Journal of Ophthalmology

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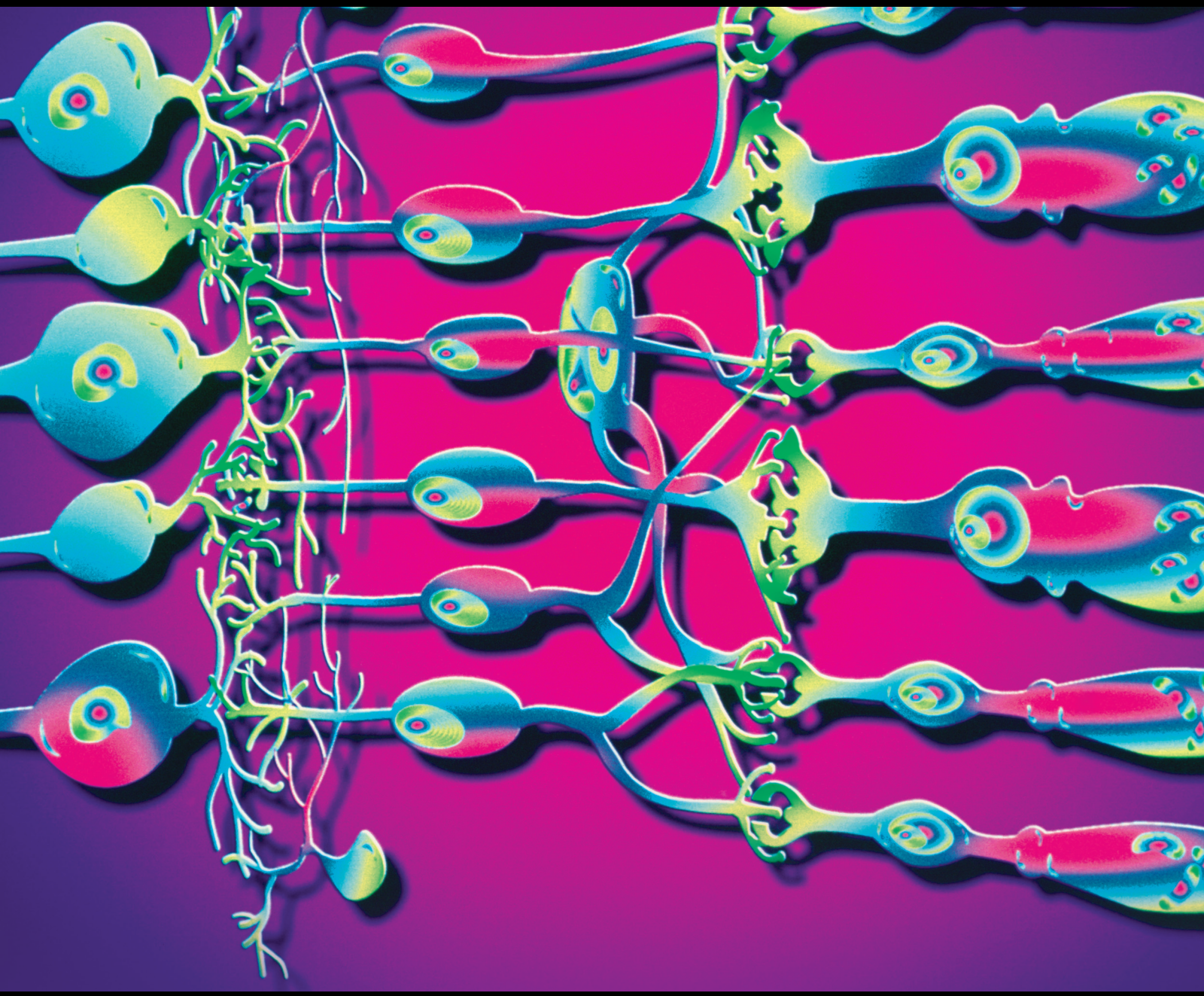

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Editorial

Different Methods of Secondary Intraocular Lens Implantation

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In modern cataract surgery, "in-the-bag" IOL placement is the ideal standard of care in order to allow excellent refractive results and fast visual recovery [1].

The precise positioning of the lens is crucial to achieve therapeutic effect, especially in case of toric lenses used to correct astigmatism. In this scenario, 1° misalignment reduces astigmatic correction by nearly 3.3%, whereas 30° misalignment might not correct or might increase astigmatism [2].

In everyday practice, several conditions may result in zonular loss and inadequate capsular support, such as lens dislocation in the vitreous chamber, posttraumatic cataract surgery, pseudoexfoliation, and Marfan and Ehlers–Danlos syndromes [3].

In this special issue, the reader will be able to cope with various surgical approaches which could be adopted in case there is the need to identify an alternative intraocular area to place the IOL.

These approaches include IOL implantation within the anterior chamber (AC-IOL), IOL fixated to the iris (IF-IOL), and IOL fixated to the sclera (SF-IOL) [4].

In AC-IOL placement, haptics are positioned in the iridocorneal angle: this is a faster and less complicated technique when compared with sutured IOLs; however, its use has been limited due to significant issues such as large corneal incision, bullous keratopathy, and secondary glaucoma [5, 6].

Furthermore, fixation to the iris involves suturing the haptics of a 3-piece IOL to the peripheral iris and it is useful in case of displacement of IOLs previously located in the sulcus and in all cases where sparing the conjunctiva or filtering bleb is needed [7].

On the other hand, this technique has been associated to secondary glaucoma, iris chafing, pigment dispersion, central macular edema (CME), and pupil distortion [8].

Another alternative surgical approach involves the Artisan Aphakic IOL (Ophtec BV, Groningen, The Netherlands), which is an iris-claw IOL currently used in Europe whose main feature is having two "claws" on both sides which allow enclavation to the iris tissue [9].

This technique has a flat learning curve, short surgical time, and low incidence of postoperative complications. On the negative side, it also has a slow visual recovery due to high postoperative astigmatism which creates a discomforting period of low visual acuity [10].

Scleral-fixated intraocular lenses need to be anchored to the sclera by sutures or sutureless techniques: in both cases, the technique is more complex than AC-IOL or IF-IOL and an anterior or pars plana vitrectomy is required as well as an anterior chamber maintainer in order to preserve intraocular pressure during surgery [11].

Scleral fixation allows IOL placement in the posterior chamber leading to greater refractive results and it is useful in case of a low endothelial cell count. On the other hand,

this technique might face suture-related complications, such as breakage and conjunctival erosion, which are associated with a higher risk of endophthalmitis [12].

In recent years, new materials have been successfully introduced, such as Gore-Tex monofilament, which has superior tensile strength and increased durability compared to the previously used Prolene. This allows fixation of several nonfoldable scleral IOLs (such as Alcon CZ70BD and Bausch and Lomb Akreos A60) and thus reducing sutures-related complications [13].

Moreover, sutureless scleral fixation has become increasingly popular due to the absence of complications associated with large wounds or stitches [14].

First described by Shin Yamane in 2017, the flanged intrascleral IOL fixation technique is a double-needle technique which entails the externalization of two haptics using a 30-gauge thin-wall needle at 2 mm away from the limbus. After externalization, low-temperature cautery is performed at the tip of the haptics, creating flanges which can be embedded within the sclera [15].

It has also been proved that this technique can be safely performed with 27-gauge needles, extending its accessibility to countries where 30-gauge needles are not available [15].

In order to optimize refractive results, studies have underlined the urge to use the Yamane stabilizer, which allows the placement of 2 opposite sclerotomies at exactly 180°, and to heat the last 2 mm of the IOL haptics.

However, this technique has been standardized only with the preloaded 3-piece IOL (Kowa PU6AS, Japan), so further investigations regarding other types of IOLs are therefore needed [16].

In recent years, Carlevale et al. have developed a new foldable scleral IOL (Soleko) provided by scleral harpoons which enable sutureless anchorage to the sclera by a 23-gauge sclerotomy [10, 17].

The anchors allow precise centration, which was demonstrated by a vertical and horizontal tilting not exceeding 5°, and prevent posterior dislocation which might explain the low incidence of vitreous hemorrhage and retinal tears or detachment [2].

This special issue will also focus on expected refractive results of each of these techniques.

In fact, iris-claw IOL [18], flanged transscleral-fixated IOL (Yamane technique), and sutureless transscleral hook IOL fixation (Carlevale IOL) showed a similar functional recovery and a similar myopic shift.

At the moment, there is still no consensus on the target of spheric equivalent [11].

In conclusion, this special issue has a platter of original research articles and experimental studies, as well as case series on secondary intraocular lens implantation, illustrating and discussing refractive outcomes and how to deal with postoperative complications.

This work will hopefully offer readers a new perspective in dealing with insufficient capsular support and thus stimulating further research.

Conflicts of Interest

The editors declare that they have no conflicts of interest regarding the publication of this Special Issue.

Matteo Forlini
Boris Malyugin
Ike Ahmed
Gabor Scharioth
Rodolfo Mastropasqua
Alessandro Mularoni

References

[1] J. J. Gicquel, M. E. Langman, and H. S. Dua, "Iris claw lenses in aphakia," *British Journal of Ophthalmology*, vol. 93, no. 10, pp. 1273–1275, 2009.

[2] J. Wu, C. Yang, Y. Yin, L. Liu, and H. Wang, "Impact of material and lens design on repositioning surgery of toric intraocular lenses: a single-arm meta-analysis," *Journal of Ophthalmology*, vol. 2022, Article ID 6699596, 10 pages, 2022.

[3] R. Fernández-Buenaga, J. L. Alio, A. L. Pérez-Ardoy et al., "Late in-the-bag intraocular lens dislocation requiring explantation: risk factors and outcomes," *Eye*, vol. 27, no. 7, pp. 795–802, 2013.

[4] M. Forlini and R. Bedi, "Intraocular lens implantation in the absence of capsular support: scleral-fixated vs retropupillary iris-claw intraocular lenses," *Journal of Cataract & Refractive Surgery*, vol. 47, no. 6, pp. 792–801, 2021.

[5] D. J. Apple, R. N. Brems, R. B. Park et al., "Anterior chamber lenses. Part I: complications and pathology and a review of designs," *Journal of Cataract & Refractive Surgery*, vol. 13, no. 2, pp. 157–174, 1987.

[6] S. R. Patel, D. S. Chu, B. D. Ayres, and P. S. Hersh, "Corneal edema and penetrating keratoplasty after anterior chamber phakic intraocular lens implantation," *Journal of Cataract & Refractive Surgery*, vol. 31, no. 11, pp. 2212–2215, 2005.

[7] J. J. Mura, C. J. Pavlin, G. P. Condon et al., "Ultrasound biomicroscopic analysis of iris-sutured foldable posterior chamber intraocular lenses," *American Journal of Ophthalmology*, vol. 149, no. 2, pp. 245–252.e2, 2010.

[8] W. J. Stark, G. Goodman, D. Goodman, and J. Gottsch, "Posterior chamber intraocular lens implantation in the absence of posterior capsular support," *Ophthalmic Surgery, Lasers and Imaging Retina*, vol. 19, no. 4, pp. 240–243, 1988.

[9] G. S. Negretti, W. O. Chan, and M. M. K. Muqit, "Artisan iris-claw intraocular lens implantation in vitrectomised eyes," *Eye*, vol. 35, no. 5, pp. 1393–1397, 2021.

[10] D. Boccuzzi, D. Purva, V. Orfeo et al., "Supporting IOL'S in a deficient capsular environment: the tale of no tails," *Journal of Ophthalmology*, vol. 2021, Article ID 9933486, 7 pages, 2021.

[11] T. Yu, M. Yu, W. Wu et al., "Outcomes and complications of sutured scleral-fixated foldable intraocular lens implantation: a retrospective study of 5-year follow-up," *Journal of Ophthalmology*, vol. 2021, Article ID 5525064, 8 pages, 2021.

[12] F. K. Obeng, V. K. Vig, P. Singh, R. Singh, B. Dhawan, and N. Sahajpal, "Posterior chamber scleral fixation of intraocular lenses in post-vitrectomised aphakic eyes," *Journal of Clinical and Diagnostic Research: Journal of Clinical and Diagnostic Research*, vol. 11, no. 3, pp. NC09–NC13, 2017.

[13] M. Leuzinger-Dias, M. Lima-Fontes, R. Rodrigues et al., "Scleral fixation of Akreos AO60 intraocular lens using gore-tex suture: an eye on visual outcomes and postoperative complications," *Journal of Ophthalmology*, vol. 2021, Article ID 9349323, 8 pages, 2021.

[14] N. T. Gurney and Z. Al-Mohtaseb, "Intraocular lens implantation in the absence of capsular support," *Saudi journal of ophthalmology*, vol. 36, no. 2, pp. 157–162, 2022.

[15] E. Suren, M. Kalayci, E. Cetinkaya et al., "Evaluation of the findings of patients who underwent sutureless flanged transconjunctival intrascleral intraocular lens implantation with or without pars plana vitrectomy," *Journal of Ophthalmology*, vol. 2021, Article ID 4617583, 6 pages, 2021.

[16] G. Besozzi, C. Posarelli, M. C. Costa et al., "Standardized flanged intrascleral intraocular lens fixation with the double-needle technique for cataract luxation in the vitreous chamber during phacoemulsification," *Journal of Ophthalmology*, vol. 2021, Article ID 9998482, 5 pages, 2021.

[17] E. Abed, M. Forlini, E. Bendo et al., "One year outcomes and stability of a novel scleral anchored intraocular lens," *Journal of Ophthalmology*, vol. 2021, Article ID 3838456, 6 pages, 2021.

[18] M. Forlini, W. Soliman, A. Bratu, P. Rossini, G. M. Cavallini, and C. Forlini, "Long-term follow-up of retropupillary iris-claw intraocular lens implantation: a retrospective analysis," *BMC Ophthalmology*, vol. 15, no. 1, pp. 143–146, 2015.

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Review Article

Impact of Material and Lens Design on Repositioning Surgery of Toric Intraocular Lenses: A Single-Arm Meta-Analysis

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Aim. To analyze the pooled incidence rate in repositioning surgery by considering different materials and designs. *Methods*. All published studies investigating the repositioning surgery of toric intraocular lenses (IOLs) before September 1, 2020, were searched and evaluated. The R3.5.2 software was used to extract the data, and a single arm meta-analysis was performed. *Results*. 19 cases from 18 published studies articles were included in the meta-analysis. The pooled incidence rate in repositioning surgery was 2% ($I^2 = 53\%$, $P_{\text{heterogeneity}} < 0.01$). Plate and silicone IOLs had significantly higher incidence rates (6% for each) than loop (2%) and hydrophobic acrylate (2%). Incidence rates of Acrysof, Staar, TECNIS, PhysIOL SA, T-flex 623T, and Microsil 6116TU groups were 1% (95% CI [1%–2%]), 6% (95% CI [4%–9%]), 3% (95% CI [2%–4%]), 1.40% (1/71), 3.03% (1/33), and 4.76% (1/21), respectively. *Conclusions*. The pooled incidence rate of repositioning surgery in IOLs was 2%. Materials and designs would be risk factors for the rotational stability of the toric IOLs. Pooled incidence rates of the hydrophobic acrylate and loop group were lower than those of the silicone and plate group. Product identity is the main driver of heterogeneity.

1. Introduction

Toric intraocular lenses (IOLs) have been designed to restore visual acuity deteriorated by cataract and correct corneal astigmatism. Clinical studies have reported that toric IOLs have become a safe and effective method to treat cataract patients with preoperative refractive problems [1–3]. However, the precise positioning of the lens in relation to the intended alignment axis is crucial to achieve the intended effect. Toric IOL misalignment by approximately 1° will reduce astigmatic correction by nearly 3.3%, while a 30° misalignment may not correct or increase the astigmatism [4, 5]. Tognetto et al. [6] applied visual information fidelity to analyze the image quality at the IOL rotational step. Previous experiments have illustrated that image quality reduction was observed with a rotation of 30°; subsequently, the images at 45° have the same quality without toric correction.

Thus far, only a small number of studies have examined the rotational stability of different toric IOLs. We aimed to evaluate the postoperative rotation and surgical repositioning of toric IOLs in different materials and designs, through this systematic review and meta-analysis.

2. Methods

2.1. Search Strategy and Inclusion Criteria. We screened the PubMed, Web of Science, Cochrane Library, ClinicalTrials.gov, CNKI, and Wanfang databases for original articles that were published before September 1, 2020. The searches were conducted using free combinations of the following keywords in both English and Chinese: "toric intraocular lenses," "toric IOL," "intraocular lens rotation," "toric intraocular lens," "toric phakic intraocular lens," and "rotation." Furthermore, we checked the reference lists of the papers selected. Literature search was independently

conducted by two researchers (Jing Wu and Changping Yang), followed by resolving of any disagreements via consensus. The included studies met the following inclusion criteria: (1) original research papers regarding the repositioning surgery of toric rotation and (2) randomized controlled clinical trials, nonrandomized clinical trials, cohort studies, uncontrolled cohort studies, and case-control studies. We excluded studies with two or more lens subgroup variations which cannot be combined to obtain their respective incidence rates, along with those that did not satisfy one or more inclusion criteria.

2.2. Data Extraction and Study Quality Assessment. Two researchers (Jing Wu and Changping Yang) independently determined whether each study met the inclusion criteria. The following data were subsequently extracted from the included studies using a standardized form: name of the first author, publication year, country, age range, sample size, case, follow-ups, and toric types (shown in Supplementary Table 1). The characteristics of included toric IOLs are shown in Table 1. We used the Newcastle–Ottawa Scale [7] to evaluate the cohort and case-control studies. Quality of the nonrandomized interventional studies was evaluated using the methodological index for nonrandomized studies (MINORS) [8].

