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ORIGINAL RESEARCH

Evaluating the Predictive Accuracy of an AI-Based Tool for Postoperative Vault Estimation in Phakic Intraocular Lens Implantation

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Introduction: Phakic intraocular lenses are widely used for refractive error correction, with the EVO ICL delivering excellent visual outcomes. Achieving an optimal postoperative vault is critical to minimize complications. The purpose of this study was to evaluate the predictive accuracy of an AI-based tool that integrates high-resolution ultrasound biomicroscopy (UBM) imaging with biometric data, for estimating postoperative vault in myopic patients.

Settings: The study was performed at four centers: Instituto Zaldivar (Argentina), Wellington Eye Clinic (Ireland), Medipolis Eye Center (Belgium), and Asian Eye Institute (Philippines).

Methods: In this retrospective, multicenter study, 347 eyes from 228 myopic patients (mean age 31.3 ± 7.7 years) underwent ICL implantation. Preoperative biometric parameters and UBM imaging were utilized to generate vault predictions using the AI-based tool. Predicted vault values were compared with clinical measurements obtained at 1 day and 1 month postoperatively. Statistical analyses, including Spearman correlation and multivariable linear regression, were conducted to assess the agreement between predicted and measured vaults and to identify significant predictive factors.

Results: At 1 day postoperatively, the mean clinical vault was 520.97 ± 178.73 μm versus a predicted vault of 508.16 ± 163.00 μm, with a mean signed difference of −12.81 μm (r^2=0.621, $p<0.001$). Subgroup analyses across the four centers demonstrated stable predictions, with no significant inter-center differences in either clinical or predicted vault measurements ($p>0.05$). Multivariable regression identified ARise and spherical power as significant predictors of vault discrepancy, with uniform effects across diverse populations.

Conclusion: The ICLGuru™ reliably predicts postoperative vault with clinically acceptable accuracy. These findings underscore the generalizability and reliable performance of the AI-based tool across varied clinical settings. Its integration into preoperative planning may enhance ICL sizing and reduce complications in myopic patients.

Plain Language Summary: Phakic intraocular Collamer lenses (ICLs) are special lenses implanted in the eye to correct vision problems like nearsightedness. Choosing the right size is crucial to ensure the lens fits well and does not cause complications. Doctors currently use different methods to estimate the best lens size, but these are not always perfect.

This study tested a new artificial intelligence (AI) tool that predicts how much space (or "vault") will be left between the implanted lens and the eye's natural structures after surgery. The aim is to know if this tool could accurately estimate the vault before surgery, helping doctors choose the right lens size.

To find out, 347 eyes from 228 patients who had ICL surgery in four different eye clinics around the world were analyzed. The AI tool used high-resolution ultrasound images and biometric data (measurements of the eye) to predict the vault. These predictions were then compared with actual vault measurements taken after surgery.

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The results showed that the AI-based tool was highly accurate, with only a small difference between predicted and actual vault values. The tool worked well across different patient groups and clinic locations. The study also identified factors, such as the shape of the eye, that slightly affected prediction accuracy.

These findings suggest that AI can help eye surgeons make better decisions about lens sizing, potentially reducing the risk of complications and improving surgical outcomes for patients.

Keywords: phakic intraocular lens, implantable collamer lens, lens size, vault, artificial intelligence

Introduction

Phakic intraocular lenses have gained increasing popularity worldwide as an excellent surgical option to correct refractive errors. One type of posterior chamber phakic intraocular lens is the EVO Implantable Collamer Lens (ICL, Staar Surgical, Monrovia, CA). The number of ICL implantations has risen considerably, accompanied by a growing body of literature assessing their outcomes for correcting myopia and myopic astigmatism.[1] Beyond the many studies focusing on refractive and visual outcomes, an important area of research has centered on optimal ICL sizing to maintain a safe vault and minimize complications. In this sense, some publications have explored nomograms and planning methods for predicting vault and size selection.[1,2] Different methods, including those based on white-to-white (WTW), sulcus-to-sulcus (STS), ciliary body inner diameter (CBID), and angle-to-angle (ATA) for predicting vault and selecting ICL size produce acceptable outcomes.[1,2] Nomograms are a valuable tool in deciding the best ICL size and are based on several preoperative measurements that are not universally agreed upon as necessary.[3]

Artificial intelligence (AI) techniques are already well established in intraocular lens power calculation, where data-driven formulas such as Hill-RBF, Kane, PEARL-DGS and other neural-network or gradient-boosting models consistently outperform or equal state-of-the-art theoretical formulas, especially in challenging biometry (eg, very short or long eyes).[4–6] AI technology has also been used during the last years in ophthalmology to diagnose eye diseases such as glaucoma, diabetic retinopathy and age-related macular degeneration. AI and machine learning (ML), a subset of AI that automatically enables a machine or system to learn and improve from experience, have been also applied recently to understand which factors may affect postoperative vault and used to help for choosing the size of the lens. Both traditional statistical models and these new approaches have been used in the development of nomograms, and each has their strengths and weaknesses.[3] Some recent papers have applied this technology to improve the outcomes of this refractive procedure.[7–22] It has been indicated that AI has allowed significant advancements in sizing predictability and ML algorithms analyze large amount of data to find patterns contributing to optimal sizing.[21] The performance of ML-based models has been proved to be significantly superior to that of the conventional linear regression model.[18] This technology, therefore, can be used to predict ICL size and postoperative vault more accurately, assisting surgeons in choosing optimal ICL size to reduce postoperative complications.

