


Comparison of Four Lens Power Formulas for Sutureless Scleral-Fixated Carlevale Lens

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Purpose: To assess the predictability of intraocular lens (IOL) power calculation formulas for sutureless scleral fixation (SSF) of the Carlevale IOL.

Methods: A prospective, single-center, interventional case series was conducted to compare predicted refractive outcomes using the SRK/T, Barrett II, Hoffer Q, and Holladay 1 formulas in patients undergoing SSF of the Carlevale IOL. The main outcomes included mean prediction error (PE), median absolute error (MedAE), mean absolute error (MAE), and the percentage of eyes with a PE within ± 0.50 and ± 1.0 diopters (D).

Results: Sixty-nine eyes of 69 patients were included. Only the Barrett II formula resulted in a systematic myopic error ($p=0.014$). The PE of SRK/T, HofferQ, and Holladay 1 was closer to 0, indicating that the post-operative refractive outcome was nearer to the predicted value than that of Barrett II ($p=0.002$, $p<0.001$, $p=0.003$, respectively). MedAE and MAE ranged from 0.41 to 0.53 D and 0.6 to 0.67 D, respectively, without significant differences between the formulas. The percentages of eyes with PE within ± 0.50 and ± 1.00 D varied from 47.8 to 56.5% and 79.7 to 87%, respectively, showing no significant differences across the assessed formulas.

Conclusion: The SRK/T, Hoffer Q, and Holladay 1 formulas provide favorable refractive outcomes for the SSF of Carlevale IOL. The Barrett II formula is less accurate and is not recommended due to its systematic myopic refractive error.

Keywords: Carlevale IOL, sutureless scleral fixation, IOL power formula, refractive results, refractive prediction error

Introduction

There is no clear evidence of the optimal intraocular lens (IOL) implantation technique in the absence of capsular support,¹ though sulcus implantation is gaining traction.² In fact, the use of this technique for secondary IOL implantation has risen from 7% in 2015 to 64% in 2021.² Sutureless methods have emerged to mitigate long-term suture complications.

The recently introduced Carlevale IOL,³ a sutureless scleral-fixated IOL (SSF-IOL), offers favorable safety and visual outcomes. However, limited evidence exists regarding optimal refractive prediction formulas for the SSF of the Carlevale IOL.

Additionally, there is an indirect assumption that the effective lens position (ELP) is the same as the one obtained in a standard in-the-bag IOL placement, which is very likely not the case. On the contrary, higher variability of the IOL position is anticipated, so the true accuracy of IOL power calculation may be lower than expected.⁴⁻⁸

This study assesses the accuracy of four popular formulas for SSF Carlevale IOL in patients with insufficient capsular support.

Methods

This prospective, single-center, non-comparative, interventional case series included patients with insufficient capsular support undergoing secondary IOL implantation with Carlevalle IOL combined with 25-gauge (25G) pars plana vitrectomy (PPV). The study was approved by the Research Committee of the Institut Català de Retina and the external independent Research Ethics Committee (REC)/ Institutional Review Board (IRB) of the Grupo Hospitalario Quironsalud-Catalunya. The study followed the principles of the Declaration of Helsinki, and written informed consent was obtained. Inclusion criteria were complete pre-operative biometric data and post-operative refractive information 3 months after the surgery, when refraction is considered stable,⁹ corrected distance visual acuity (CDVA) of 20/40 or better, since refraction accuracy decreases with VA.⁹ One eye was randomly selected if both eyes met the eligibility criteria.⁹ Previously existing ophthalmological pathologies were not a reason for exclusion if the patients met the above-mentioned inclusion criteria.

Pre-Operative and Post-Operative Evaluation

All patients underwent a comprehensive ophthalmological examination, including manifest refraction, within one month before and at least three months after surgery.