2.3. Statistical Analyses. Single-rate meta-analyses were carried out using the R statistical software package (version 3.5.2). We combined the experimental data and nonrandomized controlled trials with data from observational studies to perform a single-arm meta-analysis. We used five methods to combine the pooled incidence rate of repositioning surgery of toric intraocular lenses and eventually selected the Freeman–Tukey double arcsine transformations that were closest to normal distribution. Meta-analysis was individually performed for toric intraocular lenses of different materials. All meta-analyses were evaluated for heterogeneity using the chi-square based I^2 test and Q test. An interstudy I^2 score <50% or P value >0.10 was considered nonheterogeneous; furthermore, we used a fixed-effects model for the meta-analysis. Conversely, we used the random-effects model for meta-analysis in the presence of heterogeneity. The meta-analysis results were based on the forest plot, and the effect size was the combined incidence rates and 95% confidence interval. Subgroup analysis was performed using the χ^2 test, with $P < 0.05$ indicating statistical significance. Additionally, we applied the funnel plot and Egger's linear regression to analyze the publication bias. We also performed the Duval and Tweedie nonparametric "trim and fill" procedure to further assess the possible effects of publication bias in our meta-analysis.

3. Results

3.1. Characteristics of Included Studies. After a systematic literature, we identified 701 articles, of which we thoroughly examined 22 full-length articles. We applied the inclusion and exclusion criteria to select 18 studies which included 14 nonrandomized interventional studies [9–21] and 4 cohort and case-control studies [1, 22–24]. The remaining 4 articles were excluded due to the following reason: absence of sufficient information to obtain a definite incidence rate [25–28] (Figure 1).

Characteristics of the included studies have been summarized (shown in the supplementary table see here). We only included the toric IOL subgroup from 3 articles that compared toric and nontoric IOLs [1, 23, 24]. One article with two different datasets was considered as two separate studies [22]. In addition, 4 articles which reported a failure of the relocation surgery were included for subgroup analysis [11, 12, 24, 29]. All included studies were determined to be moderate-to-high-quality studies.

3.2. Single-Arm Meta-Analysis. We included 19 cases from the 18 articles in the meta-analysis. The pooled incidence rate of repositioning surgery was 2.0% (95% CI: 1%–3%) ($I^2 = 53\%$, $P_{\text{heterogeneity}} < 0.01$) in toric IOLs. We used the random-effects model for the meta-analysis considering the presence of statistical heterogeneity (Figure 2).

We performed a subgroup analysis of the studies adjusted for haptic designs. The pooled incidence rate of repositioning surgery of plate-haptic toric was significantly higher than that of loop-haptic (2% and 6%, respectively) (OR: 0.264, 95% CI: 0.160–0.436, $P < 0.001$) (Figure 3 and Table 2).

Furthermore, we performed a subgroup analysis of the studies adjusted based on the materials. Hydrophobic acrylic materials had a lower incidence rate of repositioning surgery of 2% (95% CI: 1–2%), and silicone materials showed a significantly higher incidence rate for the need of a repositioning surgery of 6% (95% CI: 4%–9%) (OR: 0.289, 95% CI: 0.164–0.441, $P < 0.001$) (Figure 4 and Table 2).

Subgroup analysis was also conducted based on products from different companies. We classified the included toric according to their respective companies or commercial names as Acrysof, Staar, TECNIS, PhysIOL SA, T-flex 623T, and Microsil 6116TU. There were 9 studies in the Acrysof, 5 studies in the Staar, and 2 studies in the TECNIS subgroups. The pooled incidence rate of repositioning surgery was 1% (95% CI: 1%–2%), 6% (95% CI: 4%–9%), and 3% (95% CI: 2%–4%), respectively. Subgroups were compared via the list χ^2 test, which revealed a statistically significant difference ($x^2 = 36.383$; $P < 0.001$) (Figure 5 and Table 2).

We further used the partitions of the χ^2 method to perform pairwise comparison of multiple sample rates (Table 3). PhysIOL SA, T-flex 623T, and Microsil 6116TU were all included in one study, demonstrating incidence rates of 1.40% (1/71), 3.03% (1/33), and 4.76% (1/21), respectively.

All subgroup comparisons passed the criteria required for the heterogeneity test; subsequently, the fixed-effects models were used for meta-analysis.

3.3. Publication Bias. We used the R software with "metabias," and the Egger funnel plots are shown in Figure 6. The regression line in the Egger funnel plot did not pass the 0

Table 1: Characteristics of toric IOLs included in the meta-analysis.

Country	Company	Commercial name	Spherical power	Cylinder power	Design	Haptic	Material
USA	Alcon	Acrysof TIOL SN60TT	+6D~+34D	+1.5D~+6.0D	Single-piece	Loop	Hydrophobic acrylic
		Acrysof IQ toric IOL SN6AT	+6D~+34D	+1.5D~+6.0D	Aspheric optic	Loop	Hydrophobic acrylic
USA	Abbott Medical Optics	TECNIS	+5D~+34D	1.00D, 1.50, 2.25, 3.00, 4.00D	Single-piece	Loop	Hydrophobic acrylic
USA	Staar	AA 4203TF/TL	+10D~+28D	+2D, 3.5D	Single-piece	Plate	Silicone
Germany	Human Optics	Microsil 6116TU	−3D~+30D	+2D~+12D	3-Piece	PMMA Z-design	Silicone

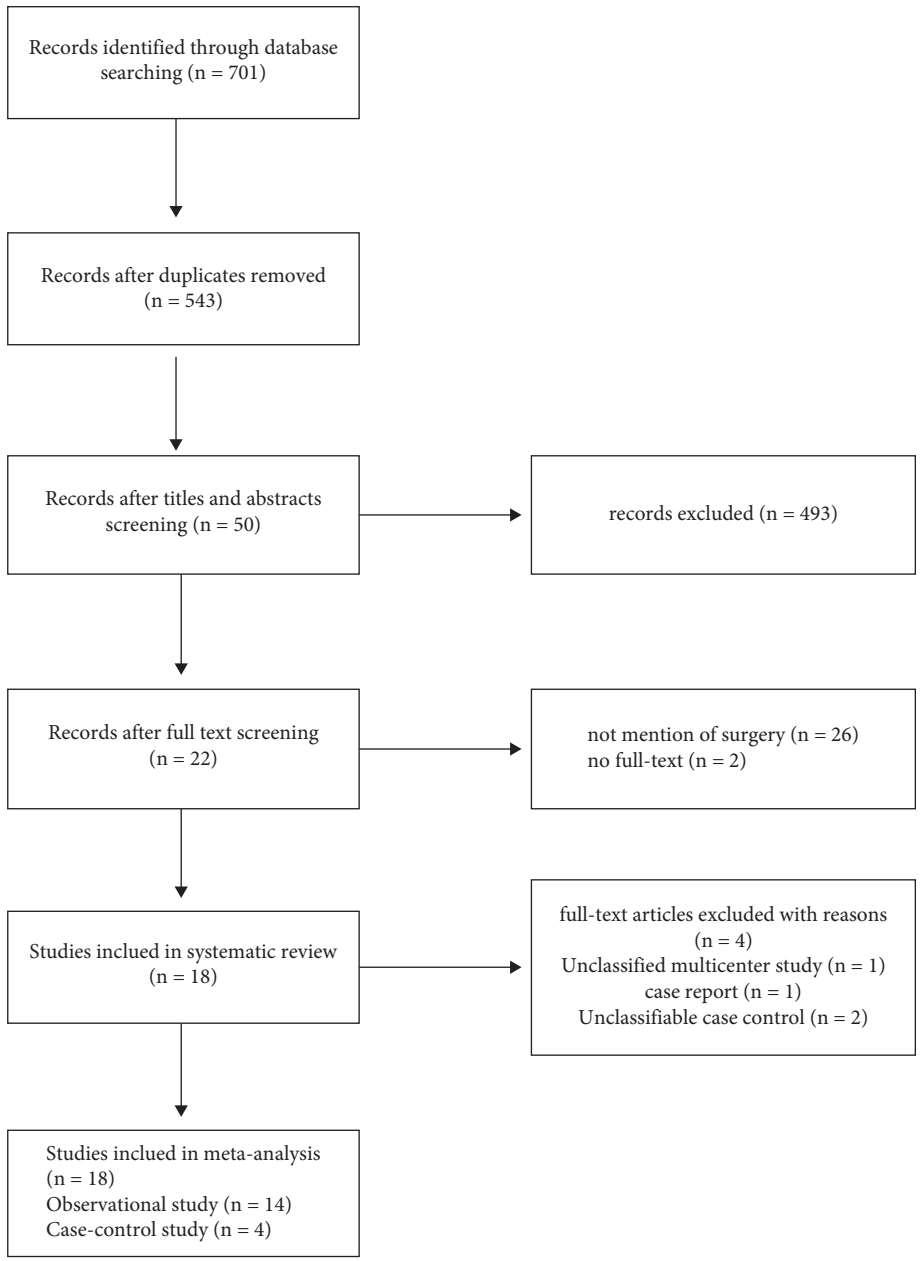


Figure 1: Flowchart demonstrating how the identified published studies were included in the meta-analysis.

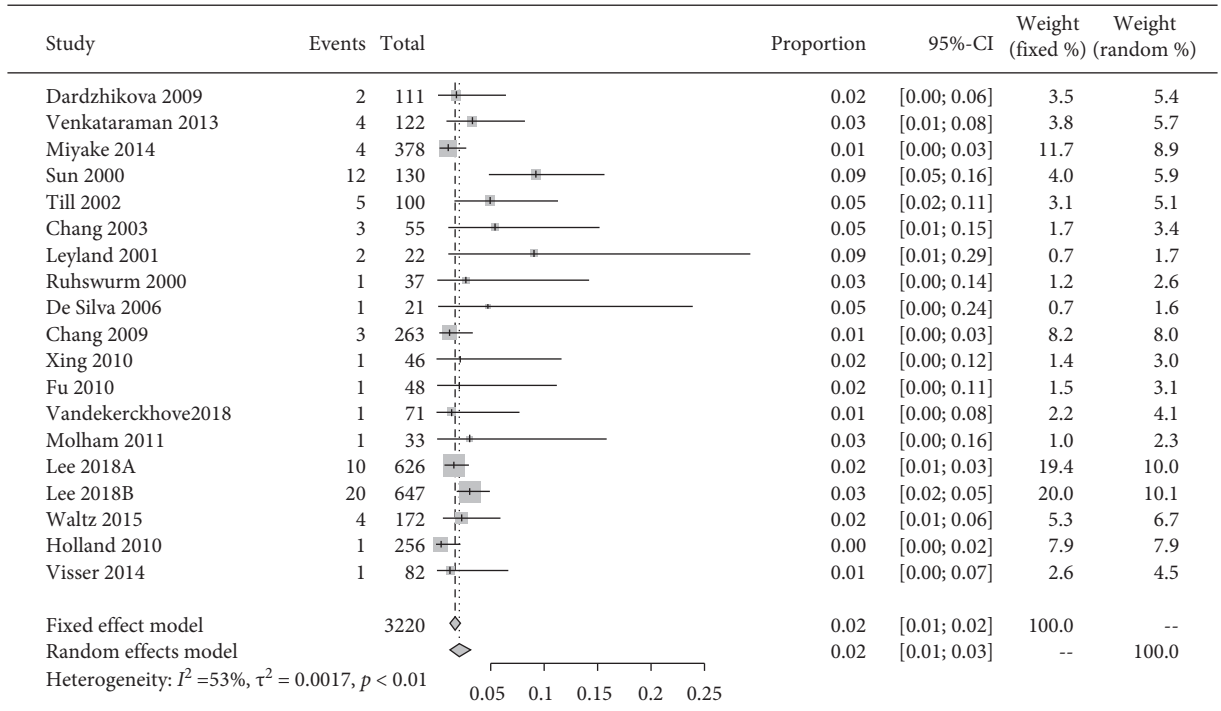
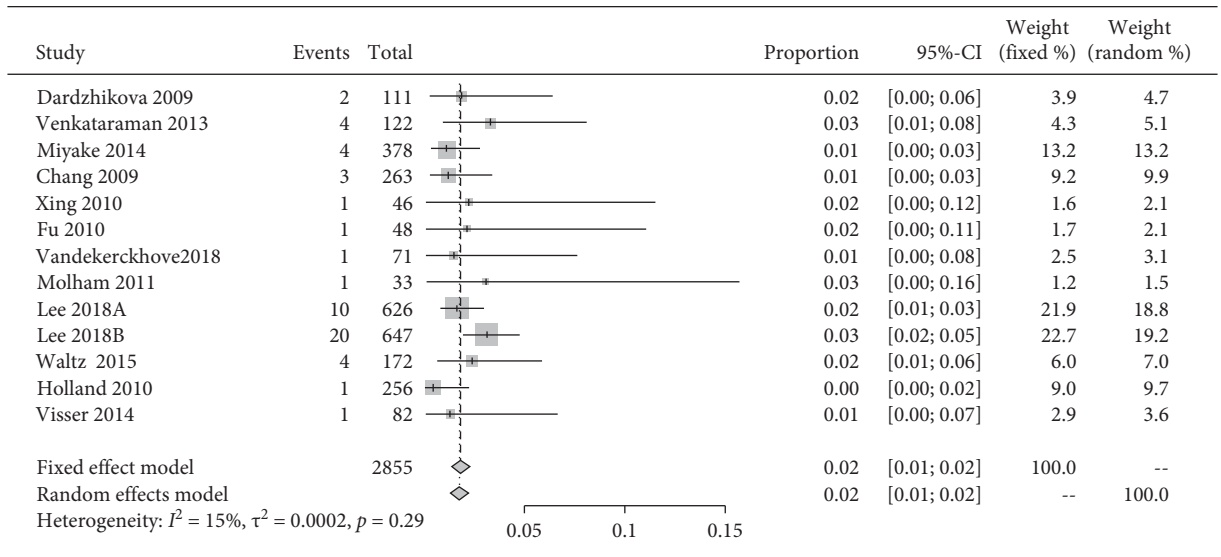
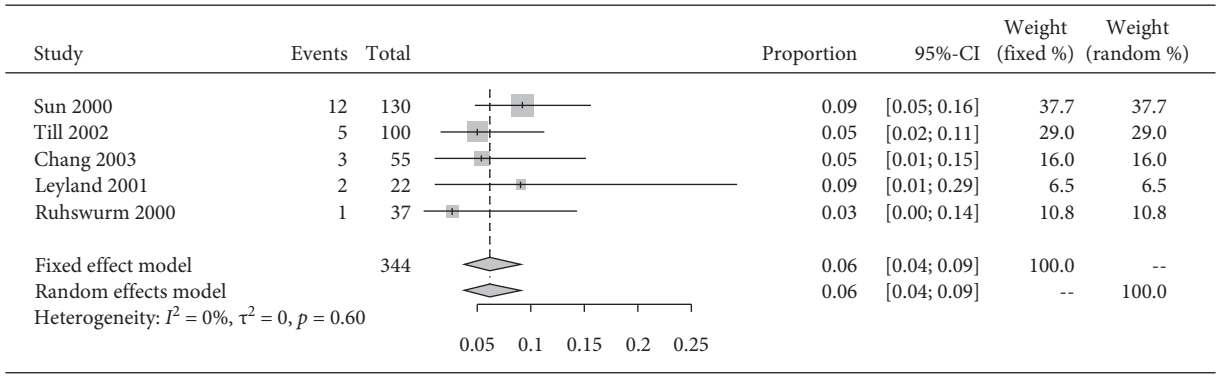


Figure 2: The forest plot displaying the pooled incidence rate of repositioning surgery of toric IOL.



(a)

Figure 3: Continued.



(b)

Figure 3: The forest plots displaying the pooled incidence rate of repositioning surgery of (a) loop-haptic toric IOLs and (b) plate-haptic IOLs.

Table 2: The pooled incidence rate of repositioning surgery with different subgroups.

Variable	Number of articles	Case/ total	Pooled estimate [95% CI]	Heterogeneity I^{2*} (%)	Q value	OR (95% CI)	P value
Total	19	77/3220	2 [1–3]	53	0.01		
Haptic							
Loop	13	53/2855	2 [1–2]	15	0.29	0.264 (0.160–0.436)	≤0.001
Plate	5	23/344	6 [4–9]	0	0.60	1.00	
Material							
Silicone	6	24/365	6 [4–9]	0	0.63	1.00	
Hydrophobic acrylic	13	53/2855	2 [1–2]	15	0.29	0.289 (0.164–0.441)	≤0.001
Products							
Acrysof	9	27/1932	2 [1–2]	0	0.63	0.198 (0.112–0.349)	0.003
Staar	5	23/344	6 [4–9]	0	0.60	1.00	≤0.001
TECNIS	2	24/819	3 [2–4]	0	0.58	0.421 (0.234–0.757)	0.003
PhysIOL SA	1	1/71					
T-flex 623T	1	1/33					
Microsil 6116TU	1	1/21					

*The chi-square test was used for two sample rates and list χ^2 test was used for multiple sample rates. $P < 0.05$ was considered statistically significant.

points, suggesting the presence of publication bias in the literature (Egger's $P = 0.05184$). We performed a sensitivity analysis using the trim and fill method to rectify the same [30], which conservatively imputes the hypothetical negative unpublished studies to mirror the positive studies causing funnel plot asymmetry. After including 7 studies, it produced a symmetrical funnel plot (Figure 6). The pooled incidence rate and 95% CI did not change significantly (1.18%, 95% CI, 0.46%–2.11%). Therefore, the results were considered to be robust and demonstrated a certain degree of reference significance.

4. Discussion

Toric IOLs have become an effective tool for patients to eliminate preoperative astigmatism. However, the rotational stability of toric is a significant factor that affects the performance of corrected visual acuity after cataract surgery.

We included of 19 studies comprising 3220 eyes, which showed a 2% pooled incidence rate of repositioning surgery. This incidence observed here was lower than that in previous studies (3–9.2%) [23, 25]. Moreover, Oshika et al. [26] incorporated a large number of case series with 6431 eyes and reported that the overall incidence of repositioning surgery was 0.653%. The lower incidence rate observed in the study may be associated with the distribution of the data. Here, we only included the studies with acrylic foldable toric IOLs; furthermore, all patients with a significant amount of misalignment did not undergo a repositioning surgery. Patients who had no obvious symptoms and those with IOL misalignment and did not consent for further surgical intervention were not included.