Taken into account that accurate sizing is mandatory to maintaining a safe vault and achieving a successful ICL implantation procedure, in the present study, we have evaluated the predictive accuracy of an AI-based tool for postoperative vault estimation after ICL implantation in a cohort of myopic patients.

Methods

This retrospective study evaluates the predictive capabilities of an AI-based tool for estimating the vault of ICLs based on biometric parameters and the application of a proprietary algorithm. The methodology focuses on the integration of advanced Ultrasound Biomicroscopy (UBM) imaging with AI to ensure precise and personalized surgical planning.

This study included 348 eyes from 228 patients (mean age of 31.2±8.0 years old, ranging from 18 to 59) with myopia and astigmatism (76 male and 152 female) who were implanted with an ICL for myopia at one of 4 institutions: Instituto Zaldivar (Mendoza, Argentina), Wellington Eye Clinic (Dublin, Ireland), Medipolis Eye Center (Antwerpen, Belgium), and Asian Eye Institute (Makati City, Philippines). In all participating centers, the EVO Visian ICL (model V4c) is licensed for patients 18 years old and above, and national regulators permit its use in this age group. To address concerns regarding refractive stability in younger eyes, documented spherical-equivalent change ≤0.50 D during the 12 months

Table 1 Descriptive Statistics of the Sample Analyzed

	Zaldivar Institute		Wellington Eye Center		Medipolis Med. Res. Inst.		Asian Eye Institute		p-value
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	
Age (years)	32.08 ± 6.92	19–51	31.81 ± 8.88	19–59	32.43 ± 9.12	18–51	27.90 ± 7.15	19–48	0.005
ACD (mm)	3.11 ± 0.24	2.58–3.77	3.25 ± 0.26	2.81–3.79	3.24 ± 0.24	2.80–3.84	3.02 ± 0.13	2.80–3.28	<0.001
ATA (mm)	10.98 ± 0.56	9.40–12.43	12.02 ± 0.43	10.92–12.95	11.14 ± 0.48	9.87–12.03	11.28 ± 0.33	10.57–11.89	<0.001
Arise (mm)	−0.02 ± 0.14	−0.36–0.45	0.52 ± 0.16	0.02–0.82	0.05 ± 0.19	−0.56–0.41	0.16 ± 0.13	−0.14–0.41	<0.001
WTW (mm)	12.17 ± 0.42	11.2–13.43	11.90 ± 0.45	10.50–12.74	11.79 ± 0.56	9.45–12.48	11.55 ± 2.26	11.1–11.96	<0.001
Preop CDVA (LogMAR)	0.13 ± 0.20	0.00–1.00	−0.02 ± 0.12	−0.11–0.40	0.01 ± 0.04	−0.10–0.20	−0.02 ± 0.06	−0.30–0.00	<0.001
ICL Sphere Power (D)	−9.66 ± 3.63	−1.25 to −18.0	−8.77 ± 2.71	−3.00 to 17.00	−7.10 ± 2.43	−13.00 to −2.00	−9.08 ± 3.27	−18.00 to −3.00	<0.001
ICL Cylinder Power (D)	0.55 ± 1.17	0.00–6.50	1.42 ± 1.60	0.00–6.00	1.22 ± 1.59	0.00–6.00	1.90 ± 1.48	0.00–6.00	<0.001

Abbreviations: SD, standard deviation; ACD, anterior chamber depth; Arise, anterior rise; ATA, angle-to-angle; WTW, white-to-white; CDVA, corrected distance visual acuity; ICL, implantable Collamer lens.

preceding surgery was required, a threshold aligned with current consensus recommendations for phakic IOL implantation. Descriptive statistics of the sample are summarized in Table 1. Inclusion criteria considered patients submitted to successful ICL surgery for myopia, with or without associated astigmatism. Patients with previous eye surgeries were not included in the analysis.

Preoperative measures considered in the analysis included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction spherical equivalent (MRSE), slit-lamp biomicroscopy, and intraocular pressure measurement.

Implantable Collamer Lens

The Visian ICL V4c model for the correction myopia was used. A toric ICL and Bioptic technique (either sequential or delayed) was applied in cases with significant astigmatism. All ICLs in the analyzed sample were implanted along the horizontal axis. The Visian ICL is a phakic intraocular lens composed of Collamer, a flexible, hydrophilic, and biocompatible material with a plate-haptic design and a central convex/concave optical zone. The foldable nature of the ICL facilitates its insertion into the posterior chamber through a 3.5 mm incision or smaller. Once correctly positioned, the ICL resides entirely within the posterior chamber, situated between the iris and the crystalline lens, with support on the ciliary sulcus. The V4c model incorporates a central perforation (0.36 mm diameter) designed to enhance aqueous humor flow and minimize the risk of secondary cataract development.

Surgical Procedure

All procedures were performed under topical anesthesia by one experienced surgeon at each of the clinics (RZ, AC, EM and RA). In toric ICL cases, a technician marked the proper axis at the slit lamp in the operating room. A 3.2-mm temporal main incision and a single paracentesis (at either 8 or 2 o'clock) were created for pharmacological administration. Intracameral phenylephrine 1.5% and lidocaine 1% were injected to facilitate pupil dilation and pain control. An ophthalmic viscosurgical device (OVD) (Ocucoat®, 2% hydroxypropyl methylcellulose; Bausch&Lomb) and the ICL were then introduced into the anterior chamber using the manufacturer's injector cartridge. Additional OVD was applied before positioning the four haptics beneath the iris through the main incision with the aid of the Zaldivar ICL Manipulator® (Asico LLC, Westmont, IL, USA). The OVD was subsequently removed using coaxial irrigation/aspiration, and 2% moxifloxacin was injected intracamerally. The incisions were gently hydrated, and intracameral miotics were not administered. Postoperatively, a single oral dose of 250 mg acetazolamide was given to reduce intraocular pressure. Topical treatment with moxifloxacin 5 mg/mL (Vigamox®), prednisolone acetate 10 mg/mL (Pred Forte®), and nepafenac 1 mg/mL (Nevanac®) was prescribed four times daily for one week and then tapered over one month. Topical brimonidine 0.2% (Alphagan®P) was also administered twice daily for one month.