Routine pre-operative optical low-coherence interferometry data from IOLMaster 700 (version 1.88.1.64861; Carl Zeiss) was extracted. Biometry data was imported to calculate 2-variable vergence formulas:¹⁰ Sanders-Retzlaff-Kraff theoretical (SRK/T), Hoffer Q, and Holladay 1 results using IOLMaster EyeSuite software. Since most cases had an abnormal anterior chamber (AC), and AC depth (ACD) was lacking, the Haigis, Olsen, Hill-RBF, and Kane formulas could not be used for IOL calculation. Nevertheless, we included the Barrett Universal II formula since the online calculator of the Asia-Pacific Association of Cataract and Refractive Surgeons (https://www.apacrs.org/barrett_universal2/) allows us to perform lens power calculation despite lacking anterior segment data. The IOL constant for power calculation was provided by the manufacturer and optimized during our clinical practice before initiating this study.

The power of the implanted IOL for each patient was used to calculate the predicted refractive outcomes for each evaluated formula. All calculations assumed the same IOL position as in-the-bag implantation. The target refraction was set to emmetropia.

The prediction error (PE) was defined as the difference between measured and predicted post-operative refractive spherical equivalent (SE) (measured refraction minus predicted refraction). A negative PE indicated more myopic outcomes than predicted, and a positive PE indicated more hyperopic outcomes. Absolute error (AE) was calculated as the absolute value of the difference between the SE and predicted refraction. Additional metrics included mean PE, median AE (MedAE), mean AE (MAE), and percentages of eyes with a PE within ± 0.25 D, ± 0.50 D, ± 1.00 D, and ± 2.00 D as suggested.^{9,10}

SRK/T, Hoffer Q, and Holladay are here referred to as the 2-variable vergence formula according to Koch et al classification.¹⁰ However, they are also traditionally called the second-generation formula¹⁰ or, recently, the thin lens vergence formula without artificial intelligence.¹¹

Surgical Technique

All procedures were performed by four different surgeons using the previously described technique.¹² A complete 25G PPV (Constellation, Alcon Laboratories, Inc.) was conducted in all cases using three trocars. Two trocars were inserted through the sulcus 1.5 mm from the limbus at 0° and 180° underneath scleral flaps, while a third trocar was placed through the pars plana. If necessary, the extraction of the subluxated crystalline lens or intraocular lens (IOL), capsular tension ring, or cataract was performed. In some cases, an endoscope (Endo Optiks, Inc.) was also utilized. The Carlevalle IOL (Soleko, Italy), a single-piece acrylic hydrophilic foldable lens, was implanted in all cases through a clear corneal incision. At the same time, the plugs were externalized via trocars positioned 1.5 mm from the limbus and were covered with a scleral flap.

Statistical Analysis

Sixty-eight patients were required to detect a significant difference in AE between the two formulas based on the differences found by Botsford et al¹³ with a 10% loss in follow-up. Snellen VA was converted to the logarithm of the minimum angle of the resolution scale (logMAR) for the statistical analysis. The refractive prediction outcomes were reported in the following 3 ways: PE, MAE, and MedAE.^{9,10}

The data were analyzed using SPSS (V-29.0) for Windows software (IBM Corp.2022) and Stata (V-14.1) (StataCorp, College Station, TX, USA). The variables were defined by frequency for qualitative values and mean \pm standard deviation (SD) for quantitative values. A p-value <0.05 was considered significant. The normality of the data was checked using the Kolmogorov–Smirnov test. The Wilcoxon test was used to check post-operative CDVA gain. The 1-sample *t*-test was performed to evaluate whether the mean PE was statistically significantly different from zero. The Friedman test (with Wilcoxon signed-rank pairwise comparisons post-test) was used to evaluate differences in PE and MAE between formulas and the median test (Pearson’s chi-squared test) in MedAE. Bonferroni adjustment was used for multiple comparisons.^{13,14} The Cochran Q test was performed to compare the percentage values within ± 0.25 , ± 0.50 , ± 1.00 D, and ± 2.00 D of PE.