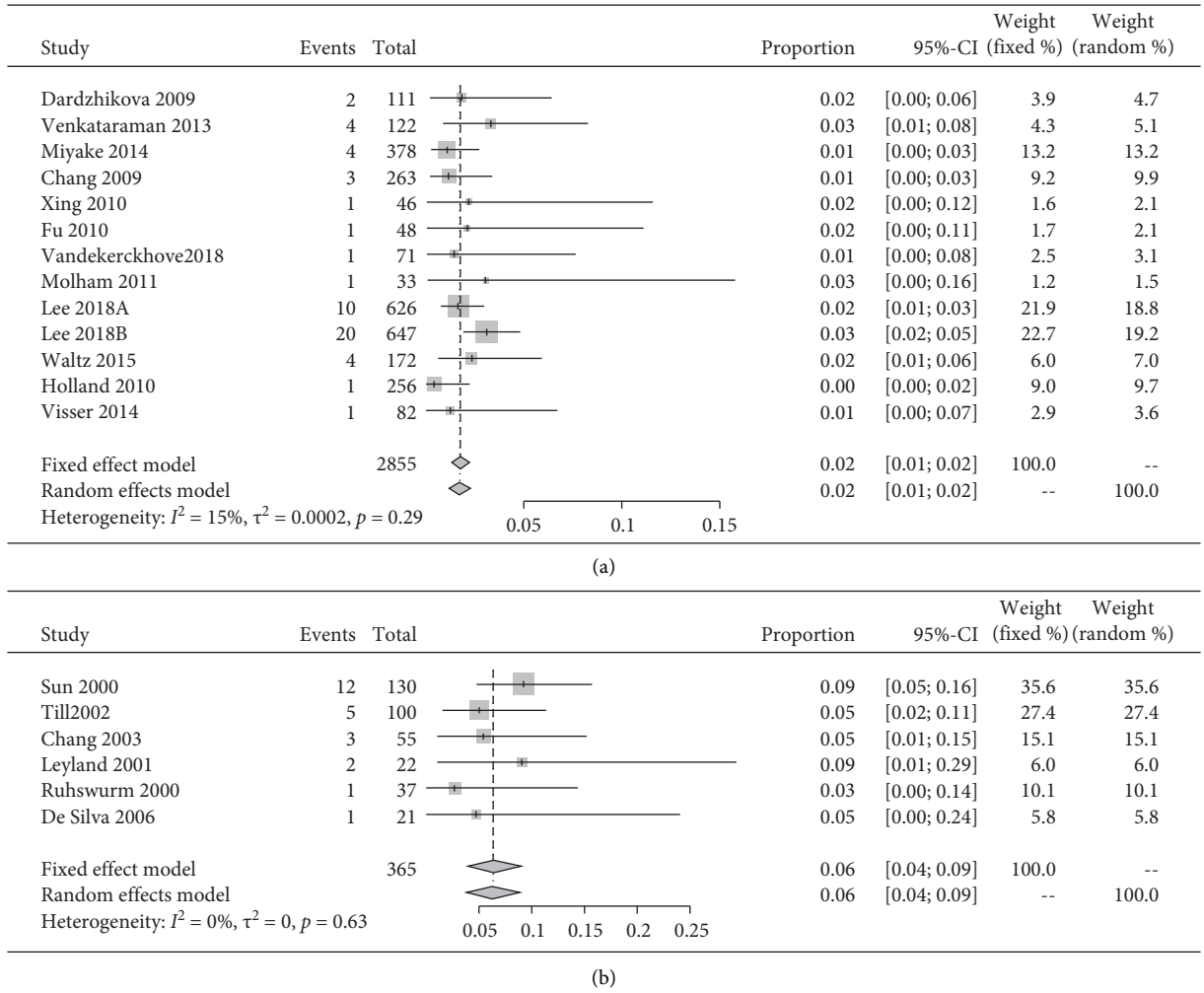


Figure 4: The forest plots displaying the pooled incidence rate of repositioning surgery of (a) hydrophobic acrylic material IOLs and (b) silicone material IOLs.

Materials used in the studies have demonstrated association with a certain degree rotation of toric IOLs. We observed that performing a subgroup analysis based on the materials demonstrated a significantly higher incidence rate of rotation in silicone IOLs than in hydrophobic acrylate IOLs (OR: 0.289, 95% CI: 0.164–0.441, $P < 0.001$). Lombardo et al. [31] reported that hydrophobic acrylic IOLs showed the highest adhesive properties, followed by hydrophilic acrylic IOLs, PMMA IOLs, and finally silicone IOLs. Linnola et al. [32] also demonstrated that acrylic IOLs had more fibronectin than silicone which had strongest adhesion with capsular bag. Therefore, hydrophobic acrylic IOLs had better rotational stability than the silicone IOLs. In addition, Draschl et al. [33] contrasted two group toric IOLs in the same design with different materials, which subsequently indicated that the hydrophobic acrylic IOLs were better than the hydrophilic IOLs. Here, we also found that the hydrophobic acrylic IOLs demonstrated the best stability.

IOL designs were important to improve the stability of IOL rotation [34]. Evidence showed that the loop-haptic design IOLs had better rotational stability than the plate-haptic (OR: 0.264, 95% CI: 0.160–0.436, $P < 0.001$). Comparing the loop-haptic and plate-haptic IOLs, Patel [35] reported that the plate-haptic tended to rotate more than the loop-haptic design in the early postoperative period. A loop-haptic was prone to a double counterclockwise turn after surgery. Venkataraman et al. [10] also observed that loop-haptic IOLs had excellent stability while early postoperative IOL rotation was more likely to occur only in larger diameter bags.

The Acrysof toric IOLs presented with the best postoperative stability considering the use of different products, followed by TECNIS and Staar IOLs. Acrysof toric IOLs are composed of a hydrophobic acrylate material, which has a particularly strong adhesion. Besides, the loop-haptic demonstrates good memory and softness that can be used to resolve the optical fluctuations caused by shrinkage of the capsular bag. Moreover, it shows a good stability in the capsular bag. Visser et al. [36] reported pooled estimates for the misalignment of more than 10°, indicating the need for a surgical repositioning 3%. Other clinical studies showed that postoperative rotation of Acrysof IOLs is most likely less

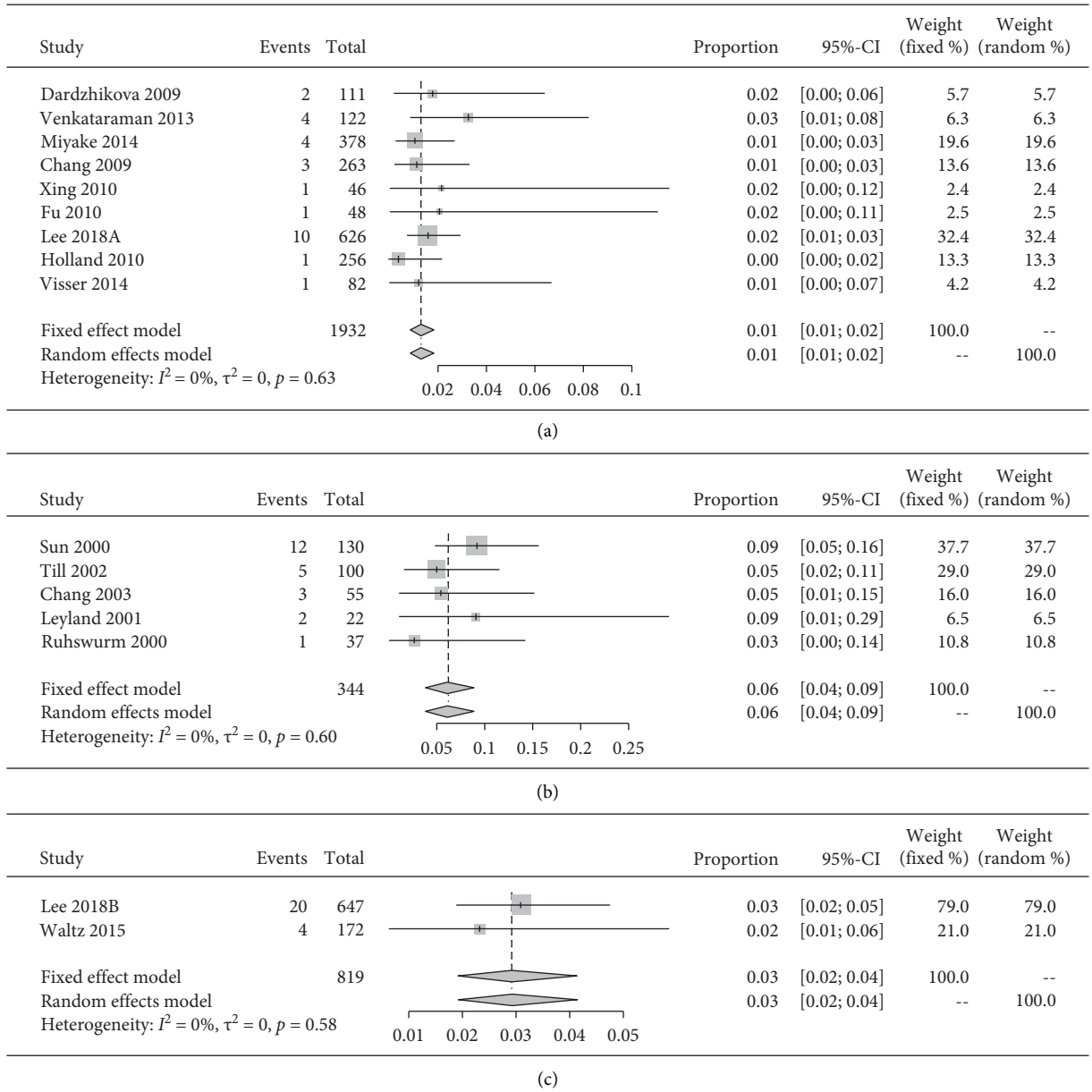


Figure 5: The forest plots displaying the pooled incidence rate of repositioning surgery of (a) Acrysof toric IOLs, (b) Staar IOLs, and (c) TECNIS toric IOLs.

Table 3: Pairwise comparison of multiple sample rates by the partitions of the $\chi 2$ method.

Subgroup	Sample	No. of samples	χ^2	P value
Acrysof	27	1905		
Staar	23	321	38.011	≤0.001
Total	40	2226		
Acrysof	27	1905		
TECNIS	24	795	7.428	0.006
Total	51	2700		
Staar	23	321		
TECNIS	24	795	8.811	0.003
Total	47	1116		

*$P < 0.0125$ was considered statistically significant.

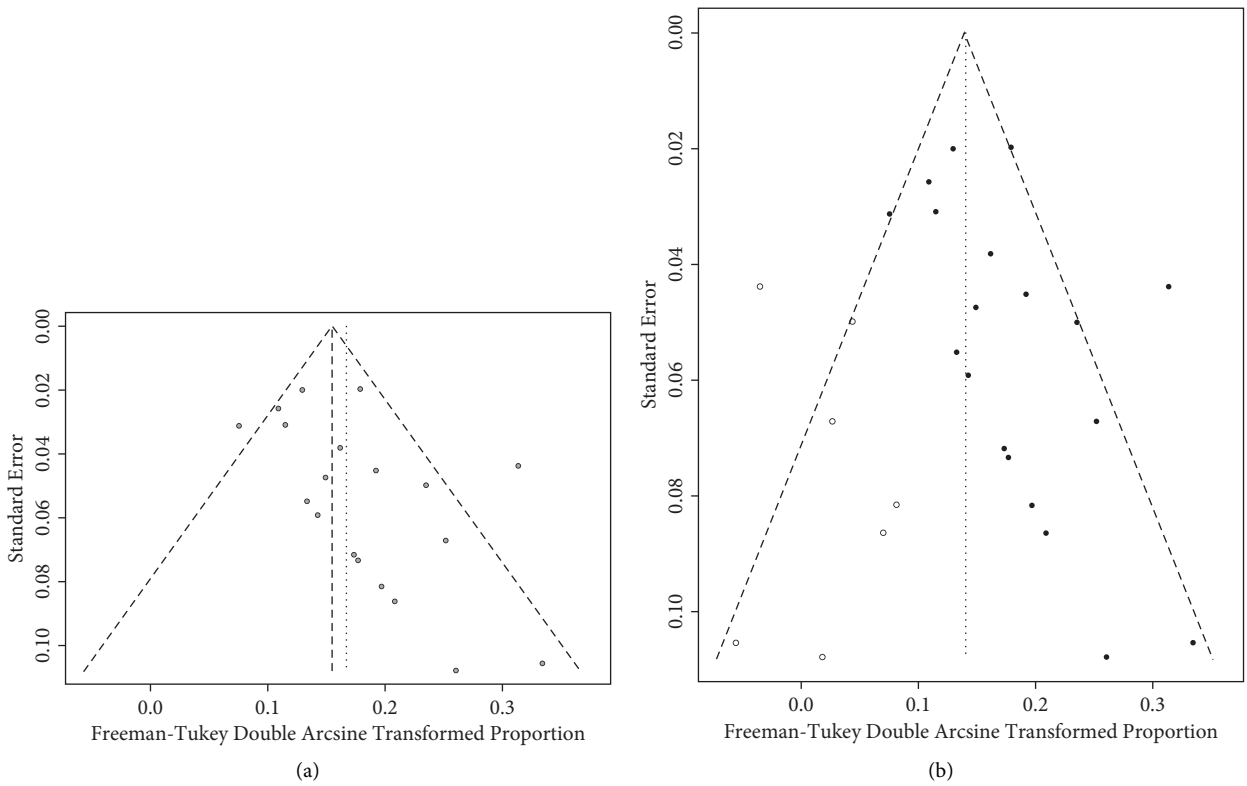


Figure 6: (a) The funnel plot displaying the pooled incidence rate of repositioning surgery of toric IOLs. (b) The filled funnel plot with pseudo-95% CI (the pseudo-95% confidence interval (CI) is computed as part of the analysis that produces the funnel plot).

than 5° [22, 37, 38], with the long AXL, WTR, and oblique astigmatism being risk factors for toric IOLs rotation [39, 40]. TECNIS IOLs have designs and materials similar to those of Acrysof, indicating the presence of a good degree of stability [41]. Hirnschall et al. [42] reported that the average rotation of TECNIS IOLs was $3.27 \pm 2.37°$. However, we found that the pooled incidence rate of repositioning surgery of TECNIS was higher than that of the Acrysof group (OR: 0.469, 95% CI: 0.269–0.819, $= 0.006$). Xue et al. [27] also reported 3 eyes (9%) that required further surgery to rectify the significant IOL rotation. Interestingly, Staar IOLs have a higher postoperative rotation; however, their shorter TF may be considered as one of the risk factors [12, 14, 29]. Chang et al. [13] reported that the TL Staar toric IOLs rotational and repositioning rates were higher than those of TF IOLs. Adequate length is a critical factor to improve the rotational stability of Staar toric IOLs, highlighting the fact that priority should be given to longer IOLs.

Only 4 of 864 eyes demonstrated a failure for repositioning surgery. Among them, Sun et al. [12] reported that the fibrosis of the capsule caused a significant degree of rotation after repositioning, which limited the effect of the position. Xue et al. [27] reported that the reason for the large degree of rotation after surgery was the fact that the patient underwent a preoperative vitrectomy procedure, which decreased the stability of the suspensory ligament. Most clinical studies determined that the IOLs reorientation should be performed within 1 to 3 weeks [26, 29]. Prematurely calibrating the same may rotate the lens again; however, a delay in calibration may become firmly fix the IOLs in the capsule, which upon rotation may cause a zonular rupture [22, 27, 29]. Therefore, good stability can be ensured by selecting appropriate timing of the repositioning procedure and assessing the patient's complications.

Above all, limitations of this study must be considered. First, most studies involved here were observation trials and therefore lacked well-designed randomized double-blind controls. Second, there were no predetermined common criteria for the repositioning surgery. The need for surgical intervention was purely decided by the surgeons responsible for the same, due to which the repositioning surgery was repeated if the patient provided for the same. However, in the absence of the patient's consent, further treatment was not performed. Alternatively, in cases where the patient was dissatisfied with the postoperative corrected vision, regardless of the minimum rotation degree, the case was inadvertently assigned for another survey. Finally, the funnel plot analysis showed some asymmetry that indicated the possibility of sample bias.

5. Conclusions

This meta-analysis suggested that the combined incidence of toric IOLs was 2%, which was lower than that reported in the current literature. There is a significant difference in the incidence with the use of different materials, with a lower incidence with regard to the hydrophobic acrylate and the loop-haptic group. Acrysof toric IOLs have better

postoperative stability than TECNIS and Staar. Further high-quality studies with more randomized double-blind control designs are needed.

Abbreviations

IOLs: Toric intraocular lenses
CI: Confidence interval.

Data Availability

All data generated or analyzed during this study are included in relevant published articles.

Conflicts of Interest

All authors of this manuscript declare that there are no conflicts of interest and have no financial relationship with organizations.

Authors' Contributions

JW and CPY contributed equally to this work and drafted the manuscript. JW and HW conceived and designed the study. JW, CPY, and YY contributed to acquisition of data. JW, CPY, and LIL analyzed and interpreted the data. YY, LIL, and HW revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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Supplementary Materials

Supplementary Table: characteristics of studies included in the meta-analysis. The data were subsequently extracted from the included studies using a standardized form: name of the first author, publication year, country, age range, sample size, case, follow-ups, and toric types. (*Supplementary Materials*)

References

[1] N. Visser, H. J. M. Beckers, N. J. C. Bauer et al., "Toric vs. aspherical control intraocular lenses in patients with cataract and corneal astigmatism," *JAMA Ophthalmology*, vol. 132, no. 12, pp. 1462–1468, 2014.

[2] Y.-C. Liu, M. Wilkins, T. Kim, B. Malyugin, and J. S. Mehta, "Cataracts," *The Lancet*, vol. 390, no. 10094, pp. 600–612, 2017.

[3] L. Kessel, J. Andresen, B. Tendal, D. Erngaard, P. Flesner, and J. Hjortdal, "Toric intraocular lenses in the correction of astigmatism during cataract surgery," *Ophthalmology*, vol. 123, no. 2, pp. 275–286, 2016.