In eyes with with-the-rule astigmatism ≤0.75 D, we placed the primary phaco/ICL tunnel incision on the steep corneal meridian without additional relaxing cuts. When WTR astigmatism measured 1.0–1.5 D, a single 5.5 mm limbal-relaxing incision (LRI) was added on that same steep meridian. For against-the-rule astigmatism up to 0.5 D, the tunnel incision alone was used on the steep axis; if ATR astigmatism was 0.5–1.0 D, we performed a 5.5 mm LRI at the steep meridian; and for ATR >1.0 D a toric ICL was selected. All LRIs were centered on the steepest axis as mapped by preoperative corneal topography.

Software and Image Acquisition

AI-Based Tool Overview

ICLGuru is a state-of-the-art software tool developed to optimize ICL size selection for refractive surgery. It leverages biometric data extracted from optimized and qualified UBM images, AI algorithms, and mathematical models to predict the central and peripheral vault of the ICL, as well as the residual iridocorneal nasal and temporal angle, ensuring a personalized and anatomically appropriate fit.

UBM Imaging Protocol

The VuMAX HD ophthalmic ultrasound system (Sonomed Escalon, NY, USA) was employed to obtain detailed visualization of the anterior segment of the eye, including all the relevant structures critical for ICL placement and vault estimation. The instrument allows to obtain standardized images through many different software features. The Eye-Tracking guides the practitioner to produce well-aligned images with visual intuitive aids, also assigning a score for each frame. This score permits to apply a configurable filter to define the minimal alignment requirements to obtain reliable predictions. It also detects the pupil size of each frame to avoid the off centers scans which will provide smaller sizes than the ideal horizontal meridional ones. Finally, it incorporates a DLL defined by Guru which analyzes each frame in advance to make sure the final calculation is doable. All images were acquired under standardized conditions and automatically processed to ensure consistency in quality and alignment.

Image Quality Requirements

The UBM images used in this study were automatically filtered using a Dynamic Link Library (DLL) that analyzes each frame beforehand to ensure it meets quality standards and that the final calculation can be performed successfully. The filtering process adheres to the following criteria:

1. Sharpness: clear delineation of ocular structures.
2. Alignment: proper representation of anatomical positions.
3. Consistency: a sequence of images maintaining temporal coherence.

Data Processing and Filtering

Image Selection

The UBM image sequences per patient ranged from 7 to 50 frames, ensuring multiple acquisitions for accurate analysis. An automated filtering algorithm was used to exclude images with: a) Low Visibility of Key Structures, that is frames where critical anatomical landmarks (such as corneal apex, sulcus, or ciliary body) were unclear; b) Artifacts or misalignments, ie images compromised by noise, blurring, or improper alignment. This automatized filtering process enhanced the reliability of the biometric data, reducing computational noise and ensuring precision in parameter extraction.

Biometric Parameter Extraction

The core analysis began with the segmentation of key anatomical structures in the filtered UBM images. These included:

- Corneal Apex and Root: Indicators of space available for the ICL.
- Iridocorneal Angle: Measures the anterior chamber's width.
- Crystalline Lens Rise: Key determinant of lens interaction.
- Ciliary Body and Zonules: Stability markers for lens positioning.

Each structure was characterized based on dimensions, symmetry, and relationships to surrounding anatomy. These parameters were inputs for the software's predictive algorithm.

Algorithm for Vault Prediction

The AI-based tool employs a dual-algorithm approach consisting of a Vault Estimation Algorithm and a Safety Band Calculation Algorithm. The Vault Estimation Algorithm predicts both the central vault, defined as the distance between the ICL and the crystalline lens along the optical axis, and the peripheral vault, referring to the separation between the ICL and the lens in more peripheral zones, specifically the limit of the optical zone of the lens, which happens to be its thickest part. The Safety Band Calculation Algorithm generates safety bands (red, yellow, green, blue, magenta) that categorize vault predictions by risk level, based on published data,[23,24] thereby aiding clinical decision-making.

Outcome Measures

Predicted Vault and Residual Iridocorneal Angles

The primary outcome was the prediction of the central and peripheral vault values, with these metrics being validated against postoperative UBM measurements.

Risk Categorization

Vault predictions were classified into safety bands to assess the clinical relevance and surgical risk of the proposed ICL size:

- Red: High risk of contact with the crystalline lens (cataractogenic risk) – Central or peripheral vault lower than 50 µm.
- Yellow: Low vault, acceptable – Central and peripheral vault between 50 and 150 µm.
- Green: Ideal vault, optimal outcome – Central and peripheral vault above 150 µm and residual iridocorneal angle above 20 degrees.
- Blue: Elevated vault, safe – Vault above 850 µm or residual iridocorneal angle between 15 and 20 degrees.
- Magenta: Excessive vault, risk of iris interaction – Residual iridocorneal angle below 15 degrees.