Results

The study included 69 eyes of 69 patients (62.3% male) with a mean (SD) age of 71.6 (12.9) years. The mean (SD) axial length (AL), corneal power (K), and IOL implanted power were 25 (1.9) mm, 43.1 (2) D, and +17.6 (4.5) D, respectively. High myopia, previous PPV, and pseudoexfoliation syndrome were the primary predisposing factors (31.9%, 30.4%, and 29%, respectively), and IOL dislocation was the most common indication for surgery (76.8%). As mentioned, a complete 25G PPV was performed in all cases, with IOL exchange as the most frequent concurrent procedure (84.1%). Vitreous hemorrhage ($n=5$, 7.2%), mild, transient corneal edema ($n=29$, 42%), and cystic macular edema detected on OCT ($n=20$, 29%) were the most common intraoperative, early (<1 month), and late complications, respectively. No retinal detachment, endophthalmitis, or IOL subluxation was observed. Special attention was given to reverse pupillary block and iris or optic capture, as these complications can alter the IOL position, but were not detected in our cohort.

The mean (SD) follow-up was 12.1 (8.1) months. Demographic and clinical characteristics are summarized in [Table 1](#).

Table 1 Baseline Characteristics

Characteristics	Data
Total No. of patients	69
Total No. of eyes	69
RE, No. (%)	39 (56.5)
LE, No. (%)	30 (43.5)
Gender, No. (%)	
Male	43 (62.3)
Female	26 (37.7)
Age (years)	
Mean \pm SD	71.6 \pm 12.9
Range	18, 93
AL (mm)	
Mean \pm SD	25.1 \pm 1.9
Range	21.7, 32.2
Short (<22.5), No. (%)	3 (4.3)
Avg (22.5, 25.5), No. (%)	44 (63.8)
Long (>25.5), No. (%)	22 (31.9)

(Continued)

Table 1 (Continued).

Characteristics	Data
WTW (mm) Mean±SD Range	12.1±0.5 10.9, 13.1
Avg K (D) Mean±SD Range	43.1±2 35.9, 46.6
IOL power (D) Mean±SD Range	17.6±4.5 7, 26
Predisposing factors, No. (%) HM PPV PSX sd. Ocular trauma Complicated cataract surgery	22 (31.9) 21 (30.4) 20 (29) 11 (15.9) 4 (5.8)
Indication for secondary IOL, No. (%) Dislocated IOL Aphakia Subluxated crystalline lens UGH sd. Refractive surprise	53 (76.8) 7 (10.1) 4 (5.8) 4 (5.8) 1 (1.4)
Concurrent procedure, No. (%) 25G PPV IOL Exchange CTR removal Phacoemulsification Endoscopy VH removal RD repair	69 (100) 58 (84.1) 9 (13) 2 (2.9) 20 (29) 1 (1.4) 4 (5.8)
Complications, No. (%) Intraoperative: VH, iris trauma, retinal tear Early postop.: corneal edema, OHT, VH, CME, hypotony, uveitis Late postop: CME, OHT, corneal edema	5 (7.2), 3 (4.3), 2 (2.9) 29 (42), 14 (20.3), 14 (20.3), 13 (18.8), 8 (11.6), 6 (8.7) 20 (29), 10 (20.3), 8 (11.6)
Follow-up, months Mean±SD Range	12.1±8.1 3, 32

Abbreviations: 25G, 25 gauge; AL, axial length; Avg, average; CME, cystoid macular edema; CTR, capsular tension ring; D, diopter; HM, high myopia; IOL, intraocular lens; K, keratometry; LE, left eye; mm, millimetres; OHT, ocular hypertension; PPV, pars plana vitrectomy; PSX sd., pseudoexfoliation syndrome; RD, retinal detachment; RE, right eye; SD, standard deviation; UGH sd., uveitis-glaucoma-hyphema syndrome; VH, vitreous hemorrhage; WTW, white-to-white.