[4] N. A. Alpins, "Vector analysis of astigmatism changes by flattening, steepening, and torque," *Journal of Cataract and Refractive Surgery*, vol. 23, no. 10, pp. 1503–1514, 1997.

[5] M. P. Weikert, A. Golla, and L. Wang, "Astigmatism induced by intraocular lens tilt evaluated via ray tracing," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 6, pp. 745–749, 2018.

[6] D. Tognetto, A. A. Perrotta, F. Bauci et al., "Quality of images with toric intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 3, pp. 376–381, 2018.

[7] H. Bissen-Miyajima, K. Negishi, O. Hieda, and S. Kinoshita, "Microincision hydrophobic acrylic aspheric toric intraocular lens for astigmatism and cataract correction," *Journal of Refractive Surgery*, vol. 31, no. 6, pp. 358–364, 2015.

[8] X. Zeng, Y. Zhang, J. S. W. Kwong et al., "The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review," *Journal of Evidence-Based Medicine*, vol. 8, no. 1, pp. 2–10, 2015.

[9] A. Dardzhikova, C. R. Shah, and H. V. Gimbel, "Early experience with the AcrySof toric IOL for the correction of astigmatism in cataract surgery," *Canadian Journal of Ophthalmology*, vol. 44, no. 3, pp. 269–273, 2009.

[10] A. Venkataraman and Kalpana, "Visual outcome and rotational stability of open loop toric intraocular lens implantation in Indian eyes," *Indian Journal of Ophthalmology*, vol. 61, no. 11, pp. 626–629, 2013.

[11] T. Miyake, K. Kamiya, R. Amano, Y. Iida, S. Tsunehiro, and K. Shimizu, "Long-term clinical outcomes of toric intraocular lens implantation in cataract cases with preexisting astigmatism," *Journal of Cataract and Refractive Surgery*, vol. 40, no. 10, pp. 1654–1660, 2014.

[12] X.-Y. Sun, "Toric intraocular lenses for correcting astigmatism in 130 eyes," *Ophthalmology*, vol. 2000, no. 107, pp. 1776–1782, 2000.

[13] D. F. Chang, "Early rotational stability of the longer Staar toric intraocular lens," *Journal of Cataract & Refractive Surgery*, vol. 2003, no. 29, pp. 935–940, 2003.

[14] M. Leyland, E. Zinicola, P. Bloom, and N. Lee, "Prospective evaluation of a plate haptic toric intraocular lens," *Eye*, vol. 15, no. 2, pp. 202–205, 2001.

[15] I. Ruhswurm, U. Scholz, M. Zehetmayer, G. Hanselmayer, C. Vass, and C. Skorpik, "Astigmatism correction with a foldable toric intraocular lens in cataract patients," *Journal of Cataract & Refractive Surgery*, vol. 26, no. 7, pp. 1022–1027, 2000.

[16] D. J. De Silva, Y. D. Ramkissoon, and P. A. Bloom, "Evaluation of a toric intraocular lens with a Z-haptic," *Journal of Cataract and Refractive Surgery*, vol. 32, no. 9, pp. 1492–1498, 2006.

[17] D. F. Chang, "Repositioning technique and rate for toric intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 35, no. 7, pp. 1315-1316, 2009.

[18] F. Shu-hua, W. Chang-yun, L. Fei, Z. Qian, and G. Fu, "Clinical study of AcrySof(R) Toric intraocular lens implantation on corneal astigmatism," *Chinese Journal of Practical Ophthalmology*, vol. 28, no. 8, pp. 881–883, 2010.

[19] X. Qian, G. Huai-jin, and W. Jian, "The study of Toric intraocular lens for corneal astigmatism correction in cataract patients," *Chinese Journal of Practical Ophthalmology*, vol. 28, no. 11, pp. 1199–1202, 2010.

[20] K. Vandekerckhove, "Rotational stability of monofocal and trifocal intraocular toric lenses with identical design and material but different surface treatment," *Journal of Refractive Surgery*, vol. 34, no. 2, pp. 84–91, 2018.

[21] M. Entabi, F. Harman, N. Lee, and P. A. Bloom, "Injectable 1-piece hydrophilic acrylic toric intraocular lens for cataract surgery: efficacy and stability," *Journal of Cataract and Refractive Surgery*, vol. 37, no. 2, pp. 235–240, 2011.

[22] B. S. Lee and D. F. Chang, "Comparison of the rotational stability of two toric intraocular lenses in 1273 consecutive eyes," *Ophthalmology*, vol. 125, no. 9, pp. 1325–1331, 2018.

[23] K. L. Waltz, K. Featherstone, L. Tsai, and D. Trentacost, "Clinical outcomes of TECNIS toric intraocular lens implantation after cataract removal in patients with corneal astigmatism," *Ophthalmology*, vol. 122, no. 1, pp. 39–47, 2015.

[24] E. Holland, S. Lane, J. D. Horn, P. Ernest, R. Arleo, and K. M. Miller, "The AcrySof toric intraocular lens in subjects with cataracts and corneal astigmatism," *Ophthalmology*, vol. 117, no. 11, pp. 2104–2111, 2010.

[25] C. Kaindlstorfer, M. Kneifl, P. Reinelt, and U. Schönherr, "Rotation of a toric intraocular lens from neodymium:YAG laser posterior capsulotomy," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 4, pp. 510-511, 2018.

[26] T. Oshika, M. Inamura, Y. Inoue et al., "Incidence and outcomes of repositioning surgery to correct misalignment of toric intraocular lenses," *Ophthalmology*, vol. 125, no. 1, pp. 31–35, 2017.

[27] K. M. Xue, J. K. Jolly, S. P. Mall, S. Haldar, P. H. Rosen, and R. E. MacLaren, "Real-world refractive outcomes of toric intraocular lens implantation in a United Kingdom National Health Service," *BMC Ophthalmology*, vol. 18, 2018.

[28] D. F. Chang, "Comparative rotational stability of single-piece open-loop acrylic and plate-haptic silicone toric intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 34, no. 11, pp. 1842–1847, 2008.

[29] J. S. Till, P. R. Yoder, T. K. Wilcox, and J. L. Spielman, "Toric intraocular lens implantation: 100 consecutive cases," *Journal of Cataract and Refractive Surgery*, vol. 28, no. 2, pp. 295–301, 2002.

[30] S. Duval and R. Tweedie, "Trim and fill: a simple funnel-plot-based method of testing and adjusting for publication bias in meta-analysis," *Biometrics*, vol. 56, no. 2, pp. 455–463, 2000.

[31] M. Lombardo, G. Carbone, G. Lombardo, M. P. De Santo, and R. Barberi, "Analysis of intraocular lens surface adhesiveness by atomic force microscopy," *Journal of Cataract and Refractive Surgery*, vol. 35, no. 7, pp. 1266–1272, 2009.

[32] R. J. Linnola, M. Sund, R. Ylönen, and T. Pihlajaniemi, "Adhesion of soluble fibronectin, vitronectin, and collagen type IV to intraocular lens materials," *Journal of Cataract and Refractive Surgery*, vol. 29, no. 1, pp. 146–152, 2003.

[33] P. Draschl, N. Hirnschall, N. Luft et al., "Rotational stability of 2 intraocular lenses with an identical design and different materials," *Journal of Cataract and Refractive Surgery*, vol. 43, no. 2, pp. 234–238, 2017.

[34] G. D. Shah, M. R. Praveen, A. R. Vasavada, V. A. Vasavada, G. Rampal, and L. R. Shastry, "Rotational stability of a toric intraocular lens: influence of axial length and alignment in the capsular bag," *Journal of Cataract and Refractive Surgery*, vol. 38, no. 1, pp. 54–59, 2012.

[35] C. K. Patel, S. Ormonde, P. H. Rosen, and A. J. Bron, "Postoperative intraocular lens rotation," *Ophthalmology*, vol. 106, no. 11, pp. 2190–2196, 1999.

[36] N. Visser, N. J. C. Bauer, and R. M. M. A. Nuijts, "Toric intraocular lenses: historical overview, patient selection, IOL calculation, surgical techniques, clinical outcomes, and complications," *Journal of Cataract and Refractive Surgery*, vol. 39, no. 4, pp. 624–637, 2013.

[37] S. A. Seth, R. K. Bansal, P. Ichhpujani, and N. G. Seth, "Comparative evaluation of two toric intraocular lenses for correcting astigmatism in patients undergoing phacoemulsification," *Indian Journal of Ophthalmology*, vol. 66, no. 10, pp. 1423–1428, 2018.

[38] D. Schartmüller, L. Schwarzenbacher, E. L. Meyer, S. Schriefl, C. Leydolt, and R. Menapace, "Comparison of long-term rotational stability of three commonly implanted intraocular lenses," *American Journal of Ophthalmology*, vol. 220, pp. 72–81, 2020.

[39] X. Zhu, W. He, K. Zhang, and Y. Lu, "Factors influencing 1-year rotational stability of AcrySof Toric intraocular lenses," *British Journal of Ophthalmology*, vol. 100, no. 2, pp. 263–268, 2016.

[40] A. Haripriya, S. Gk, I. Mani, and D. F. Chang, "Comparison of surgical repositioning rates and outcomes for hydrophilic vs. hydrophobic single piece acrylic toric IOLs," *Journal of Cataract & Refractive Surgery*, vol. 43, 2020.

[41] B. A. Kramer, D. R. Hardten, and J. P. Berdahl, "Rotation characteristics of three toric monofocal intraocular lenses," *Clinical Ophthalmology*, vol. 14, pp. 4379–4384, 2020.

[42] N. Hirnschall, S. Maedel, M. Weber, and O. Findl, "Rotational stability of a single-piece toric acrylic intraocular lens: a pilot study," *American Journal of Ophthalmology*, vol. 157, no. 2, pp. 405–411, 2014.

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Research Article

Scleral Fixation of Akreos AO60 Intraocular Lens Using Gore-Tex Suture: An Eye on Visual Outcomes and Postoperative Complications

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Purpose. "In-the-bag" placement of an IOL is the Holy Grail for any cataract surgeon. However, in the absence of capsular integrity, alternative surgical options to place the IOL must be sought. We aim to report the clinical outcomes and safety profile of scleral-fixated Akreos AO60 intraocular lens implantation using Gore-Tex suture, combined with pars plana vitrectomy. *Methods*. This is a single-center, retrospective case series descriptive study. Electronic clinical records of all patients subjected to scleral fixation of a Bausch and Lomb Akreos AO60 IOL combined with pars plana vitrectomy, between April 1, 2017, and August 1, 2021, were reviewed. Data concerning age, sex, laterality, past ophthalmological history, pre- and postoperative best-available visual acuity, surgical indication, and intra- and postoperative complications were collected. Measured outcomes were the differences in best-available visual acuity and frequency of postoperative complications. *Results*. A total of 37 eyes (20 right eyes and 17 left eyes) from 36 patients (16 females and 20 males) were included in the statistical analysis. The mean age at time of surgery was 72.0 ± 12.4 years. The mean follow-up period was 548.9 days (range 39–1564 days). Globally, the mean best-available logMAR visual acuity improved from 1.61 preoperatively (0.025 decimal equivalent) to 0.57 postoperatively (0.3 decimal equivalent), this difference being statistically significant ($P < 0.001$). Indications for surgery included aphakia due to complicated cataract surgery (24.3%; $n = 9$); subluxated IOL due to closed trauma (21.6%; $n = 8$); PEX-related subluxated IOL (16.2%; $n = 6$); non-traumatic, non-PEX-related subluxated IOL (18.9%; $n = 7$); subluxated crystalline lens due to closed trauma (8.1%; $n = 3$); aphakia due to open-globe injury (5.4%; $n = 2$); silicone-induced IOL opacification (2.7%; $n = 1$); and aphakia post-endophthalmitis (2.7%; $n = 1$). Postoperative complications included transient ocular hypertension (27.0%; $n = 10$), transient corneal edema (18.9%; $n = 7$), cystoid macular edema (18.9%, $n = 7$), self-limited hypotension (5.4%, $n = 2$), self-limited vitreous hemorrhage (2.7%, $n = 1$), central retinal vein occlusion (2.7%, $n = 1$), late retinal detachment (2.7%, $n = 1$), and Akreos IOL opacification (2.7%, $n = 1$). No suture-related complications were observed. *Conclusion*. There was a statistically significant improvement in visual acuity after scleral fixation of Akreos AO60 intraocular lens using Gore-Tex suture, with no suture-related problems recorded. This procedure seems to be a valuable alternative for posterior chamber IOL placement when secondary IOL implantation is required.

1. Introduction

Currently, "in-the-bag" placement of an intraocular lens (IOL) is the Holy Grail for any cataract surgeon. In such ideal conditions, the IOL is safely held and perfectly aligned with the pupillary axis, increasing the odds of best surgical and visual outcomes [1].

When posterior capsular integrity is disturbed, as it happens in complicated cataract surgery, but anterior capsular support is available, IOLs can be placed in the ciliary sulcus with satisfactory refractive outcomes [1].

However, in a wide range of conditions, namely, those predisposing to zonular fragility (connective tissue diseases,

pseudoexfoliation syndrome, homocystinuria, and so on), ocular trauma, or zonular damage during complicated cataract surgery, both anterior and posterior capsules are compromised, hampering classical "in-the-bag" or sulcus positioning. In this scenario, aphakia can be managed by the implantation of an anterior chamber intraocular lens (ACIOL), iris-fixated intraocular lens (IFIOL), or scleral-fixated intraocular lens (SFIOL) [1–3]. In the past, all these types of IOLs were non-foldable, thus requiring large corneal incisions for intraocular placement. Each of these techniques has its pros and cons, and none has proved to be superior to the other [4]. Thus, the choice of the best surgical modality depends on surgeon preference and experience, patient characteristics, eye anatomy, and ocular comorbidities [1, 2]. SFIOL may be valuable in cases where there is an increased risk of corneal endothelial cell loss, disqualifying an anterior chamber IOL [3]. Besides, by placing the IOL in the posterior chamber in a more physiological location, this surgical modality may potentially offer greater refractive advantages [5]. Similarly, retropupillary iris-claw IOLs could also offer such an advantageous physiological position and lower risk of endothelial cell loss [6]. However, iris structure does not always allow for IFIOL placement [7], especially in eyes that underwent trauma or complicated surgery, as it frequently is the case. Moreover, the correct enclavation of this type of IOL is a highly demanding surgical maneuver with a long learning curve [8]. Recently, a new technique using a guide needle to facilitate the enclavation was proposed by Frisina et al. with promising results [8]. Still, in either case, placing a posterior chamber iris-claw IOL usually requires large corneal incisions when compared to foldable SFIOL positioning, potentially inducing greater corneal astigmatism.

Nevertheless, SFIOL implantation is not without its drawbacks. Suture degradation and knot-related complications are chief concerns with this surgical approach. Vote and colleagues reported a proportion of suture breakage of 27.9%, with the traditionally used 10–0 polypropylene sutures [9]. Larger diameter 9–0 polypropylene sutures are theoretically more resistant, but a 2.7% rate of suture breakage is still non-neglectable considering the associated risk of sight-threatening endophthalmitis [10]. Sutureless scleral fixation techniques have been proposed with centered posterior chamber IOL positioning. These techniques may potentially solve suture-related complications, but problems associated with haptics slippage and subsequent IOL dislocation remain as important complications [1, 7, 11]. Recently, new foldable IOLs such as the Carlevale IOL have been designed for scleral fixation, allowing small incision sutureless implantation with great IOL stability and promising results [11]. In specific cases, this technique can be safely combined with other surgical procedures, as demonstrated by Kymionis et al. who performed a combined DSAEK with the scleral implantation of a Carlevale IOL in a patient with bullous keratopathy and a dislocated IOL [12]. Still, high intraocular pressure (IOP), cystoid macular edema, and iris capture by the IOL optic are reported complications with sutureless scleral fixation IOLs [11].

Classically used in heart valve and vascular surgeries, Gore-Tex is a non-absorbable, polytetrafluoroethylene monofilament suture that has recently assumed a relevant role in scleral IOL fixation due to its superior tensile strength and supposed greater resiliency, when compared to polypropylene [3]. Besides its increased durability, Gore-Tex suture is easy to control due to its reduced memory and does not induce any inflammatory response, and thanks to its white color, it is clearly distinguishable from the background tissues [3]. More importantly, there are no Gore-Tex suture breakage reports published in the literature so far.

Different types of IOLs can be scleral fixated. Alcon CZ70BD and Bausch and Lomb Akreos AO60 are two of the most used ones. The first is a non-foldable lens and has a single eyelet on each side of the optic center, and its implantation requires the construction of a scleral tunnel. The latter has two eyelets on each side of the optic center, is foldable along its axis, and is currently used off-label for this technique [3, 13].

In this study, we describe the clinical outcomes and safety profile of scleral-fixated Akreos AO60 intraocular lens implantation using Gore-Tex suture, combined with pars plana vitrectomy (PPV), performed in a Portuguese tertiary hospital. To the best of our knowledge, this is the first European study of its kind.

2. Materials and Methods

2.1. Study Design and Population. This is a single-center, retrospective case series descriptive study. Electronic clinical records of all patients subjected to scleral fixation of a Bausch and Lomb Akreos AO60 IOL combined with PPV at the ophthalmology department of Centro Hospitalar Universitário de São João between 1 April 2017 and 1 August 2021 were reviewed. The patients were selected from surgical reports for corresponding procedural codification. A total of 42 eyes of 41 patients were identified. Of these, 5 patients were excluded for a follow-up period inferior to 1 month, and 37 eyes from 36 patients were included in the statistical analysis. The study was developed in accordance with the tenets of the Declaration of Helsinki.

2.2. Data Collection and Definitions. Data concerning age, sex, laterality, past ophthalmological history, pre- and postoperative best-available visual acuity (VA), surgical indication, and intra- and postoperative complications were collected. Considered outcomes were the differences in best-available VA and frequency of intra- and postoperative complications. Visual acuity was measured by the distance Snellen chart preoperatively and at the last postoperative visit. IOP was measured by Goldmann applanation tonometry. Hypotony was defined as intraocular pressure (IOP) of 5 mmHg or less, and hypertension was defined as an IOP of 25 mmHg or more, at any postoperative visit, following previous similar definitions in other studies [3, 12, 13]. Corneal edema was defined as de novo postoperative edema persisting for more than 1 week. Cystoid macular edema was defined by the presence of de novo macular cysts, confirmed by spectral-domain optical coherence tomography (SD-OCT), performed by the first

postoperative month. Visual acuities were converted from decimal to the logarithm of the minimum angle of resolution (logMAR) equivalents for statistical analysis. As in similar studies, a VA of counting fingers and hand motions was transformed to a logMAR of 1.98 and 2.28, respectively [13].