Statistical Analysis

A priori power analysis, based on the observed standard deviation of the absolute vault-prediction error (0.12 mm), showed that 89 eyes would suffice to estimate the mean error within ± 0.025 mm at the 95% confidence level; the sample analyzed here provides therefore ample statistical power.

The predictive accuracy of AI-based tool was evaluated by comparing central preoperative predictions with post-operative OCT-measured vaults. Discrepancies were analyzed to identify potential areas for algorithm improvement. Descriptive statistics were used to summarize the biometric data and vault predictions. Bland-Altman plots and correlation coefficients were employed to assess agreement between predicted and actual vault measurements. Independent samples *t*-tests were used to determine differences between the values obtained in the different clinics. Safety band distributions were analyzed to determine the tool's predictive reliability in a clinical context.

Results

A total of 347 eyes from 228 patients (65.4% female, 34.6% male) were analyzed, with a mean age of 31.3±7.7 years (range: 18–59). All eyes underwent phakic ICL implantation for the correction of myopia and myopic astigmatism at one of four centers (Instituto Zaldivar, Wellington Eye Clinic, Medipolis Eye Center, and Asian Eye Institute). The most commonly used ICL sizes were 12.60 mm (47.3%) and 13.20 mm (40.9%), with smaller proportions receiving 12.10 mm (7.8%) or 13.70 mm (4.0%). The mean spherical power of the implanted lenses was −8.96 ± 3.26 D, whereas the cylindrical power ranged from 0.00 D to 6.50 D.

Figure 1 illustrates the cumulative histogram of preoperative CDVA and postoperative UCVA, demonstrating that all surgeries were considered successful, with most eyes gaining lines of CDVA compared to their preoperative manifest spectacle-corrected CDVA (Figure 2).

Postoperative Vault Measurements and ICL Guru Predictions

At 1 day postoperatively, the mean clinically measured vault was 520.97±178.73 µm (range: 112–1360 µm). The AI-based tool predicted a mean vault of 508.16±163.00 µm (range: 143–1183 µm). The overall mean signed difference (predicted minus actual) was −12.81±142.25 µm, indicating that, on average, the predictions were slightly lower than the measured vaults. Among 291 eyes with available 1-month follow-up data, the mean measured vault decreased to 484.81±233.43 µm (range: 166–1031 µm), while the mean difference from the AI prediction at that time was 24.95±113.51 µm. Key biometric and refractive parameters exhibited moderate variability (Table 1). Kolmogorov–Smirnov tests indicated that most continuous variables deviated from normality ($p<0.05$), with the exception of the 1-day vault measurements ($p=0.200$), justifying the use of nonparametric tests.

Correlation Analyses

A Spearman correlation (nonparametric) revealed a strong positive relationship between the AI-predicted vault and the 1-day postoperative vault ($r^2=0.621$, $p<0.001$).

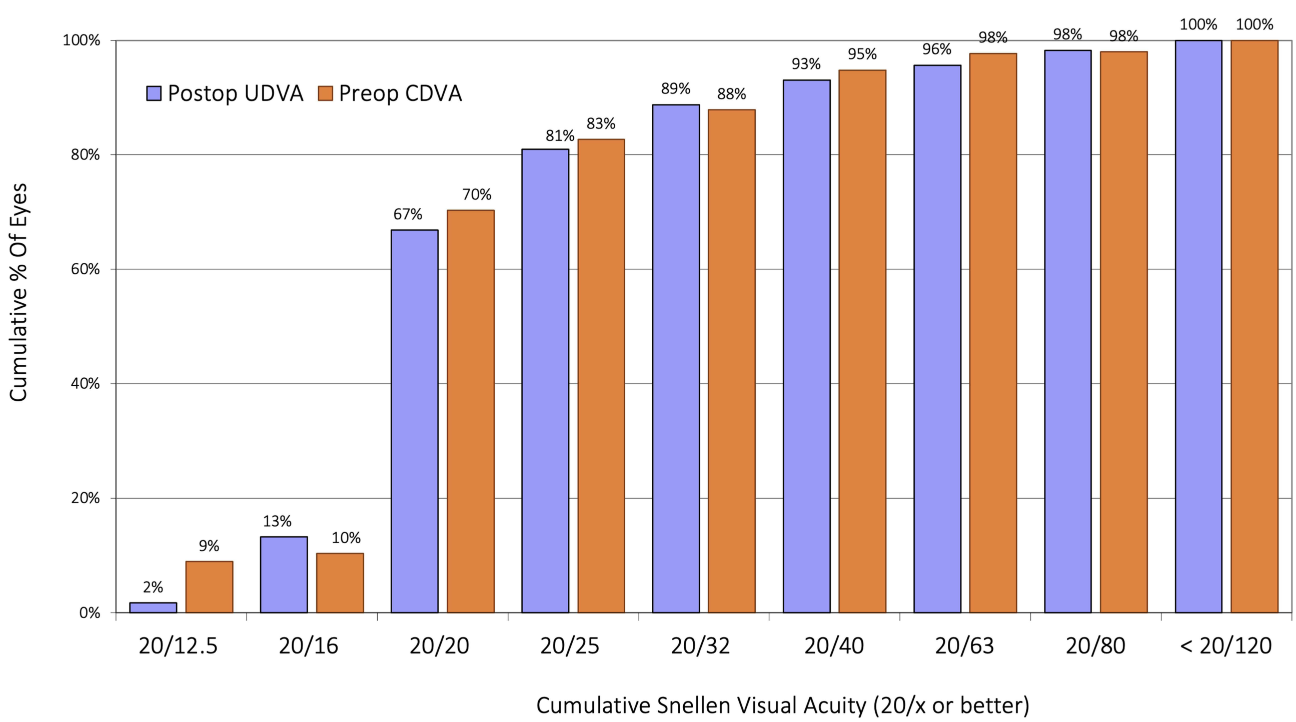

Figure 1 Cumulative histogram of preoperative corrected distance visual acuity (CDVA) and postoperative uncorrected distance visual acuity (UCVA).