CDVA improved significantly from 0.43 (0.41) to 0.11 (0.12) logMAR ($p<0.001$). 85.5% of patients improved, 10.1% remained unchanged, and only 4.3% worsened the final CDVA due to recurrent cystoid macular edema. Post-operative SE averaged (SD) -0.25 (0.75) D, with a cylinder of -1.01 (0.81) D. No significant astigmatic change was observed in the IOL extraction group ($p=0.101$), whilst a significant decrease of astigmatism was observed when the endoscope was

Table 2 Refractive Accuracy of IOL Power Formulas

Formula	SRK/T	Barret II	Hoffer Q	Holladay I
Constant	119.10	1.94	5.68	1.90
PE mean±SD	-0.11±0.92	-0.22±0.84	-0.07±0.84	-0.06±0.93
% of eyes within ±0.25 of PE	23.2	18.8	29	26.1
% of eyes within ±0.50 of PE	53.6	47.8	52.2	56.5
% of eyes within ±1.00 of PE	84.1	79.7	87	81.2
% of eyes within ±2.00 of PE	95.7	97.1	95.7	95.7
MAE mean±SD	0.65±0.66	0.67±0.53	0.6±0.60	0.65±0.68
MedAE	0.48	0.53	0.48	0.41

Abbreviations: AE, absolute error; IOL, intraocular lens; MAE, mean absolute error; MedAE, median absolute error; PE, predicted error.

used ($p=0.040$). Post-operative SE was within ± 0.25 D, within ± 0.5 D, within ± 1.0 D, and within ± 2.0 D of intended refraction in 28 of 69 patients (40.6%), 42 of 69 patients (60.9%), 61 of 69 patients (88.4%) and 68 of 69 patients (98.6%), respectively. These results were obtained with the SRK/T formula ($A=119.10$) used at the time of surgery as recommended by the manufacturer.

The refractive accuracy of IOL power formulas is displayed in Table 2, Figures 1 and 2. The negative refractive PE was statistically different from zero only for Barrett Universal II (a systematic myopic PE). The Friedman test revealed