2.3. Statistical Analysis. Statistical analysis was performed using the IBM® SPSS® Statistics software (version 27.0 for Windows; SPSS Inc., Chicago, IL, USA). Variables' normal distribution was verified by skewness, kurtosis, and Kolmogorov–Smirnov test. Parametric or non-parametric tests were used for variables comparison, according to the data distribution. The level of significance was established at a P value of <0.05.

2.4. Surgical Technique. The basic steps of this technique are represented in Figure 1. The procedure begins with a standard three-port PPV, performed with 25-gauge vitrectomy trocars. A toric lens marker, usually a Mendez ring, is then used to mark the corneal limbus at 2 different sites, 180° apart. Nasal and temporal conjunctival peritomies are created with an approximate extension of 6 mm. Then, four distinct sclerotomies (two nasal and two temporal) are made using either the 23 or 25-gauge empty trocar needle, 2.5 mm behind the limbus, 5 mm apart and centered around the horizontal axis. A superior corneal incision is done with a 3.2 mm keratome knife. Outside the eye, the 7–0 Gore-Tex suture (cut in half and with its needle removed) is passed through each pair of eyelets of the Akreos AO60 IOL, in a "U-shaped" configuration. Then, each end of the suture is transferred to the anterior chamber via the corneal incision and subsequently externalized through the corresponding sclerotomy, using non-serrated vitrectomy forceps. Afterward, the Akreos AO60 IOL is folded along its longer axis and introduced inside the eye. The Gore-Tex sutures are tied, and the knot is buried into the sclerotomy. Suture tension adjustments are made to assure that the lens is perfectly centered and adequately positioned in the posterior chamber. Finally, conjunctival peritomies are carefully closed with 7–0 vicryl. The corneal main port is usually self-sealing, but sometimes leaky incisions require a 10–0 monofilament suture.

This standard surgical technique can suffer mild modifications based on accumulated experience and the surgeon's preferences. For example, Akreos AO60 IOL can be inserted into the anterior chamber loaded in an injector, with the Gore-Tex suture being passed through the lens eyelets in the anterior chamber. This allows for a smaller corneal incision.

The surgeries were performed by three different surgeons.

IOL power was determined by traditional biometry, based on an "in-the-bag" calculation.

3. Results

3.1. Baseline Characteristics. A total of 42 eyes of 41 patients were identified. Of these, 37 eyes (20 right eyes and 17 left eyes) from 36 patients had a minimum of 1 month of follow-up and were included in the statistical analysis. 44.4% ($n = 16$) of patients were females. The mean age at the time of surgery was 72.0 ± 12.4 years old (range 31–92 years old). The mean follow-up period was 548.9 days (range 39–1564 days).

Relevant past ophthalmological history included closed-globe trauma in 12 eyes (32.4%), pseudoexfoliation (PEX) syndrome in 8 eyes (21.6%), glaucoma in 7 eyes (18.9%), previous PPV for retinal detachment repair in 5 eyes (13.5%), pathological myopia in 4 eyes (10.8%), open-globe trauma in 3 eyes (8.1%), exudative age-related macular degeneration in 2 eyes (5.4%), diabetic retinopathy without macular edema in 2 eyes (5.4%), dry age-related macular degeneration, previous penetrating keratoplasty, endophthalmitis, diabetic retinopathy with macular edema, retinal venous occlusion, toxic optic neuropathy, and Vogt–Koyanagi–Harada syndrome in 1 eye each (2.7%). Population baseline characteristics are represented in Table 1.

Indications for surgery included aphakia due to complicated cataract surgery (24.3%; $n = 9$); subluxated IOL due to closed trauma (21.6%; $n = 8$); non-traumatic, non-PEX-related subluxated IOL (18.9%; $n = 7$); PEX-related subluxated IOL (16.2%; $n = 6$); subluxated crystalline lens due to closed trauma (8.1%; $n = 3$); aphakia due to open-globe injury (5.4%; $n = 2$); silicone-induced IOL opacification (2.7%; $n = 1$); and aphakia post-endophthalmitis (2.7%; $n = 1$).

All patients underwent scleral fixation of an Akreos AO60 IOL using Gore-Tex suture, combined with either 23- or 25-gauge PPV. 1 eye (2.7%) underwent concomitant glaucoma surgery with Ahmed valve implantation.

3.2. Visual Outcomes. The mean best-available preoperative logMAR VA was 1.61 ± 0.73 (0.025 decimal equivalent). The mean best-available postoperative logMAR VA was 0.57 ± 0.66 (0.3 decimal equivalent), and, globally, the improvement from pre- to postoperative best-available VA was statistically significant ($P < 0.001$). VA was 5/10 (logMAR 0.3) or better in 3 eyes (8.1%) preoperatively, as compared to 17 eyes (45.9%) postoperatively. Subgroup analysis considering indication for surgery revealed a statistically significant postoperative vision improvement for patients with aphakia due to complicated cataract surgery ($P = 0.028$), subluxated IOL due to closed trauma ($P = 0.028$), non-traumatic, non-PEX-related subluxated IOL ($P = 0.028$), and PEX-related subluxated IOL ($P = 0.043$). Visual improvement was noted for patients in the remaining subgroups, but this difference did not reach statistical significance. Subgroups of silicone-induced IOL opacification and aphakia post-endophthalmitis included a single eye, and statistical significance could not be calculated.

During the study period, 1 eye (2.7%) had postoperative visual deterioration of 2 lines in the Snellen chart, and 7 eyes (21.6%) had no change in VA.

3.3. Intraoperative Complications. There were 3 eyes (8.1%) with reported intraoperative complications: one iatrogenic retinal hole done during vitrectomy; a flat peripherical

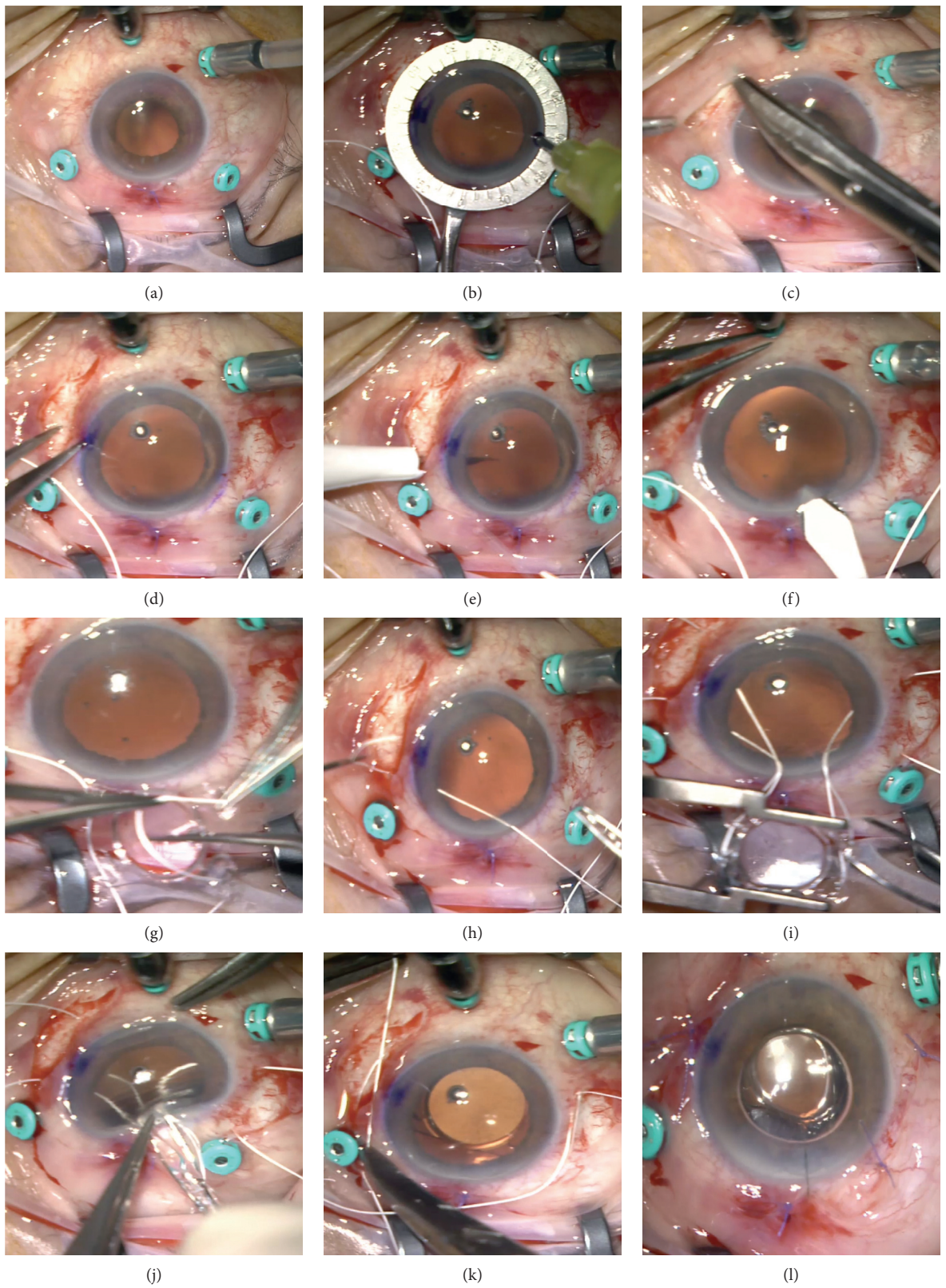

Figure 1: Illustration of basic surgical steps. The procedure begins with a standard 25-gauge three-port PPV. Here an inferior chandelier was also used (a). A Mendez ring is used to mark the horizontal axis to assure adequate sclerotomy positioning and lens centration (b), and nasal and temporal limited conjunctival peritomies are created (c). Calipers are used to mark the sclerotomy sites 2.5 mm behind the limbus and 5 mm apart (d), and four distinct sclerotomies (two nasal and two temporal) are made using the 25-gauge empty trocar needle (e). A 3.2 mm clear corneal incision is then made (f). The Gore-Tex suture is cut in half, the needle is removed, and the suture is then looped through the eyelets of the IOL (g). Each end of the suture is then transferred to the anterior chamber externalized through the corresponding sclerotomy, using non-serrated vitrectomy forceps (h). The Akreos IOL is easily folded and fits through the 3.2 mm corneal incision (i, j). The knots are tied with a 3-1-1 technique and rotated into the sclerotomy (k). Conjunctival peritomies are carefully closed with 7–0 vicryl. The corneal incision is usually self-sealing. Here a 10–0 monofilament suture was required (l).

Table 1: Patient baseline characteristics.

Total patients, *n*	36
Total eyes, *n*	37
Right eye: left eye	20 : 17
Male: female, *n*	20 : 16
Age (years)	
Mean ± SD	72.0 ± 12.4
Range	31–92
Past ophthalmic history, *n* (%)	
Closed-globe trauma	12 (32.4%)
PEX syndrome	8 (21.6%)
Glaucoma	7 (18.9%)
Retinal detachment repair by PPV	5 (13.5%)
Pathological myopia	4 (10.8%)
Open-globe trauma	3 (8.1%)
Exudative AMD	2 (5.4%)
Diabetic retinopathy without DME	2 (5.4%)
Dry AMD	1 (2.7%)
Penetrating keratoplasty	1 (2.7%)
Retinal venous occlusion	1 (2.7%)
Toxic optic neuropathy	1 (2.7%)
VKH syndrome	1 (2.7%)
Surgical indication, *n* (%)	
Aphakia due to complicated cataract surgery	9 (24.3%)
Subluxated IOL due to closed trauma	8 (21.6%)
Non-traumatic, non-PEX-related subluxated IOL	7 (18.9%)
PEX-related subluxated IOL	6 (16.2%)
Subluxated crystalline lens due to closed trauma	3 (8.1%)
Aphakia due to open-globe injury	2 (5.4%)
Silicone-induced IOL opacification	1 (2.7%)
Aphakia post-endophthalmitis	1 (2.7%)
Follow-up period, days	
Mean	548.9
Range	39–1564

AMD, age-related macular degeneration; DME, diabetic macular edema; IOL, intraocular lens; PEX, pseudoexfoliation; PPV, pars plana vitrectomy; VA, visual acuity.

serous choroidal detachment; and an intraoperative vitreous hemorrhage.

3.4. Postoperative Complications. Postoperative complications included ocular hypertension (27.0%; $n = 10$), transient corneal edema (18.9%; $n = 7$), cystoid macular edema (18.9%, $n = 7$), self-limited hypotension (5.4%, $n = 2$), self-limited vitreous hemorrhage (2.7%, $n = 1$), one case of central retinal vein occlusion (2.7%), one case of late retinal detachment (2.7%), and one case of Akreos IOL opacification (2.7%). Retinal detachment was managed with PPV with gas endotamponade; Akreos opacification is awaiting surgery to replace the IOL; the central retinal vein occlusion has been receiving intravitreal injections of 1.25 mg bevacizumab and 2 cases of macular edema resolved after intravitreal injections of corticosteroids (one case with intravitreal 2 mg triamcinolone alone, and the other with 2 mg triamcinolone, followed by 0.7 mg dexamethasone intravitreal implant). All of the other complications were managed medically, with topical treatment. No suture-related complications were observed, namely, suture breakage, IOL displacements, or suture-related inflammation. Also, there were no cases of postoperative endophthalmitis, choroidal detachment, or uveitis-glaucoma-hyphema syndrome.

Clinical outcomes are reviewed in Table 2.

4. Discussion

In the absence of capsular or iris support secondary to ocular trauma, zonular weakness, or complicated cataract surgery, scleral-sutured IOLs are a viable option in the surgical management of aphakia. Since its first description in the '80s by Malbran et al. [14], using a 10–0 polypropylene suture, the surgical technique and materials used have been evolving to improve its safety profile and success rate. Known by the resilience shown in non-ophthalmic surgery, Gore-Tex sutures have been recently used off-label in the scleral fixation of an IOL, to deal with suture-related complications associated with polypropylene. Although the theoretical benefits of Gore-Tex are obvious, long-term studies are critical to proving its practical effectiveness.

To the best of our knowledge, this is the first European case series assessing the visual outcomes and safety profile of Gore-Tex suture in the scleral fixation of Akreos AO60 intraocular lens combined with PPV, with a mean follow-up period of 548.9 days.

In our series, globally, the mean best-available logMAR VA improved from 1.61 preoperatively to 0.57 postoperatively, and this difference was statistically significant. This agrees with visual improvement observed in previous studies [3, 13].

During the study period, one eye (2.7%) had a postoperative visual deterioration of 2 lines in the Snellen chart. In this specific case, the patient's preoperative best-available VA was 10/10, and the surgery was justified by a subluxated IOL leading to unbearable monocular diplopia, rather than to low VA. Postoperatively, his best-available VA was 8/10 and there was complete resolution of the diplopia complaints, and thus it was regarded as a successful outcome. Further, 7 eyes (21.6%) presented no change in VA. 6 of these had a very low preoperative vision, with a past ophthalmological history explaining the lack of visual improvement (exudative AMD with a disciform scar, toxic optic neuropathy, terminal glaucoma, open-globe injury, bullous keratopathy, and myopic macular scar), and one developed a central retinal vein occlusion, 3 weeks after surgery, hampering visual recuperation.

Intraoperative complications were reported in 3 eyes, but all of them were minor and non-sight threatening. The serous choroidal detachment was small, flat, and peripherical and resolved by the first 24 postoperative hours. The intraoperative vitreous hemorrhage was also self-limited and managed with simple observation. The iatrogenic retinal hole occurring during vitrectomy was successfully managed with endolaser circumscribing the lesion.

Our most common postoperative complication was ocular hypertension (27.0%; $n = 10$), defined as de novo IOP of 25 mmHg or more, at any postoperative visit. Of these patients, 8 presented with conditions that can possibly facilitate such rise in postoperative IOP: 3 had a history of glaucoma, 2 underwent surgery due to

Table 2: Clinical outcomes.

Visual acuity			
	Preop. logMAR VA, mean ± SD	Postop. logMAR VA, mean ± SD	*P*
Overall ($n = 37$)	1.61 ± 0.73	0.57 ± 0.66	($P < 0.001$)
Surgical indication (*n*)			
Aphakia due to complicated cataract surgery (9)	1.46 ± 0.68	0.51 ± 0.45	0.028
Subluxated IOL due to closed trauma (8)	1,65 ± 0.83	0.44 ± 0.76	0.028
Non-traumatic, non-PEX-related subluxated IOL (7)	1.61 ± 0.75	0.65 ± 0.66	0.028
PEX-related subluxated IOL (6)	1.47 ± 0.81	0.32 ± 0.25	0.043
Subluxated crystalline lens due to closed trauma (3)	2.08 ± 0.17	1.35 ± 1.08	0.317
Aphakia due to open-globe injury (2)	2.13 ± 0.21	1.09 ± 1.26	0.317
Silicone-induced IOL opacification (1)	0.15 ± 0.00	0.00 ± 0.00	†
Aphakia post-endophthalmitis (1)	2.28 ± 0.00	0.30 ± 0.00	†
Intraoperative complications			
	n (%)	Treatment	
Iatrogenic retinal hole	1 (2.7%)	Endolaser	
Choroidal detachment	1 (2.7%)	Observation	
Vitreous hemorrhage	1 (2.7%)	Observation	
Postoperative complications			
	n (%)	Treatment	
Ocular hypertension	10 (27.0%)	Topical	
Corneal edema	7 (18.9%)	Topical	
Cystoid macular edema	7 (18.9%)	Topical + intravitreal injections*	
Hypotension	2 (5.4%)	Observation	
Vitreous hemorrhage	1 (2.7%)	Observation	
Central retinal vein occlusion	1 (2.7%)	Intravitreal injections	
Retinal detachment	1 (2.7%)	Surgical	
Akreos IOL opacification	1 (2.7%)	Surgical	

PEX, pseudoexfoliation. †This subgroup includes 1 case, and a *P* value is impossible to calculate. *Five eyes with macular edema responded to topical nepafenac 3 mg/ml + dexamethasone 1 mg/ml drops; 2 eyes were refractory to topical drops and needed intravitreal injections of corticosteroids (1 case with intravitreal 2 mg triamcinolone alone, and the other with 2 mg triamcinolone, followed by 0.7 mg dexamethasone intravitreal implant).

complicated cataract surgery with retained lens material, and 3 had a history of closed-globe trauma. All ten cases of ocular hypertension were successfully treated medically, with hypotensive drops.