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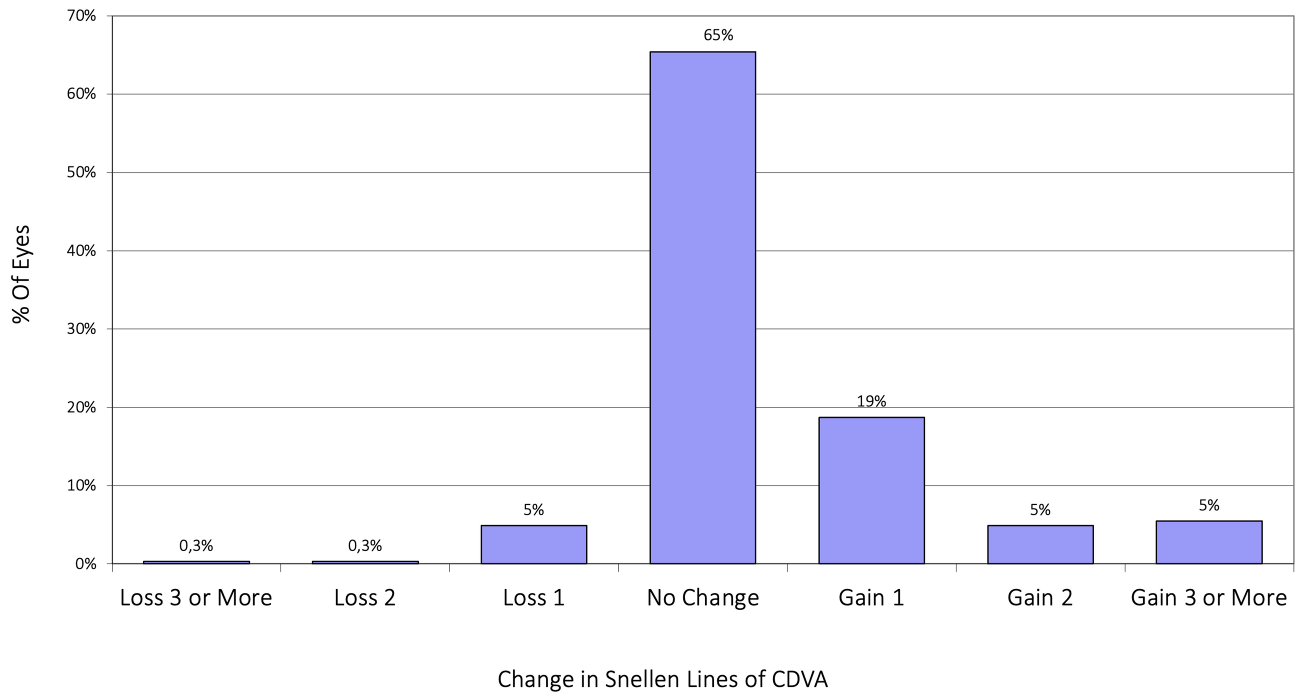

Figure 2 Change of Snellen of corrected distance visual acuity (CDVA) between pre- and post-surgery.

For the subset of 291 eyes with 1-month vault data, the correlation remained moderate (r^2=0.530, p<0.001), suggesting that the AI-based prediction still retained explanatory power at later follow-up.

The correlation between the 1-day and 1-month clinically measured vaults was r^2=0.577 (p<0.001), indicating that eyes with higher or lower vaults on day 1 tended to maintain that relative position at 1 month, despite an overall decrease in mean vault over time. At 1 day postoperatively, the mean clinically measured vault was 520.97±178.73 µm (range: 112–1360 µm). The AI-based tool predicted a mean vault of 508.16±163.00 µm (range: 143–1183 µm), yielding an overall mean signed difference of −12.81 ± 142.25 µm.

The scatterplot (Figure 3), presenting the differences between the algorithm's predicted vault values (Y-axis) against the clinically measured vault values (X-axis), aimed at assessing agreement and potential bias, demonstrated that mean difference of ~13 µm. The coefficient of determination of 0.254 indicates that approximately 25.4% of the variability in the differences can be explained by the variability in the clinically measured vault values (Figure 3). Although the value is not particularly high, it suggests a weak linear relationship between the differences and the clinical vault values. This finding indicates the presence of a proportional bias, wherein the magnitude of the prediction error varies according to the size of the clinical vault. Consequently, the Guru algorithm does not maintain consistent predictive accuracy across the entire range of vault values. However, the error margins remain within a clinically acceptable range in most cases. More than half of cases, 186 eyes, showed a difference between predicted and actual value lower than 100 µm (53.45%), for 115 eyes (33.05%) the difference was between 100 and 200 µm mm, 33 eyes (9.48%) showed a difference between 200 and 300 µm, 11 eyes (3.16%) between 300 and 400 µm, and 3 eyes (0.86%) between 400 and 500 µm.