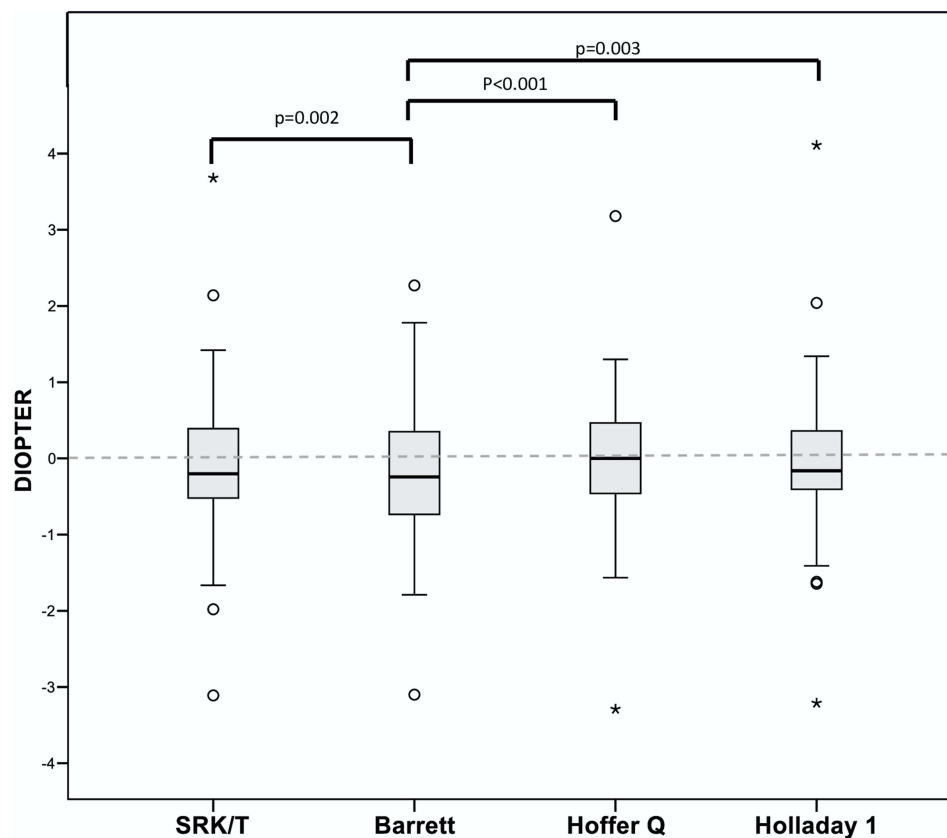


Figure 1 Box plot of the refractive prediction error for four lens power calculation formulas for the Carlevale.
Note: The gray dotted line represents emmetropia.

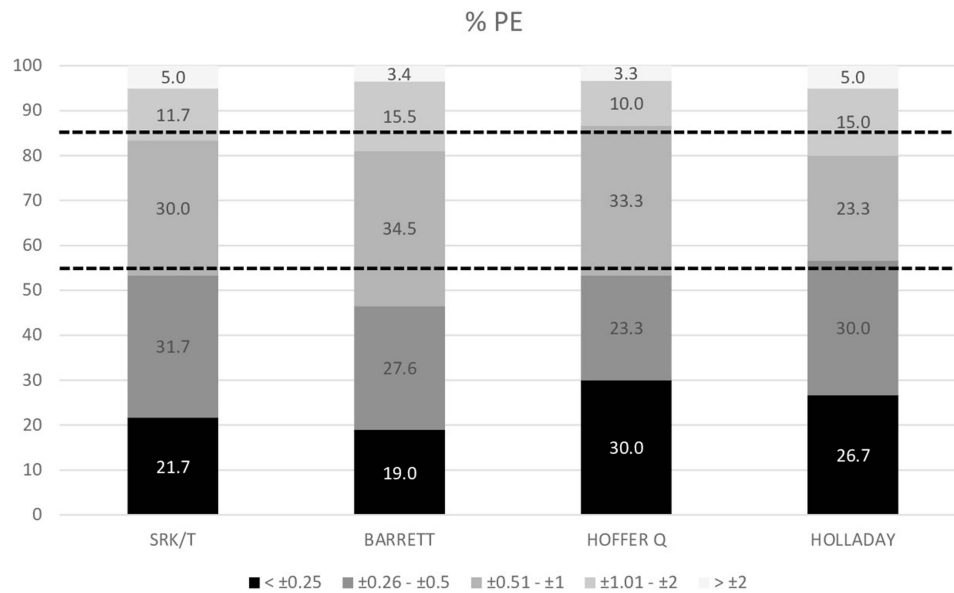


Figure 2 Histogram comparing the percentage of eyes with a given prediction error (PE).

Notes: The black dotted line represents 55% of eyes with PE for ± 0.5 D and 85% for ± 1.0 D from UK National Health Service guidelines.¹⁵

a significant difference in PE by formula ($p=0.004$). Post hoc analysis, using Wilcoxon signed-rank pairwise comparisons for nonparametric samples, demonstrated a significant difference between pairs: SRK/T and Barrett II ($p=0.002$), Hoffer Q and Barrett II ($p<0.001$) and Holladay 1 and Barrett II ($p=0.003$). When adjusted for multiple comparisons using Bonferroni correction, pairwise comparisons remained statistically significant ($p<0.0083$).

The SRK/T, Hoffer Q, and Holladay 1 formulas were significantly closer to target emmetropia (Figure 1).

MAE and MedAE did not differ significantly across formulas ($p=0.145$ and $p=0.641$, respectively).

The Cochran Q test did not reveal any significant difference regarding the percentage of eyes with a PE within ± 0.25 D ($p=0.421$), ± 0.50 D ($p = 0.404$), ± 1.0 D ($p= 0.232$), and 2.0 D ($p = 0.733$) between formulas, as detailed in Table 2 and Figure 2.