In our series, transient hypotony (defined as de novo IOP of 5 mmHg or less, at any postoperative visit) occurred in 5.4% of cases ($n = 2$). This value is lower than what was previously described [3, 13]. Such a low rate might be explained by the predominant use of small gauge vitrectomy instrumentation (25-gauge) that diminishes leakage from sclerotomy sites.

Our rate of postoperative cystoid macular edema (18.9%, $n = 7$) was higher than that in other reports [3, 13]. Of these eyes, 3 underwent PPV with posterior phaco-fragmentation due to complicated cataract surgery with retained lens material; 2 had a history of PEX syndrome and the other 2 were diabetic patients (one without diabetic retinopathy and the other with minimal non-proliferative diabetic retinopathy). Such pro-inflammatory conditions might justify the development of this complication [15, 16]. All eyes were treated with topical nepafenac 3 mg/ml and dexamethasone 1 mg/ml drops. Two of those eyes were resistant to medical treatment, and edema resolution required intravitreal injections of corticosteroids (1 case with intravitreal 2 mg triamcinolone alone, and the other with 2 mg triamcinolone, followed by 0.7 mg dexamethasone intravitreal implant).

We reported a case (2.7%) of macula-on retinal detachment, occurring 5 months after surgery. This postoperative complication had never been reported in the literature so far with this technique. This patient underwent PPV with posterior phaco-fragmentation due to complicated cataract surgery with retained lens material and she had no relevant past ophthalmic history. Therefore, a cause-effect relationship is difficult to establish. Our 2.7% value is lower than that in previous studies with different techniques. Vote et al. reported an 8.2% rate of retinal detachment after combined PPV and scleral fixation of an Alcon CZ 70 BD IOL using 10–0 polypropylene suture [9], and Czajka et al. described a 3.8% rate of retinal detachment occurring after combined PPV and sutureless scleral fixation of a three-piece IOL [7].

No suture-related complications were observed, namely, suture breakage, IOL displacements, or suture-related inflammation (Figure 2), even in eyes with the longest follow-up period (1564 days). But additional long-term follow-up studies would be important to confirm the resilient profile of Gore-Tex sutures over time.

Recently, a foldable, single-piece, sutureless SFIOL called Carlevale has been introduced. Besides being devoid of suture-related complications, Carlevale IOL has been reported to have a great stability profile with no IOL displacement or haptic breakage, providing good refractive outcomes. Moreover, its innovative design with two small and flexible plugs at the end of each haptic, anchoring the IOL to the scleral tissue, theoretically reduces surgical complexity and time [11, 12].

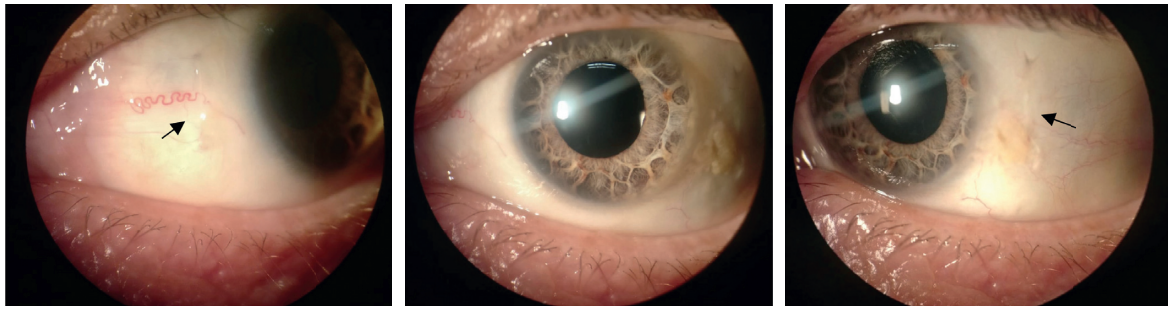

Figure 2: Slit-lamp photograph of a patient's left eye, 2 months after scleral fixation of an Akreos AO60 due to aphakia after complicated cataract surgery. The Gore-Tex suture (arrows) is barely visible underneath the conjunctiva, the knots are adequately buried into the sclerotomy, and there is no suture-related inflammatory reaction. The middle panel shows a perfectly centered IOL (courtesy of Dr. Sónia Torres-Costa).

A comparative analysis between scleral-fixated IOLs using Gore-Tex suture and this novel sutureless technique is lacking.

The advantages of Akreos AO60 IOL have been described elsewhere [2, 3, 13] and include its stability and an inferior chance of lens tilt and induced astigmatism, due to its two pairs of eyelets allowing for a 4-point scleral fixation, along with its ability to be easily folded and introduced in the eye through smaller corneal incisions. However, cases of optic opacification have been described with these hydrophilic lenses after both anterior and posterior segment procedures [17–19]. Indeed, we reported one case of IOL opacification, severely compromising VA. Considering that this was a late complication, occurring 2 years postoperatively, a longer follow-up period would be critical to understanding the real burden of this issue. Comparative studies, using different types of IOLs would help to determine the best IOL to implant.

In our series, all patients underwent scleral fixation of an Akreos AO60 IOL using Gore-Tex suture, combined with PPV. However, it is important to recognize that scleral-fixated IOLs can be placed without the need for concurrent PPV, with good results [20].

This study has some limitations, primarily related to its retrospective design.

Best-corrected VA determined after objective or/and subjective refraction was not always available, and the best-available VA with pinhole was considered in those cases. Therefore, an underestimation of the final visual outcomes might have occurred. Secondly, the surgeries were performed by three distinct surgeons with different surgical experience and preferences, introducing some variability to the standard technique, as was mentioned above, which could limit generalizability. Also, there was a large interval in follow-up duration, ranging from 39 to 1564 days. There were 21 eyes (56.8%) with a follow-up of less than 1 year. Thus, potential late complications in this group could not be assessed. Finally and importantly, there was a wide range of surgical indications and complex ophthalmological backgrounds that might confound the interpretation of the postoperative outcomes and complications. Although we believe that we have a real-world representative sample, a larger population would further increase the power of the results.

5. Conclusions

Our study reports a statistically significant improvement in VA after scleral fixation of Akreos AO60 intraocular lens using Gore-Tex suture, with no suture-related complications. This technique can be safely combined with PPV and can thus be a valuable option for posterior segment surgeons when both vitreoretinal surgery and secondary IOL implantation are required. In future, prospective studies with a longer follow-up period and a larger population would be important to prove the long-term safety profile of this procedure. Also, comparative analysis with other IOL types and with other treatment strategies for aphakia would be necessary to conclude the advantages of Gore-Tex scleral-fixated Akreos AO60 IOL over them.

Data Availability

The data used to support the findings of this study cannot be made publicly available, as no patient approval has been obtained for sharing coded data. Output of statistical analyses can be made available upon request.

Conflicts of Interest

The authors declare that they have no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Supplementary Materials

The supplementary material includes a video showing the surgical technique in detail (https://drive.google.com/file/d/1-ae40KWv_w2TjBt-K193CqyrJ8ZaKx93/view?usp=sharing). (*Supplementary Materials*)

References

[1] M. S. Stem, B. Todorich, M. A. Woodward, J. Hsu, and J. D. Wolfe, "Scleral-fixated intraocular lenses: past and present," *Journal of VitreoRetinal Diseases*, vol. 1, no. 2, pp. 144–152, 2017.

[2] B. W. Botsford, A. M. Williams, I. P. Conner, J. N. Martel, and A. W. Eller, "Scleral fixation of intraocular lenses with gore-tex suture: refractive outcomes and comparison of lens power formulas," *Ophthalmology Retina*, vol. 3, no. 6, pp. 468–472, 2019.

[3] M. A. Khan, O. P. Gupta, R. G. Smith et al., "Scleral fixation of intraocular lenses using Gore-Tex suture: clinical outcomes and safety profile," *British Journal of Ophthalmology*, vol. 100, no. 5, pp. 638–643, 2016.

[4] M. D. Wagoner, T. A. Cox, R. G. Ariyasu, D. S. Jacobs, and C. L. Karp, "Intraocular lens implantation in the absence of capsular support: a report by the American academy of ophthalmology," *Ophthalmology*, vol. 110, no. 4, pp. 840–859, 2003.

[5] M. A. Khan, A. T. Gerstenblith, M. L. Dollin, O. P. Gupta, and M. J. Spirn, "Scleral fixation of posterior chamber intraocular lenses using gore-tex suture with concurrent 23-gauge pars plana vitrectomy," *Retina*, vol. 34, no. 7, pp. 1477–1480, 2014.

[6] P. Mora, G. Calzetti, S. Favilla et al., "Comparative analysis of the safety and functional outcomes of anterior versus retropupillary iris-claw IOL fixation," *Journal of ophthalmology*, vol. 2018, Article ID 8463569, 2018.

[7] M. P. Czajka, A. Frajdenberg, M. Stopa, T. Pabin, B. Johansson, and G. Jakobsson, "Sutureless intrascleral fixation using different three-piece posterior chamber intraocular lenses: a literature review of surgical techniques in cases of insufficient capsular support and a retrospective multicentre study," *Acta Ophthalmologica*, vol. 98, no. 3, pp. 224–236, 2020.

[8] R. Frisina, E. Pilotto, L. Tozzi, R. Parrozzani, and E. Midena, "A new technique of needle-guided retropupillary fixation of iris-claw intraocular lens," *Journal of Cataract & Refractive Surgery*, vol. 45, no. 3, pp. 267–271, 2019.

[9] B. J. Vote, P. Tranos, C. Bunce, D. G. Charteris, and L. Da Cruz, "Long-term outcome of combined pars plana vitrectomy and scleral fixated sutured posterior chamber intraocular lens implantation," *American Journal of Ophthalmology*, vol. 141, no. 2, pp. 308–312, 2006.

[10] F. K. Obeng, V. K. Vig, P. Singh, R. Singh, B. Dhawan, and N. Sahajpal, "Posterior chamber scleral fixation of intraocular lenses in post-vitrectomised aphakic eyes," *Journal of Clinical and Diagnostic Research*, vol. 11, no. 3, pp. Nc09–nc13, 2017.

[11] T. Fiore, M. Messina, A. Muzi et al., "Comparison of two different scleral fixation techniques of posterior chamber Carlevale lens," *Medicine*, vol. 100, no. 32, Article ID e26728, 2021.

[12] G. Kymionis, M. Petrelli, L. Schmutz, and A. Petrovic, "New sutureless, scleral-fixated intraocular lens (Carlevale, soleko) implantation combined with descemet stripping automated endothelial keratoplasty: an innovative surgical approach," *Cornea*, vol. 39, no. 11, pp. 1460–1462, 2020.

[13] M. A. Khan, W. A. Samara, A. T. Gerstenblith et al., "Combined pars plana vitrectomy and scleral fixation of an intraocular lens using gore-tex suture: one-year outcomes," *Retina*, vol. 38, no. 7, pp. 1377–1384, 2018.

[14] E. S. Malbran, E. Malbran Jr., and I. Negri, "Lens guide suture for transport and fixation in secondary IOL implantation after intracapsular extraction," *International Ophthalmology*, vol. 9, no. 2-3, pp. 151–160, 1986.

[15] L. Ilveskoski, C. Taipale, E. J. Holmström, and R. Tuuminen, "Macular edema after cataract surgery in eyes with and without pseudoexfoliation syndrome," *European Journal of Ophthalmology*, vol. 29, no. 5, pp. 504–509, 2019.

[16] L. H. P. Wielders, J. S. A. G. Schouten, B. Winkens et al., "Randomized controlled European multicenter trial on the prevention of cystoid macular edema after cataract surgery in diabetics: ESCRS PREMED Study Report 2," *Journal of Cataract & Refractive Surgery*, vol. 44, no. 7, pp. 836–847, 2018.

[17] V. Balendiran, K. MacLean, N. Mamalis, M. Tetz, and L. Werner, "Localized calcification of hydrophilic acrylic intraocular lenses after posterior segment procedures," *Journal of Cataract & Refractive Surgery*, vol. 45, no. 12, pp. 1801–1807, 2019.

[18] A. Kalevar, M. Dollin, and R. R. Gupta, "Opacification of scleral-sutured akreos ao60 intraocular lens after vitrectomy with gas tamponade: case series," *Retinal Cases & Brief Reports*, vol. 14, no. 2, pp. 174–177, 2020.

[19] L. Werner, G. Wilbanks, C. P. Nieuwendaal et al., "Localized opacification of hydrophilic acrylic intraocular lenses after procedures using intracameral injection of air or gas," *Journal of Cataract & Refractive Surgery*, vol. 41, no. 1, pp. 199–207, 2015.

[20] M. D. Sindal, C. P. Nakhwa, and S. Sengupta, "Comparison of sutured versus sutureless scleral-fixated intraocular lenses," *Journal of Cataract & Refractive Surgery*, vol. 42, no. 1, pp. 27–34, 2016.

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Research Article

Supporting IOL'S in a Deficient Capsular Environment: The Tale of No "Tails"

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Purpose. To evaluate the efficacy and safety of the following three distinct surgical procedures for secondary IOL implantation without capsular support: Iris-claw lens, flanged transscleral fixated IOLs (Yamane technique), and sutureless transscleral hook IOL fixation (Carlevale IOL). *Materials and Methods*. In this retrospective comparative study, three different sutureless IOL implantation techniques were compared in patients without any capsular support. Visual acuity and outcomes were analyzed in 24 eyes of 23 patients (14 male and 9 female). Study included 13 iris-claw lenses (Artisan Ophtec), 6 flanged transscleral fixated IOLs (Yamane technique using a MA60MA Alcon Inc IOL), and 5 transscleral Carlevale IOLS (Carlevale IOL, Soleko, Italy). *Results*. logMAR mean best-corrected visual acuity (BCVA) improved from 0.49 ± 0.19 to 0.19 ± 0.10 at three months after surgery ($p < 0.05$). Postoperative BCVA was similar in all three groups, and no intergroup difference was noted. Three eyes (12.5%) had a raised IOP >25 mmHg, 2 eyes (8%) presented a subluxated/dislocated IOL, 4 eyes (16%) had corneal edema longer than 7 days, 3 eyes (12.5%) had irregular pupil profile, 2 eyes (8%) had vitreous hemorrhage, 7 eyes had (29%) corneal astigmatism over 3 diopters, and one patient (4%) developed cystoid macular edema (CME). *Conclusions*. All three surgical procedures can be considered adequate to correct aphakia in patients without capsular support with significant improvement in visual acuity and low complication.

1. Introduction

Modern cataract surgery has excellent results and a rapid visual recovery after intraocular lens (IOL) implantation in the capsular bag (PC-IOL). However, lens dislocation in the vitreous cavity, posttraumatic cataract surgery, pseudoexfoliation (PXF), Marfan syndrome, and Ehlers Danlos syndrome may encounter an issue of inadequate capsular support not suitable for in-the-bag or ciliary sulcus IOL implantation [1].

Sutured transscleral IOL fixation of three-piece posterior chamber IOLs is a valid procedure for these patients. The downside of this procedure is longer surgical time and a higher complication rate [2–8]. Hence, there is a need for a simpler procedure with the lower complication rate and faster functional recovery.

Various procedures such as iris-claw, flanged transscleral fixated IOLs (Yamane technique), and sutureless transscleral hook IOL fixation (Carlevale IOL) have been described for the considered indications.

This comparative retrospective study aims to evaluate and compare these three surgical procedures with respect to their outcomes and complications.

2. Materials and Methods

This is a nonrandomized comparative retrospective study carried out on 23 patients (24 eyes). The study was conducted between January 2017 and December 2018 at Clinica Mediterranea, Naples, Italy. Relevant data of the study population were drawn from informatics medical records. All subjects had lens-related issues with an inadequate capsular support and needed IOL implantation. All patients were informed about the risks and benefits of the surgery, and a written informed consent was obtained. The study was conducted in accordance with the tenets of the Helsinki Declaration.

Preoperative and postoperative ophthalmic evaluation included Snellen BCVA, slit lamp examination, Goldman applanation tonometry for intraocular pressure (IOP) measurement, and a detailed fundus examination. All surgical procedures were performed under complete aseptic precautions. Surgeries were performed under peribulbar anesthesia (ropivacaine hydrochloride 10 mg/ml).

Low intraocular pressure was considered at IOP <6 mm Hg, while a reading of more than 25 mm Hg was considered as high. Biometry was performed in all patients, including the pseudophakic eyes, and IOL power was calculated with Haigis, SRK-T, Holladay 1 e Hoffer Q formulas. We defined primary surgery as the first surgical intervention (PHACO, femtolaser-assisted capsular surgery, FLACS, or intracapsular extraction (ICCE). Late onset subluxation secondary to PXF was also included here. Secondary surgery was defined as the surgical approach necessary for extraction of subluxated/dislocated IOL or residual lens remnants along with secondary IOL implantation (anterior vitrectomy (AV) or PPV). The documentation included the type of surgical procedure for cataract remnants removal, surgical procedure for IOL implantation, perioperative complications, and outcomes at the end of the 6 months follow-up period.

2.1. Surgical Technique. Cataract surgery was performed using a phacomachine with a combined torsional and longitudinal US system (Centurion Vision System, Alcon, Fort Worth, Texas, USA.). In aphakic patients without nuclear fragments in the vitreous, the anterior vitrectomy was performed with a 23G vitrector (Centurion Vision System, Alcon, Fort Worth, Texas, USA).