By 1 month postoperatively, among the 291 eyes with available follow-up data, the measured vault decreased to 484.81±233.43 µm (range: 166–1031 µm), while the mean difference from the AI prediction at that time was 24.95 ±113.51 µm. A subset analysis of eyes with 1-day vault measurements in the 250–750 µm window showed a mean absolute error similar to the full cohort, indicating that the algorithm is generally effective for selecting lens sizes that yield vaults in the desirable clinical range. A standard linear regression model was applied. The model was significant

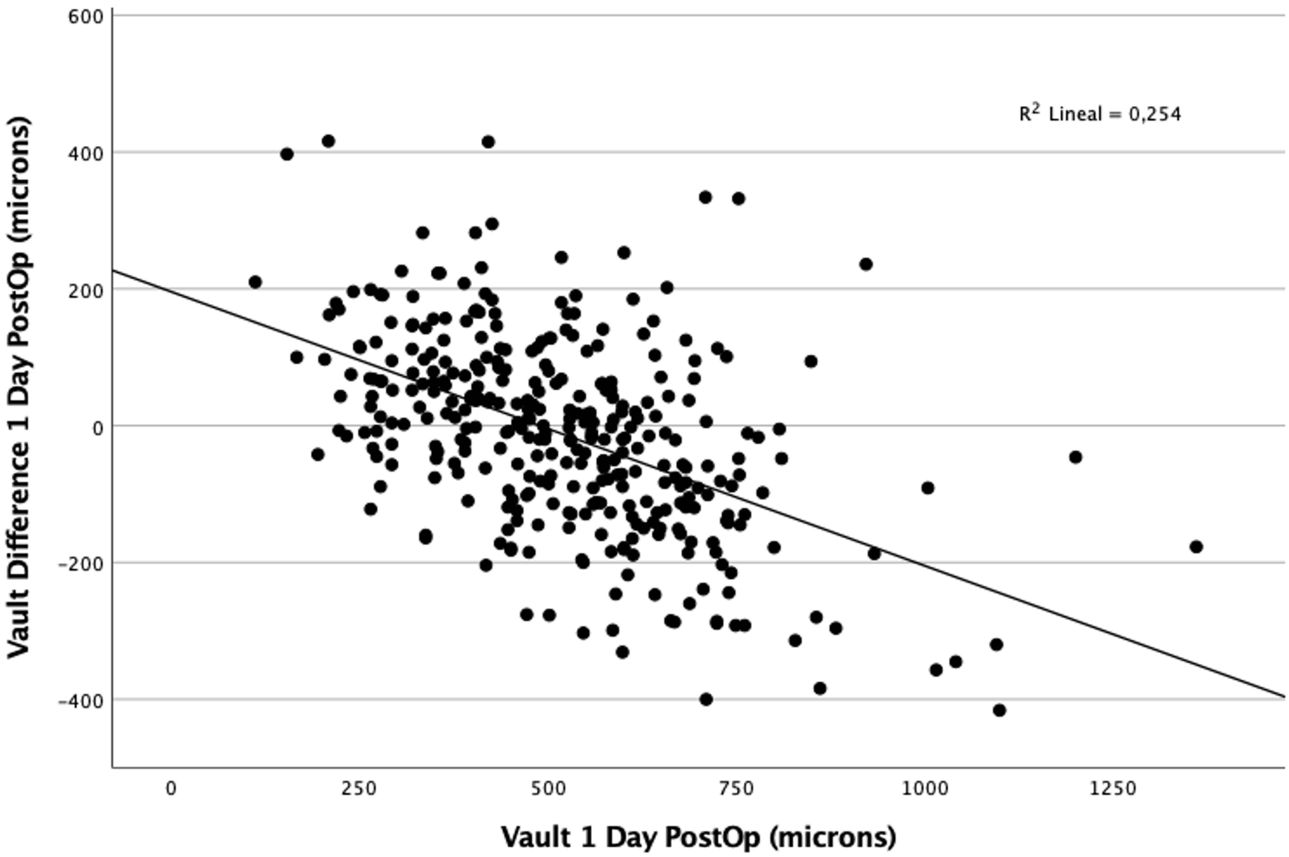

Figure 3 Scatterplot showing the differences between the algorithm's predicted vault values and the clinically obtained vault values (Y-axis) against the clinically measured vault values (X-axis).

overall ($p=0.006$), with an $r^2=0.093$ and an adjusted $r^2=0.054$, indicating that approximately 9.3% of the variance in the 1-day vault was explained by these factors. Two predictors emerged as significant:

- Arise ($\beta=-104.514\pm42.153$, $p=0.014$): A higher anterior rise (as measured by UBM) was associated with a more negative vault discrepancy, suggesting overestimation of vault in eyes with lower ARise values.
- Spherical Power ($\beta=6.407\pm3.090$, $p=0.039$): Each additional diopter of spherical correction predicted a modest (~6.4 µm) increase in the discrepancy, indicating that higher myopic corrections might require finer adjustments for optimal vault prediction.

These findings highlight that specific anatomic (ARise) and refractive (spherical power) factors might affect prediction accuracy and could be considered for refining the AI model.

Inter-Center Comparisons

As displayed in Table 1, Kruskal–Wallis tests showed statistically significant differences in biometric and preoperative visual acuity parameters among the four centers ($p<0.05$), reflecting variability in patient profiles or local practices. However, neither the 1-day vault nor the AI-predicted vault differed significantly across centers ($p>0.05$), suggesting that, overall, the algorithm's performance remained consistent. The signed discrepancy (predicted minus actual) varied modestly among centers ($p=0.023$), but the absolute error did not ($p=0.728$). Some centers tended to slightly over- or underestimate the vault on average, but no site had systematically larger errors. Figure 4 shows a boxplot of discrepancies by center, and displays the slight differences across centers.