Discussion

The secondary SSF of Carlevalle IOL gained popularity due to its relative simplicity, short surgical time, safety profile, and ability to restore vision in patients with insufficient capsular support. However, limited data exist on the accuracy of IOL power calculation and refractive outcomes.

Over time, various IOL power calculation formulas have been developed for special situations, like phakic lens formulas or post-refractive formulas. However, no specific formula exists for aphakic patients. As a result, calculation formulas for in-the-bag IOLs are often used in patients without capsular support. Still, we expect higher variability in the ELP compared to standard in-the-bag implantation or sulcus placement with optic capture.¹⁶

Since ACD data were often missing, we relied on 2-variable vergence formulas (SRK/T, Hoffer Q, and Holladay 1). Those formulas are based on AL and K.^{10,11} The Barrett II formula was also considered, as it has been used in other studies for calculating iris and scleral-fixated IOL power.^{6,17} Its online platform permits lens power calculation even when the anterior segment data is missing. The application of different formulas with more variables was not possible because the necessary data could not be obtained in cases of dislocated IOL or aphakia. Furthermore, although “newer” is often better, it is not always the case; in more complex eyes, comparable accuracy was found between two 2-variable vergence formulas and newer formulas.^{10,18} This may be the case with ELP prediction, which remains a challenge,¹⁰ the fundamental issue, since the accuracy of the refractive power of the IOL implant depends not only on the accuracy of the preoperative biometric data but most of all on ELP estimation resulting from the selection of the appropriate formula.

Numerous case series studies have been reported on secondary IOL implantation in the sulcus. However, most studies are retrospective, involve small samples, employ various lens models and techniques, and lack a robust methodology for refractive analysis. Consequently, results are often contradictory, making precise conclusions challenging.

When placing the IOL in the sulcus, which position is more anterior, some recommend targeting an IOL that is 0.50 D to 1.00 D more hyperopic.^{6,7,19–22} Brunin et al²³ reported that sutured scleral-fixated IOLs had the most myopic mean PE (SD) -0.23 (0.79) D compared to other IOL locations, though hyperopic PE (+0.08 D) has also been observed.²⁴

For scleral-sutured IOLs, post-operative mean PE (SD) showed a slight myopic shift in all formulas: Barrett II: -0.15 (0.87) D, SRK/T: -0.10 (0.81) D, Holladay 2: -0.15 (0.84) D, Haigis: -0.28 (0.94) D, except Hoffer Q: $+0.01$ (0.80) D.¹³ In long eyes (AL>25mm), PE was consistently myopic.¹³ However, the statistical significance of these differences was not assessed.^{13,23,24}

Sutureless intrascleral fixation of IOLs has emerged as an alternative to sutured scleral fixation of posterior chamber IOL. This procedure typically involves creating two scleral tunnels 180° apart to secure the haptics of a 3-piece IOL. Variations of this technique have shown mixed refractive outcomes, ranging from myopic shift (-0.21 ²⁵ and -0.57 D²⁶) to hyperopic shift (from $+0.04$ to $+0.85$ D).^{6–8,22} The hyperopic shift was observed for Holladay 2 and Barrett II ($+0.78$ and $+0.04$, respectively).⁸

The Carlevalle IOL was recently introduced as an on-label lens for sutureless transscleral fixation. Of the limited studies reporting refractive outcomes with this lens,^{4,27–32} most found mean (SD) myopic PE ranging from -0.04 (0.74) D⁵ to -0.31 (0.71),^{29,30} though mean (SD) hyperopic PE $+0.46$ (0.36) D^{5,31} has also been observed. We noted negative mean PE (SD) across the cohort from -0.06 (0.93) to -0.22 (0.84) D, with Barrett II outcomes being significantly more myopic than expected.