A 23G pars plana vitrectomy (PPV) (Constellation Vision System, Alcon, Fort Worth, Texas, USA.) was done when nuclear fragments or IOLS were dislocated in the vitreous cavity. Nuclear fragments were removed after core vitrectomy, inducing posterior vitreous detachment and vitreous base shaving [9]. Perfluorocarbonate liquid (PFCL) was injected for macular and posterior pole protection. Nuclear fragments were removed using the phacofragmatome or vitrectomy cutter. When an IOL subluxation occurred with the bag itself, a posterior vitrectomy was performed to release the vitreous adhesions with the bag-IOL complex. The lens itself was brought into the anterior chamber using vitreous forceps.

2.2. Iris-Claw Surgical Technique. Artisan (Ophtec, Groningen, Netherlands) iris-claw lens was used wherever indicated. This is a 5 mm biconvex PMMA lens with a greater diameter of 8.5 mm. IOL power was calculated using SRK/T formula. The constant for the correct IOL power calculation in the anterior chamber (over the iris) was 115.0.

A superior 5 mm clear cornea incision with two side ports 180° apart was performed. After a thorough anterior/posterior vitrectomy, miosis was achieved by injecting acetylcholine chloride in the anterior chamber (Miovisin, Farmigea, 2 mg/2 ml). Sodium hyaluronate 1.4% (Healon GV, Johnson & Johnson Vision) was injected for maintenance of the anterior chamber endothelial protection and to facilitate IOL handling. The IOL was inserted in the anterior chamber in a vertical position to take advantage of the smaller diameter of the lens and then was rotated by 90° for the correct position and enclavation on the iris. The lens was held with Buratto's forceps for the enclavation procedure. The IOL was enclaved using a needle through a lateral paracentesis side port. At the end of the procedure, a small iridectomy was performed to avoid pupillary block. The main incision was sutured with four interrupted 10/0 nylon sutures. Healon was washed out from the anterior chamber, and 1 mg of cefuroxime (Aprokam, Theà) was injected in the anterior chamber [10] (Supplementary Video 1: https://drive.google.com/file/d/1a6SridVD9ZBNOmdvftMtTeK-NH3-nf7Y/view?usp=sharing).

2.3. Transscleral Implantation Technique. The three-piece IOL, when present, was unleashed from the capsular bag and prepared to be implanted using the transscleral technique. One of the haptics was extruded from the main incision to avoid a subluxation of the lens itself. This sutureless intrascleral three-piece IOL fixation is a technique also known as flanged IOL fixation and was described by Yamane et al. in [11]. When a single-piece IOL was present, the lens was cut with scissors and explanted from the main incision itself. Three-piece IOL (MA60MA, Alcon Inc.) was injected in the anterior chamber leaving the trailing haptic out of the main incision to avoid the lens drop in the vitreous cavity. An angled sclerotomy was made through the conjunctiva using a 30-gauge thin-wall needle (TSK ultrathin-wall needle, Tochigi Seiko, Tochigi, Japan) at 2 mm from the limbus. The leading haptic was threaded into the lumen of the needle using forceps. A second sclerotomy then was made with a 30-gauge thin-wall needle that was 180° from the first sclerotomy. The trailing haptic was inserted into the lumen of the second needle, while the first needle was put on the eye lid. Both haptics were externalized onto the conjunctiva using the double-needle technique. The ends of the haptics were cauterized using an ophthalmic cautery device (Accu-Temp Cautery, Beaver Visitec, Waltham, MA) to make a flange with a diameter of 0.3 mm. The flange of the haptics was pushed back and fixed into the scleral tunnel. A peripheral iridotomy was performed using the vitrectomy cutter after miosis to avoid iris capture of the IOL. At the end of surgery, 1 mg of cefuroxime (Aprokam, Theà) was injected in the anterior chamber.

2.4. Carlevale's Lens Implantation Technique. Carlevale's lens is a single piece, 25% water hydrophilic acrylic IOL, with a 6.5 mm optic, a 13.5 mm diameter, and 10° vaulted haptic with a retina vault and retina convexity. Carlevale IOL has a correct direction of the implant, indicated by the presence of two small tags on the haptics and a harpoon for sutureless transscleral fixation. IOL's power range is between −5 and +35 diopters, and the A constant is 118.5. After corneal white to white diameter evaluation (WTW), the infusion line is positioned at inferotemporal quadrant. A limited conjunctival peritomy, 2 partial 4 × 4 mm thickness scleral flaps were made and hinged at the limbus 180° apart. Then, two sclerotomies using a 25-gauge needle were placed at 1.5–2.0 mm from the limbus in correspondence to the three and nine o clock position (Supplementary video 2: https://drive.google.com/file/d/1uR_B8y4j0Nwi3LerWOMcoCmwGam7-ktU/view?usp=sharing). The Carlevale IOL was injected into the anterior chamber through a corneal tunnel using a Viscojet injector (Medical Viscojet 2.2 mm), and the leading plug was grasped with crocodile tip forceps inserted into the vitreous chamber through the sclerotomy and then externalized under the scleral flap in a single maneuver. Then, the trailing plug was grasped and externalized with 2 forceps using the handshake technique; IOL centration was achieved without performing extra-intraoperative maneuvers. Scleral flaps and conjunctival wound were sealed with nylon 10/0 and polyglactin 8/0 (Vicryl), respectively. A 10/0 nylon stitch is positioned on the main incision suture, and 1 mg cefuroxime is injected in the anterior chamber [12, 13].

2.5. Statistical Analysis. Statistical analysis was performed using SPSS software (version 26, IBM Corp.) A paired *t*-test was used to compare preop and postop visual acuity of the three groups. A p value of less than 0.05 was considered statistically significant. Visual acuity was converted to a logarithm of the minimum angle of resolution (logMAR) for analysis. The ANOVA analysis followed by the Bonferroni test was used to compare postop visual acuity between the three groups.

3. Results

We have compared postop visual acuity and complications of three different sutureless IOL implantation techniques in patients without any capsular support. Out of 23 patients, 14 were male (60%) and 9 were female (40%).

We used three implantation techniques for this cohort of patients: in group 1 (13/24 eyes, 54.1%), iris-claw lenses were implanted in the anterior chamber (Artisan Ophtec). In group 2 (6/24 eyes, 25%), sutureless intrascleral three-piece IOL (MA60MA, Alcon Inc.) was used. In group 3 (5 out of 24 eyes, 20.8%), transscleral IOL fixation with an intrascleral plug using Carlevale's IOL (Carlevale IOL, Soleko, Italy) placement was done. Various etiological causes of insufficient capsular support with the type of different IOLs are given in Table 1.

Table 2 provides the etiology of loss of capsular support, surgery type (kind of vitrectomy).

Ten out of 24 eyes (41.6%) had a posterior capsular rent (PCR) during cataract surgery. Out of 10 PCR cases, 6 eyes (25%) required PPV to remove cataract remnants dislocated in the vitreous cavity, while 4 eyes (16%) required only anterior vitrectomy. Out of 10 PCR cases, 6 eyes had PXF with zonular deficiency. Out of 6 PXF cases, 1 case was planned for intracapsular cataract extraction (ICCE) with vitrectomy due to evident phacodonesis in more than 270°. Three cases required a posterior approach to complete the vitrectomy, and 3 cases were managed with anterior vitrectomy alone.

Three eyes (12.5%) had IOL-bag complex subluxation due to PXF. All cases needed 3 ports PPV with IOL removal. In 2 eyes, the subsequent same three-piece IOL was used for transscleral IOL fixation. In the third eye, an iris-claw was implanted. In 3 cases (12.5%) with Marfan's-associated subluxation, 2 eyes underwent PHACO with anterior vitrectomy with iris-claw implantation. In 1 case, FLACS (femtolaser-assisted cataract surgery) was used for capsulorrhexis and nucleus fragmentation where Carlevale's lens were implanted (Figure 1). Two patients (8%) had a traumatic subluxated cataract that required PPV with Carlevale's lens implantation.

Patients were followed up at postop day one and then at one week and one month. The last follow-up was at six months.

Improvement in mean visual acuity (BCVA) is given in (Table 3).

BCVA comparison evaluated with ANOVA followed by Bonferroni's test didn't show any statistical significance (significant $p > 0.05$) related to the different surgical techniques used (Table 4).

3.1. Complications. Some complications were noted after primary surgery, but none resulted in diminished visual acuity. Complications related to the lens implanted are given in Table 5. Raised IOP was noted in 4 eyes (16%). One patient (total 8%) in the transscleral flanged group and in the iris-claw group had IOL malposition and subluxation. The one in the iris-claw group required secondary surgery because of the loss of hooking on the iris.

Four of the 24 eyes (16%) had corneal edema secondary to raised IOP, which lasted over 7 days (two in the transscleral flanged group and two in the iris-claw group). It resolved with topical antiglaucoma therapy.

Cystoid macular edema (CME) occurred in just one eye (4%) in the iris-claw group that required NSAID eye drops. The CME resolved after one month of topic therapy.

Three eyes (12.5%) showed pupillary anomalies in the iris-claw group, related to improper iris hooking. None required IOL repositioning. In two eyes (one each in the transscleral and Carlevale's group), vitreous hemorrhage (VH) occurred possibly following near-to-limbus sclerotomy. Seven eyes (all from iris-claw group) developed high postoperative astigmatism (>3D). This was tackled by sequential removal of the main incision sutures over a period of time. Yet, one patient had persistent astigmatism >3D until final follow-up. There was no incidence of retinal or choroidal detachment or endophthalmitis.

Table 1: Causes of capsular inadequate support and types of IOL implanted.

	Eyes (*n*)	Percentage (%)	Iris-claw	Intrascleral fixation	Carlevale's lens
Posterior capsular rent (PCR)	10	41	6	4	0
Subluxation secondary to PXF	6	25	3	0	3
Subluxation secondary to Marfan's syndrome	3	12.5	2	0	1
IOL subluxation	3	12.5	1	2	0
Traumatic cataract	2	9	1	0	1
Total	24	100	13	6	5

Table 2: Primary or secondary type of surgery.

	Eyes (*n*)	Primary surgery				Secondary surgery	
		PHACO	FLACS	ICCE	Subluxation secondary to PXF	Anterior vitrectomy	Posterior vitrectomy
PCR	10	10	0	0	0	4	6
PXF subluxation	6	5	0	1	0	3	3
Marfan's subluxation	3	2	1	0	0	3	0
IOL subluxation	3	0	0	0	3	0	3
Traumatic cataract	2	2	0	0	0	0	2
Total	24	19	1	1	3	10	14

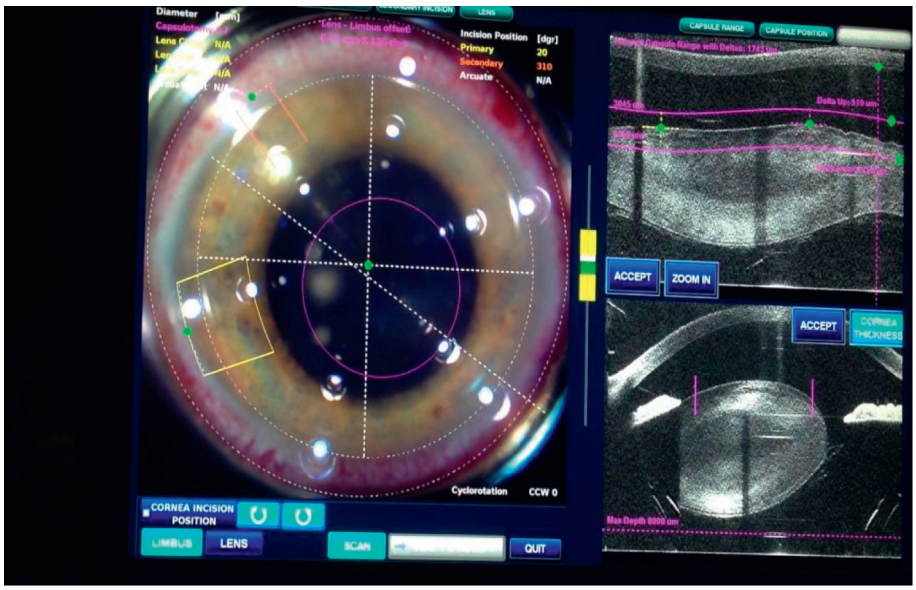

Figure 1: Femtolaser-assisted cataract surgery in Marfan's syndrome demonstrating zonular disinsertion with nucleus subluxation.

Table 3: Mean preop and postop mean visual acuity.

BCVA	Preop	Postop	*P* value
logMAR	0.49 ± 0.2	0.19 ± 0.1	<0.0001

Table 4: Intergroup postop visual acuity results of ANOVA and Bonferroni test.

Postoperative BCVA	Carnevale vs. iris-claw	Carnevale vs. transscleral	Iris vs. transscleral	ANOVA
(logMAR) *p* values	0.672	1	1	0.458

4. Discussion

Aphakia with inadequate capsular support can be seen in several conditions such as postcomplicated cataract surgery, PXF syndrome, subluxation secondary to capsular instability in Marfan's syndrome, Ehlers Danlos, or in traumatic cataract. These conditions require an individualized approach with different IOL implantation techniques. Angle-supported, scleral or iris-supported IOLs are used, each having their pros and cons. The main purpose of the study was to

Table 5: Incidence of complications related to the lens implanted.

	Eyes (n)	Percentage	Iris-claw	Transscleral	Carlevale
Raised IOP	4	16	2	2	0
IOL malposition	2	8	1	1	0
Corneal complications	4	16	2	2	0
CME	1	4	1	0	0
RD	0	0	0	0	0
Pupillary anomalies	3	12.5	3	0	0
VH	2	8	0	1	1
High astigmatism	7	29	7	0	0

evaluate three different surgical techniques and compare their efficacy and complications.

Secondary IOL implantation can be divided into sutured and sutureless techniques. Sutured surgical techniques require a 10/0 or 9-0 Prolene suture to secure the IOL to the scleral tissue. Sutured techniques are associated with complications such as suture breaks (Prolene), conjunctival erosion, cheese wiring, and rarely secondary retinal detachment [14–16]. Hence, sutureless techniques were the need of the hour (2–8).

Gabor and Pavilidis first described a new sutureless technique in which the haptics were extruded out by a sclerotomy and tucked in a scleral tunnel prepared ad hoc [17, 18]. A faster glued IOL technique was described by Agarwal et al., wherein he used fibrin glue to fix the scleral flaps. [19]. Both the Scharioth and Agarwal sutureless surgical procedures are prone to postoperative hypotony [18, 19].

In 2017, Yamane et al. proposed the flanged intrascleral IOL fixation, which could be considered the optimization of both the Scharioth and Agarwal techniques [11]. This double-needle technique entailed externalization of two haptics using a 30-gauge thin-wall needle (TSK ultrathin-wall needle; Tochigi Seiko, Tochigi, Japan) at 2 mm from the limbus. This not only provided guidance for extrusion of the haptics but also eliminated the need of peritomy and scleral flap creation. This technique avoids all complications related to sutures. The small size of the tunnel incision reduces the risk of iris prolapse, leakage, anterior chamber shallowing, and suprachoroidal hemorrhage. Suture less techniques are quicker with a shorter rehabilitation period. It also allows salvage of the previously implanted three-piece IOL. We have also been able to do the same in one of our patients. This technique may require a fair learning curve so as to avoid tilt or decentration [20–22].

Worst et al. (in 1972) original iris-claw lens has been modified over time (Artisan (Ophtec)) to avoid corneal decompensation. [23] Verisyse (2005, AMO, presently Johnson & Johnson) is another lens with similar features. Iris-claw lenses are fixed to the midperiphery of the iris and do not need the support of the angle or ciliary sulcus and hence do not interfere with normal anatomical structures. Due to its vaulted structure, it has the advantage of decreasing the risk of pupillary blockade. Iris-claw lenses can be placed in anterior or posterior to iris tissue. Mora et al. in their retrospective comparative study found comparable safety and functional outcomes between the anterior vs. retropupillary iris-claw groups. [24] Forlini et al. published a retrospective analysis of long-term follow-up of retropupillary ICIOL implantation in 320 patients and concluded that complications related to retropupillary iris-claw were minimal compared with its benefits [25]. This technique has an easy learning curve, short surgical time, and low incidence of perioperative complications. Complications include large corneal incision, iritis, cystoid macular edema, raised intraocular pressure, and irregular shape of pupil. We found the comparable rate of complications when compared to other studies [10, 26, 27].

A single patient had an iris-claw drop, which required a secondary surgical procedure for reenclavation. The slow visual recovery related to high postop astigmatism and slow refraction stability hampers a correct postop lens prescription, creating a long discomforting period of low visual acuity. Astigmatic stabilization can occur even after 6 months, as previously described by Chen et al. [28]. This makes the iris-claw lens relatively less desirable owing to reduced patient's satisfaction and prolonged visual recovery time. Moreover, the pupil deformation risk related to a wrong enclavation procedure could be responsible for the patient's dysphotopic phenomenon [10, 27]. To avoid complications related to abnormal pupillary shape, a newer surgical technique using a guide needle to facilitate exact and equidistant enclavation has been tried [29].

Carlevale et al. in 2020 introduced a new type of lens (SOLEKO) [12, 13]. This lens is provided by a small harpoon suited for the sutureless lens anchorage to the sclera by a 23G sclerotomy protected by a scleral flap. Carlevale's IOL is a hydrophilic one-piece IOL with a 6.5 mm optic plate and a wide diameter of 13.5 mm. This allows the use of the previous phacoincision along with the minimally invasive injection technique for IOL insertion (medical Viscoject 2.2 mm). The advantage is the possibility of a rapid visual recovery with less induced astigmatism. Complications such as vitreous hemorrhage can occur, which was seen in one of our patients. Lens injection maneuver requires skill and caution in a dilated pupil with the absence of capsular support. There is a chance of subluxation of the IOL in the vitreous cavity. This complication did not occur in our cohort of study.

All three surgical procedures for secondary IOL implantation showed similar functional recovery without statistically significant differences ($p > 0.05$). The Carlevale's IOL group showed higher postop corrected visual acuity,

although this was not statistically significant ($p > 0.05$). A longer follow-up period may possibly capture some complications not manifested during the study period.