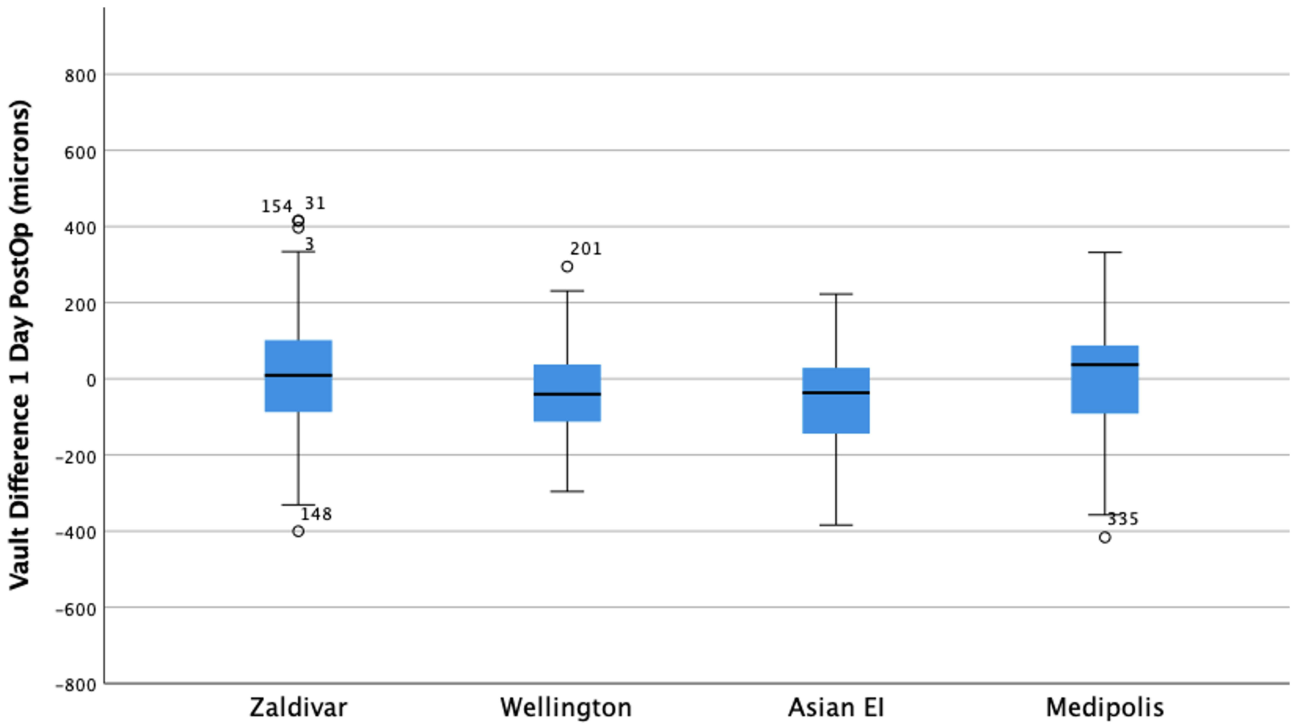

Figure 4 Boxplot of 1-Day Vault Difference (Predicted minus Clinical) for the different centers. The plot displays the median, interquartile range, and outliers of the vault discrepancy in microns.

Overall, the multicenter dataset confirms that AI-based tool's predictions correlate moderately well with actual postoperative vault measurements at day 1 (r^2=0.621). The mean signed error remains relatively small (~−13 µm at day 1), and error magnitudes in the vault range of 250–750 µm are comparable to the overall cohort. While certain biometric factors (eg, ARise, spherical power) significantly influence the discrepancy, the results support the clinically usefulness of ICL Guru for ICL sizing. Incorporating these additional predictors into future refinements of the AI algorithm might further enhance its accuracy and consistency across diverse patient populations and surgical centers.

Discussion

Modern refractive practice recognises that keratorefractive procedures and ICLs each occupy a well-defined niche. The ICL is considered an alternative to laser vision correction with excellent efficacy, safety, and patient outcomes.[25] Meta-analyses show that, within the –3 to –6 D range, uncorrected distance visual acuity and patient-reported outcomes are broadly comparable between modern LASIK and ICL, while the phakic lens may yield better contrast sensitivity and induce fewer higher-order aberrations,[26] although at the cost of intraocular surgical risk and the need for lifelong vault surveillance.

It has been shown that ICL implantation induces significantly fewer ocular higher-order aberrations than wavefront-guided LASIK,[27] and changes in corneal structure may affect the optical and visual performance.[28–30] Wavefront aberrometers may be used to establish higher order aberrations prior to refractive surgical techniques, and appropriate interpretation of their output is critical to successful surgical outcomes.[31] The present study investigates whether an AI-guided sizing model can enhance safety and predictability when an ICL is already the selected modality. The use of ICL for correcting refractive errors has increased during last years, and there has been a consistent increase in the number of original articles published on these lenses over the past two decades.[32] Over the past four years, the number of ICL publications has doubled, representing 43% of all related documents published in the last two decades.[32] These findings indicate that the current research interests are centered on the perioperative management and the safety and size selection of V4c ICL.[32] Then, the application of new technologies based on AI and ML are one of the hot topic interests in ICL research. Our study aimed to prove the accuracy of an AI-based tool for postoperative vault estimation after ICL implantation in a cohort of myopic patients and to help in the decision of the optical size in daily practice for refractive surgeons. Accurate vault estimation can reduce the incidence postoperative complications, thus improving the safety profile of ICL implantation.