The most used formula for Carlevalle IOL power calculations is the SRK/T, followed by the Hoffer Q, Holladay 1, and Barrett II.^{4,5,28,29,31,32} Previous studies by Vaiano et al,⁴ Schranz et al⁵ and Courat et al³¹ found no significant differences between the 2-variable vergence formulas. Furthermore, no differences were observed when these formulas were compared to the Barrett II formula. However, these findings were based on studies involving a small number of eyes: 25, 29, and 30, respectively. In contrast, our study, which utilized a pre-calculated sample size, revealed that Barrett II was significantly less accurate than the SRK/T, Hoffer Q, and Holladay 1 formulas. Although the Barrett Universal II formula was originally designed to enhance IOL calculation precision using AC data, our findings indicate reduced accuracy when ACD is unavailable.

Although our cohort was larger than in previous studies, we could not evaluate formula performance in AL-dependent subgroups. Detecting statistically significant differences would require a minimum of 68 eyes per subgroup. More research is needed since some formulas demonstrate greater accuracy than others based on the AL data.^{18,33} It would also be useful to investigate potential differences in the accuracy of IOL prediction formulas considering Carlevalle IOL toricity, as this aspect has not been previously studied. However, as mentioned earlier, the number of toric IOLs implanted to date has been insufficient to draw a statistically significant conclusion.

The variability of the IOL position in the sulcus can impact refractive outcomes. Contributing factors include the distance of sclerotomies from the limbus, white-to-white distance, AL, IOL diameter, haptic angle, and whether anterior or posterior vitrectomy was performed.^{22,34} Some studies suggest that pars plana vitrectomy (PPV) may lead to myopic outcomes³⁴ which were not observed with our 2-variable vergence formulas. Moreover, we did not detect a hyperopic shift, despite all plugs being positioned 1.5 mm from the limbus. In contrast, Abby et al reported a hyperopic shift of 0.23D when comparing the placement of a three-piece IOL at 1.5 mm versus 2 mm from the limbus. In scleral fixation techniques, the distance from the limbus varied from 1 mm to nearly 2.5 mm.^{35,36}

Moreover, placing an IOL in the sulcus is a “blind” procedure without an endoscopic visualization. UBM studies have shown that only 55% of haptics sutured to the sclera were correctly positioned in the sulcus, with 27.5% placed more anteriorly and 17.5% posteriorly.³⁷ Misplacement of the Carlevalle IOL^{12,17} could similarly increase refractive variability.

Furthermore, surgical technique and experience significantly influence outcomes. Our study included cases operated on by four surgeons with varying expertise levels, enhancing our results’ generalizability. This contrasts with single-surgeon studies^{4,5} that may not reflect broader clinical practice.

High refractive accuracy is essential for patient satisfaction,⁹ but is challenging in complicated cataract surgeries or secondary IOL implantation. The UK National Health Service recommends achieving PE within ± 0.50 D for at least 55% and within ± 1.00 D for 85% of eyes.¹⁵ Our best results, reached with Holladay 1 and Hoffer Q, met these benchmarks.

However, outcomes for Carlevale IOL still lag those for uncomplicated in-the-bag IOL implantation,³⁸ highlighting the need for further optimization.

This study, the largest prospective analysis of Carlevale lens power calculations up to date, has several limitations: first, the relatively small sample despite statistical pre-specification; second, the absence of a control group for comparison with other scleral fixation techniques or other IOLs; third, low representation of short eyes in the sample, which may limit the generalization of our results in this kind of eye; and forth, the lack of heteroscedastic statistics to compare PE standard deviation as recommended by Holladay et al.³⁹

In the era of refractive cataract surgery, the refractive outcomes have gained importance for both surgeons and patients. It is also relevant in complicated cases where the IOL must be fixed to the sclera, as those patients were spectacle-free before.

Although the results are not as good as those obtained with modern phacoemulsification combined with in-the-bag IOL implantation, our findings confirm that 2-variable vergence formulas are accurate for secondary Carlevale IOL implantation. Furthermore, the Barrett II formula demonstrated significantly lower precision and a higher tendency towards myopic outcomes compared to other formulas, suggesting that it should not be the preferred choice.

Further research is needed to optimize refractive results and explore underrepresented subgroups, such as toric IOLs and eyes with extreme AL.

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Disclosure

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