at 6 months of follow-up. Mean central vault was $< 100 \mu\text{m}$ in 1 eye and 3 eyes showed a mean central vault $> 900 \mu\text{m}$. Table 3 shows the vault distribution.

As for adverse effects and complications, one case of intraocular inflammation was observed (preoperative ACD of 3.18 mm, WTW of 12.2 mm, with the implant of a 13.2 lens) diagnosed with post-ICL uveitis. One case of early post-

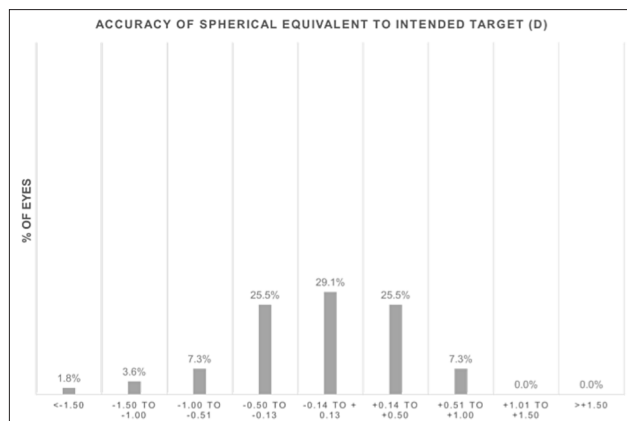


Figure 3. Distribution of the attempted versus achieved correction of manifest spherical equivalent.

Table 3. Vault Distribution.

Vault (μm)	n (%)
0-100	1 (1.2)
100-250	3 (3.5)
250-500	23 (27.1)
50-750	44 (51.8)
750-900	11 (12.9)
900-1000	2 (2.4)
>1000	1 (1.2)

operative acute angle closure glaucoma due to high vault (>1000) was reported (preoperative ACD of 3.10 mm, WTW of 12.0 mm, with the implant of a 13.2 lens). These two cases led to ICL explantation, at 3 months and 2 days postoperative, respectively. No other lens was later implanted in both eyes. There was one case of ICL exchange, due to significant axis rotation of a T-ICL model (preoperative ACD of 3.24, WTW of 11.8, with the implant of a 12.6 lens at 7 grades). At one-month postoperative ICL vault was 189 μm , with a significant rotation of the lens (25 degrees), which was exchanged for a 13.2 lens, with a postoperative vault of 435 μm and a final refraction of -0.50×170 . These three cases correspond to a global complications rate of 3.5%.

No intraoperative or severe postoperative complications occurred, such as hyphema, crystalline or cornea damage, macular oedema, endophthalmitis or retinal detachment. No case of corneal oedema, pupillary block or postoperative chronic hypertension was observed. No case of anterior subcapsular opacity nor postoperative cataract was reported. Two cases reported some degree of halos which improved over time.

DISCUSSION

The present study reports the visual and refractive outcomes of V4c/V5/T-ICL implantation for myopia and myopic astigmatism, showing considerable success of the

procedure, with both efficacy and safety index above 1.0. Moreover, our results report an almost insignificant ECD loss over the first months, as well as adverse event and complication rates.

The safety index was similar to those previously reported in various studies, and a significant increase was found from preoperative to postoperative CDVA.¹⁰⁻¹³ More than 96% of the eyes achieved a CDVA of 20/25 or better and more than 92% a CDVA of 20/20. These results confirm the safety of the procedure. The efficacy index was 1.03, which agrees with those previously reported.¹⁰⁻¹³ This result implies that the postoperative UDVA is equal to or better than preoperative CDVA. Our refractive outcomes also confirmed satisfactory predictability results. With 81.8% and 94.5% of eyes within ± 0.50 D and ± 1.00 D of the intended target, respectively, in agreement with previously reported findings.¹⁰⁻¹³ Postoperative manifest sphere was -0.03 ± 0.62 and the manifest cylinder was -0.67 ± 1.05 , highlighting a significant reduction in myopia and astigmatism. Mean spherical equivalent (SE) decreased from -9.74 D preoperatively to -0.19 D postoperatively, emphasizing the excellent refractive results of this procedure.