It must be taken into account that all vault measurements in this study were taken under standard photopic illumination (≈300 lux). González-Lopez et al[33] demonstrated that "dynamic vaulting" in V4c ICLs can shift the lens-to-crystalline-lens distance by 30–80 µm between photopic and mesopic conditions, with the smallest gap occurring when the pupil dilates in dim light. Therefore, the present AI-based tool is predicting the photopic vault midpoint, not the full vault range. This limitation was mitigated in two ways: (i) by defining the optimal safety zone broadly (250–750µm), which already incorporates the expected physiologic excursion, and (ii) by flagging values <50 µm as "red-band" precisely because dynamic narrowing could bring the ICL into intermittent contact with the anterior capsule.

González-Lopez et al[33] have shown that long-term crystalline-lens clarity can be maintained even when the central-hole ICL vault remains well below 100 µm: in their 24-eye cohort (mean photopic vault 52 ± 19 µm, 5.8-year follow-up) only one eye (4.2%) developed anterior sub-capsular opacities, leading the authors to conclude that low vaulting, by itself, is not cataractogenic in the V4c model. The decision to flag vaults <50 µm as a "red-band" condition in the risk categorization by the AI-based tool is not meant to contradict that evidence but to provide a conservative safeguard: at this ultra-low separation the value approaches both the axial resolution of current anterior-segment OCT systems and the amplitude of potential vault fluctuations, so the recorded gap may intermittently fall to zero, allowing mechanical lens-ICL contact. The <50 µm threshold thus functions as an early-warning marker that prompts closer follow-up or elective lens exchange rather than asserting a proven cataract risk.

In contrast to other AI-based methods for ICL vault estimation that rely heavily on traditional imaging or limited user-based input, the one assessed in the present study integrates high-resolution ultrasound imaging with a proprietary algorithm to refine and personalize vault predictions. The present study is unique as it the first systematically evaluating this AI-based tool in a real-world clinical setting, thus extending the existing literature by offering a formal assessment of this specific tool. By using a sizeable cohort, consistent measurement protocols, and a multicentric design, this study demonstrates the software's robust performance across various ICL sizes and populations highlight how its outputs compare to actual postoperative vault measurements. While other AI and machine learning approaches to lens sizing exist, this is the first to validate ICLGuru for clinical use, shedding light on both its strengths and potential avenues for enhanced accuracy in routine practice.

Although a moderate linear association and proportional bias were observed, the prediction errors largely remained within acceptable limits. This finding is encouraging, as it suggests that the tool can reliably guide ICL sizing decisions in routine practice.

One notable aspect of the present analysis is the identification of specific biometric factors that influence prediction accuracy. In particular, parameters such as ARise and spherical power were found to have a significant impact on the vault discrepancy. These results imply that incorporating these factors could further refine its predictions, thereby improving the tool's performance in cases with extreme biometric values.

Despite inherent differences in patient demographics and preoperative measurements across the four centers, inter-center comparisons revealed consistent performance of the ICL Guru regarding vault predictions. Although some centers exhibited slight systematic differences in the signed vault discrepancy, the absolute error remained comparable across sites. This consistency reinforces the robustness of the tool and supports its generalizability in diverse clinical settings.

The relatively modest explanatory power of the regression model suggests that additional variables, possibly related to surgical technique, lens positioning, or other anatomical nuances, may further influence vault outcomes. Future research should aim to identify these factors, perhaps through more advanced modeling approaches or prospective studies, to enhance predictive accuracy.

In summary, the findings of the present multicenter study underscore the practical utility of ICLGuru for ICL vault estimation. Even so, several features invite further refinement. First, the aforementioned prediction under photopic conditions, whereas vault is known to vary dynamically with illumination and accommodation; integrating pupil-size metadata will allow forthcoming versions to output a physiologic vault range. Second, the work is retrospective; a prospective protocol is already in progress to verify these findings under real-time conditions. Third, although the cohort spans –3 to –20 D and three continents, it remains skewed toward young, highly myopic Asian eyes; planned multicentre recruitment in Europe and North America should balance the ethnic and refractive spectrum. Taken together, these limitations guide the next phase of validation rather than detract from the present evidence that the AI-based tool can markedly enhance ICL sizing accuracy.

While there is always room for refinement, the current performance indicates that the ICL Guru accurately predicts postoperative vault and, when coupled with standardized, high-resolution UBM imaging, offers a synergistic approach that can further refine ICL size selection and enhance safety. By integrating high-resolution UBM data with a readily deployable AI sizing tool, this work provides surgeons with a quantitative decision-support layer that can be applied chair-side, without altering the established imaging workflow. Continued research and prospective validation will be essential to further improve its accuracy and consistency, and confirm the model's generalizability, ultimately enhancing patient outcomes in phakic ICL implantation.

Data Sharing Statement

The datasets analyzed in the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

The study was conducted according to the tenets of the Declaration of Helsinki. This study was approved by the Institutional Review Boards of the centers participating in the study. Informed consent was obtained from all the patients prior to enrolment.

Author Contributions

All authors made substantial contributions to the conception and design, data acquisition, analysis and/or interpretation; took part in drafting the article or revising it critically for significant intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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Disclosure

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