Our results did not reveal a statistically significant change in ECD, which agrees with several published literature, showing that the ICL does not induce a significant ECD loss over time.^{11,14-16} In the 4 eyes with a vault greater than 800 μm , a slightly superior ECD loss rate was observed, as expected. Knowing that excessively high vault values increase the risk of ECD loss,¹⁷ high vault should be avoided and corrected.

Regarding IOP, the central hole offers surgical advantages, sparing the need of preoperative iridotomy or intraoperative iridectomy, to prevent IOP increase related to pupillary block or chronic pigment dispersion.⁶⁻⁸ In our study, no complication as such was reported, corroborating previous findings. Despite the statistically significant increase, from mean preoperative IOP of 12.82 to 14.13 mmHg postoperative, it did not represent a clinically significant increase. From the 4 eyes with vault greater than 800 μm , 2 had a transient postoperative IOP of more than 20 mmHg or an increase higher than 5 mmHg, but both cases were successfully controlled with mono anti-glaucoma therapy within one week after starting the treatment. We believe the transient IOP rise might also be explained by iris manipulation, pigment dispersion or reminiscence of ophthalmic viscosurgical devices. Former studies showed that there is no significant IOP variation from 1 month postoperative onwards, associated with ICL V4c/V5 implantation.^{8,11,13} Analyzing the entire follow-up interval available for each eye, no chronic hypertension was reported.

The opacity development and incidence of cataract was lower than the reported in literature.^{1,4,6,16,18} That might be partly explained by our mean follow-up interval of 3.15 ± 2.18 years, which is shorter than some studies, and shorter than the expected mean time-interval of lens opacity and cataract development.¹¹ However, even in the 18 eyes with a follow-up greater than 5 years, no case of cataract and lens opacity was developed. One of the main risk factors associated with

developing anterior capsular cataract with ICL models is a low vault such as 200 μm or less,¹¹ and in our study only one eye had such vault. These findings might also corroborate the impact of the central hole of the ICL model on preventing cataract development, since it allows the circulation of the aqueous humor, reducing the risk of lens malnutrition.^{19,20}

The case of ICL explantation due to early postoperative high vault, represented a case of inadequate lens sizing, since the ICL implanted was the one recommended. It may be explained by either imprecise preoperative measurements or inaccuracy in the manufacturers' modified vertex formula. The case of post-ICL uveitis occurred in a patient with autoimmune medical history, and was successfully controlled with oral corticosteroids after the ICL explantation. The case of a T-ICL exchange due to significant axis rotation, might have been influenced by the relatively low vault of 189 μm . The use of an intraoperative OCT might be of great value to help determining the lens vault intraoperatively, allowing us to avoid both excessive and very low vaults.

The strengths of our study included good sample size, comprehensive and consistent clinical examination, and regular protocol. The limitations of our study included a retrospective design and variable follow-up. The visual and refractive outcomes have been proved to remain stable from one-month after surgery on, so our data collection at 1-6month postoperative was reasonable.^{2,11,14,15} The same has been proved to IOP over time¹¹. However, follow-up of more than 5 years is crucial for evaluating potential complications and adverse effects (such as ECD loss, cataract formation) associated with ICL, since their rate increases with time.¹¹ In our study, only 18 of eyes had a follow up longer than 5 years, so larger prospective studies are recommended.

The use of intraoperative OCT might also represent a great tool to prevent potential complications related to inadequate vault, as it allows to measure the vault intraoperatively. In cases of extreme intraoperative vault, the ICL could be rotated during the same surgical procedure so future studies using intraoperative OCT would be interesting.

CONCLUSION

It has been previously demonstrated that ICL implantation is a safe and stable procedure for myopia and myopic astigmatism correction. In our study, ICL implantation achieved excellent visual and refractive outcomes, with safety, efficacy and predictability comparable to literature. Our safety profile was very good, highlighting the importance of a precise lens sizing, and the advantage of the central-hole in V4c and V5 ICL models.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO:

BC: Responsible for gathering the data, presenting the results, and creating the manuscript.

EL: Contributed for the data collection.

DHF: Responsible for the statistical analysis.

PG, SC, VM, NA, JF: Supervised this project and contributed with their expertise to its conclusion.

All the authors read and approved the final manuscript. All the authors had full access to all the data and take full responsibility for the integrity of the data and the accuracy of the data analysis; all were responsible for conceiving this research.

RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

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Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2013 e da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

ETHICAL DISCLOSURES

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of data from patients.

Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2013).

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