5. Conclusions

All procedures resulted in good visual outcome in the included cohort. The associated complications were infrequent, treatable, and not related to visual acuity. Relatively small study population was one of the limitations of this study.

We feel that a randomized trial with a higher number of subjects and a longer follow-up period may possibly confirm our findings.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Supplementary Materials

Video 1. Surgical technique of anterior iris-claw fixation. Video 2. Carlevale technique of IOL fixation. (*Supplementary Materials*)

References

[1] J. J. Gicquel, M. E. Langman, and H. S. Dua, "Iris claw lenses in aphakia," *British Journal of Ophthalmology*, vol. 93, no. 10, pp. 1273–1275, 2009.

[2] L. A. Gess, "Scleral fixation for intraocular lenses," *American Intra-Ocular Implant Society Journal*, vol. 9, no. 4, pp. 453–456, 1983.

[3] E. S. Malbran, E. Malbran, and I. Negri, "Lens guide suture for transport and fixation in secondary IOL implantationafter intracapsular extraction," *International Ophthalmology*, vol. 9, no. 2-3, pp. 151–160, 1986.

[4] W. J. Stark, G. Goodman, D. Goodman, and J. Gottsch, "Posterior chamber intraocular lens implantation in the absence of posterior capsular support," *Ophthalmic Surgery, Lasers and Imaging Retina*, vol. 19, no. 4, pp. 240–243, 1988.

[5] D. H. Shin, "Implantation of a posterior chamber lens without capsular support during penetrating keratoplasry or as a secondary lens (letter)," *Ophthalmic Surgery*, vol. 19, 1988.

[6] A. V. Spigelman, R. L. Lindstrom, B. D. Nichols, T. D. Lindquist, and S. S. Lane, "Implantation of a posterior chamber lens without capsular support during penetrating keratoplasty or as a secondary implant," *Ophthalmic Surgery, Lasers and Imaging Retina*, vol. 19, no. 6, pp. 396–398, 1988.

[7] B. V. Hu, D. H. Shin, K. A. Gibbs, and Y. J. Hong, "Implantation of posterior chamber lens in the absence of capsular and zonular support," *Archives of Ophthalmology*, vol. 106, no. 3, pp. 416–420, 1988.

[8] L. J. Girard, "PC-IOL implantation in the absence of posterior capsular support," *Ophthalmic Surgery, Lasers and Imaging Retina*, vol. 19, no. 9, pp. 680–682, 1988.

[9] K. Ghasemi Falavarjani, M. Hashemi, A. Jalili Fazel, M. Modarres, H. Nazari, and M. M. Parvaresh, "Pars plana vitrectomy and intravitreal phacoemulsification for dropped nuclei," *Journal of Ophthalmic and Vision Reserach*, vol. 7, no. 2, pp. 125–129, 2012.

[10] S. R. De Silva, K. Arun, M. Anandan, N. Glover, C. K. Patel, and P. Rosen, "Iris-claw intraocular lenses to correct aphakia in the absence of capsule support," *Journal of Cataract and Refractive Surgery*, vol. 37, no. 9, pp. 1667–1672, 2011.

[11] S. Yamane, S. Sato, M. Maruyama-Inoue, and K. Kadonosono, "Flanged intrascleral intraocular lens fixation with double-needle technique," *Ophthalmology*, vol. 124, no. 8, pp. 1136–1142, 2017.

[12] F. Barca, T. Caporossi, L. de Angelis et al., "Trans-scleral plugs fixated IOL: a new paradigm for sutureless scleral fixation," *Journal of Cataract and Refractive Surgery*, vol. 46, no. 5, pp. 716–720, 2020.

[13] T. Rossi, D. Iannetta, V. Romano et al., "A novel intraocular lens designed for sutureless scleral fixation: surgical series," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 259, no. 1, pp. 257–262, 2021.

[14] D. C. Terveen, N. R. Fram, B. Ayres, and J. P. Berdahl, "Small-incision 4-point scleral suture fixation of a foldable hydrophilic acrylic intraocular lens in the absence of capsule support," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 2, pp. 211–216, 2016.

[15] M. D. Sindal, C. P. Nakhwa, and S. Sengupta, "Comparison of sutured versus sutureless scleral-fixated intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 1, pp. 27–34, 2016.

[16] B. J. Vote, P. Tranos, C. Bunce, D. G. Charteris, and L. Da Cruz, "Long-term outcome of combined pars plana vitrectomy and scleral fixated sutured posterior chamber intraocular lens implantation," *American Journal of Ophthalmology*, vol. 141, no. 2, pp. 308–312, 2006.

[17] S. G. B. Gabor and M. M. Pavlidis, "Pavlidis sutureless intrascleral posterior chamber intraocular lens fixation," *Journal of Cataract and Refractive Surgery*, vol. 33, no. 11, pp. 1851–1854, 2007.

[18] G. B. Scharioth, S. Prasad, I. Georgalas, C. Tataru, and M. Pavlidis, "Mitrofanis pavlidis intermediate results of sutureless intrascleral posterior chamber intraocular lens fixation," *Journal of Cataract and Refractive Surgery*, vol. 36, no. 2, pp. 254–259, 2010.

[19] A. Agarwal, D. A. Kumar, S. Jacob, C. Baid, A. Agarwal, and S. Srinivasan, "Fibrin glue-assisted sutureless posterior chamber intraocular lens implantation in eyes with deficient posterior capsules," *Journal of Cataract and Refractive Surgery*, vol. 34, no. 9, pp. 1433–1438, 2008.

[20] Y. Matsui, H. Matsubara, T. Hanemoto, and M. Kondo, "Exposure of haptic of posterior chamber intraocular lens after sutureless intrascleral fixation," *BMC Ophthalmology*, vol. 15, no. 1, p. 104, 2015.

[21] D. A. Kumar, A. Agarwal, S. Packiyalakshmi, S. Jacob, and A. Agarwal, "Complications and visual outcomes after glued foldable intraocular lens implantation in eyes with inadequate capsules," *Journal of Cataract and Refractive Surgery*, vol. 39, no. 8, pp. 1211–1218, 2013.

[22] K. Hayashi, H. Hayashi, F. Nakao, and F. Hayashi, "Intraocular lens tilt and decentration, anterior chamber depth, and refractive error after trans-scleral suture fixation surgery," *Ophthalmology*, vol. 106, no. 5, pp. 878–882, 1999.

[23] H. B. Dick and A. J. Augustin, "Lens implant selection with absence of capsular support," *Current Opinion in Opthalmology*, vol. 12, no. 1, pp. 47–57, 2001.

[24] P. Mora, G. Calzetti, S. Favilla et al., "Comparative analysis of the safety and functional outcomes of anterior versus retropupillary iris-claw IOL fixation," *Journal of ophthalmology*, vol. 2018, Article ID 8463569, 8 pages, 2018.

[25] M. Forlini, W. Soliman, A. Bratu, P. Rossini, G. M. Cavallini, and C. Forlini, "Long-term follow-up of retropupillary iris-claw intraocular lens implantation: a retrospective analysis," *BMC Ophthalmology*, vol. 15, no. 1, p. 143, 2015.

[26] C. Sumitha, V. Pai, and M. Thulasidas, "Retropupillary iris-claw intraocular lens implantation in aphakic patients," *Indian Journal of Ophthalmology*, vol. 68, no. 4, pp. 597–602, 2020.

[27] N. M. Jare, A. G. Kesari, S. S. Gadkari, and M. D. Deshpande, "The posterior iris-claw lens outcome study: 6 month follow-up," *Indian Journal of Ophthalmology*, vol. 64, pp. 878–883, 2016.

[28] Y. Chen, Q. Liu, C. Xue, Z. Huang, and Y. Chen, "Three-year follow-up of secondary anterior iris fixation of an aphakic intraocular lens to correct aphakia," *Journal of Cataract and Refractive Surgery*, vol. 38, no. 9, pp. 1595–1601, 2012.

[29] R. Frisina, E. Pilotto, L. Tozzi, R. Parrozzani, and E. Midena, "A new technique of needle-guided retropupillary fixation of iris-claw intraocular lens," *Journal of Cataract and Refractive Surgery*, vol. 45, no. 3, pp. 267–271, 2019.

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Research Article

Evaluation of the Findings of Patients Who Underwent Sutureless Flanged Transconjunctival Intrascleral Intraocular Lens Implantation with or without Pars Plana Vitrectomy

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Purpose. To compare the visual outcomes and complications of patients who underwent flanged transconjunctival sutureless intrascleral intraocular lens (SIS IOL) implantation after anterior and pars plana vitrectomy. *Methods*. All patients who underwent flanged transconjunctival SIS IOL fixation using a 27-gauge needle between September 2017 and November 2019 and were followed up for at least six months were evaluated. The cases in which anterior vitrectomy was performed were classified as Group 1, and those that underwent pars plana vitrectomy were classified as Group 2. The best-corrected visual acuity (BCVA), spherical equivalent values, corneal endothelial cell density, and intraocular pressures were compared between the two groups before and after the operation. Intraoperative and postoperative complications were assessed. *Results*. The study included 108 eyes of 108 patients who were included in the study. Group 1 consisted of 48 patients and Group 2 comprised of 60 patients. When the findings between Groups 1 and 2 were compared in the postoperative period, there was no statistically significant difference in terms of the mean intraocular pressure increase, endothelial cell density, BCVA, and spherical equivalent value ($P = 0.818$, 0.601, 0.368, and 0.675, respectively). When all the patients were considered as a single group, the mean spherical value at the sixth postoperative month was 0.3 ± 2.2 D (min-max, (−5.5)–(+6)), the mean cylindrical value was -1.7 ± 2.4 D (min-max, (−9.25)–(+4)), and the mean spherical equivalent value was -0.5 ± 2.3 D (min-max, (−6.5)–(+6)). *Conclusion*. The flanged transconjunctival SIS IOL fixation technique performed using a 27-gauge needle is safe and effective in the patient group with aphakia and lens/IOL dislocation or subluxation. However, in patients planned to undergo flanged transconjunctival SIS IOL implantation, pars plana vitrectomy seems to be a more suitable option than anterior vitrectomy to reduce complications.

1. Introduction

The ideal location of the intraocular lens (IOL) is inside the capsular bag where the crystalline lens is located [1]. Today, during cataract surgery, IOL is inserted into the capsular bag after cataract extraction. However, in cases where capsule support is insufficient secondary to pseudoexfoliation, trauma, Marfan syndrome, and complicated cataract surgery, there is a need to identify an alternative intraocular area to place the IOL [2]. These options include anterior chamber, iris, and scleral fixations of IOL [3]. Although iris-fixed IOLs fixed to the anterior surface of the iris using a claw-shaped haptic device have been widely used in the past for the correction of aphakia, they are no longer recommended due to their high complication rates and suboptimal visual outcomes [4]. However, both the anterior and posterior iris-claw IOLs have undergone significant design changes, including vault modifications [4].

Since the introduction of the IOL fixation technique by creating an intrascleral tunnel without requiring sutures by

Gabor in 2007, surgeons have focused on scleral-fixated IOL techniques that do not require sutures [5]. In the same year, Agarwal et al. developed a sutureless technique in an attempt to prevent IOL dislocation by applying fibrin glue to the tip of the intrasclerally placed haptics [6]. However, neither Gabor using a 24-gauge needle nor Agarwal et al. using a 23-gauge needle to perform these operations were successful in preventing the postoperative hypotonia risk.

The introduction of sutureless intrascleral fixation of IOL by Yamane et al. using a 27-gauge needle in 2014 has led to this technique becoming increasingly popular worldwide [7]. Furthermore, in 2017, Yamane et al. further developed this technique by flanging the tip of the intrasclerally placed haptics through low-temperature cautery, thus solving the problem of haptic dislocation in IOL. The Yamane technique has since attracted increasing interest of ophthalmic surgeons since it does not cause conjunctival scars because of the absence of conjunctival dissection, nor does it require the use of tunnel or fibrin glue; furthermore, the tilt rate of IOLs fixed with this technique is similar to that of in-the-bag IOLs [8].

Yamane et al. applied the flanged sutureless intrascleral (SIS) IOL technique using a 30-gauge needle, but this type of needle may not be easily available in many countries. In addition, although in the technique, vitreous cleaning was undertaken by anterior vitrectomy or pars plana vitrectomy (PPV), there is currently no study in the literature that evaluates the effect of these two operations on flanged transconjunctival SIS IOL fixation. In this study, we aimed to evaluate the results of this technique using 27-gauge needles after anterior vitrectomy and PPV.

2. Methods

All patients who underwent flanged transconjunctival SIS IOL fixation using 27-gauge needles between September 2017 and November 2019 were examined. All operations were performed by a single surgeon (M.K.E.) at Antalya Training and Research Hospital using the same method. The study protocol was approved by the Ethics Committee of Antalya Training and Research Hospital. All clinical procedures were carried out in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all patients.

Basic demographic data, such as age, gender, and the operated eye, were recorded. The patients that underwent SIS IOL fixation after anterior vitrectomy were classified as Group 1 and those that underwent SIS IOL fixation after PPV were classified as Group 2. All patients were followed up for at least six months. The best-corrected visual acuity (BCVA) evaluation, slit-lamp examination, intraocular pressure (IOP) measurement with a Goldmann applanation tonometer, and dilated fundus examination of all patients were undertaken at all clinic visits before and after surgery, and the results were recorded. Corneal endothelial cell density was measured with a specular microscope (Tomey EM-3000, Nagoya, Aichi, Japan) at six months before and after surgery. Patients with visually significant pathologies, such as corneal scar, retinal detachment, epiretinal membrane, macular edema, and glaucomatous optic atrophy, and those that were followed up for less than six months were excluded from the study. In addition, pediatric cases and those with trauma endophthalmitis were excluded from the study.

Optical coherence tomography (OCT) (Zeiss Cirrus 5000 HD-OCT, Carl Zeiss Meditec, Dublin, CA, USA) was performed preoperatively in patients with clear media and at the first, third, and sixth months postoperatively in all patients. Optical biometry was undertaken using a Lenstar LS 900 device (Haag-Streit, Switzerland), and the SRK-*T* formula was used for the IOL power calculations. Immersion biometry was used in cases where the measurements could not be obtained by optical biometry. The value found by subtracting 0.50 diopters from the measurement value obtained from all patients was determined as the target value.

In patients that developed nucleus drop or posterior capsule rent, anterior vitrectomy or PPV was performed according to the surgeon's preference when the complication developed, and then flanged transconjunctival SIS IOL fixation was undertaken, with the whole operation being completed in one session. In patients who were referred to or presented to our clinic from an external center (those with aphakia, subluxated or dislocated cataracts, and dislocated IOLs), flanged transconjunctival SIS IOL fixation was performed following anterior vitrectomy or PPV in a single session. Eyecryl Plus monofocal three-part intraocular lenses were used in all patients (Biotech, Luzern, Switzerland).

Complications, such as postoperative hyphema, transient corneal edema, endophthalmitis, increased IOP, postoperative hypotonia, vitreous hemorrhage, retinal detachment, haptic erosion, optic capture, macular edema, and reverse pupillary block (RPB), were recorded. Hypotonia was defined as an IOP of ≤5 mmgHg.

2.1. Surgical Procedure. The patients were placed under retrobulbar anesthesia, and the surgery was performed from conjunctival entry points 2 mm behind the limbus at 3 o'clock and 9 o'clock positions with a 180-degree angle in between. Of the patients included in the study, 60 underwent PPV and 40 underwent anterior vitrectomy. Following vitrectomy, after a limbal incision, a three-piece IOL placed in a cartridge was implanted using an injector, with the anterior haptic and optic part being in the anterior chamber and the posterior haptic left outside the limbal incision. A 27-gauge needle was inserted into the sclera from the conjunctival entry point and advanced to the posterior, parallel to the iris, forming an angle. Using serrated jaws microforceps (D.O.R.C. International, Zuidland, the Netherlands) with a 23-gauge needle, the anterior haptic of a three-piece IOL was inserted from the side parasynthesis to the needle end seen behind the iris in the anterior chamber, and the needle was advanced through the lumen. Then, it was removed from the sclera and conjunctiva from the needle entry point. The anterior haptic was held, and the end of the haptic was cauterized using an ophthalmic cautery device (Accu-Temp Cautery, Beaver-Visitec International, Inc., Waltham, USA) to flange the end of the haptic at a diameter of 0.3 mm. The flanged end was implanted intrasclerally, as

described by Yamane et al. The same technique was applied at a 180-degree opposite angle to the following haptic for intrascleral fixation. Peripheral iridotomy was performed using a vitrectomy cutter to prevent the iris capture of IOL formation after myosis. The viscoelastic substance was aspirated, and the anterior chamber was formed using a balanced salt solution. In patients who underwent pars plana vitrectomy, the cannula was removed, and wound integrity was provided at the end of the procedure.

In addition, IOL fixation was not preferred if the dislocated lens was a monofocal three-piece IOL.

2.2. Statistical Analysis. The Statistical Package for the Social Sciences (SPSS v. 23.0, Chicago, USA) was used for the statistical analyses. Descriptive statistics, i.e., mean ± standard deviation (SD) values, were used to describe quantitative data, and frequencies and percentages were used for qualitative data. Preoperative and postoperative data were analyzed using the paired t-test. Student's t-test was conducted to compare the data between the two groups. $P < 0.05$ was considered statistically significant. Visual acuity was converted to the logarithm (logMAR) of the minimum resolution angle for the analysis.

3. Results

The mean follow-up time was 15.2 ± 6.3 months in Group 1 and 13.8 ± 6.8 months in Group 2. There was no statistically significant difference between the two groups in terms of the follow-up time ($P = 0.282$). The mean age of the patients was 63.1 ± 10.7 years in Group 1 and 61.9 ± 8.8 years in Group 2, indicating no significant difference ($P = 0.534$). Indications for surgery were dislocated posterior chamber IOL in 52 patients (48.2%), aphakia in 39 patients (36.1%), and crystalline lens subluxation in 17 patients (15.7%). Patient characteristics are shown in Table 1.

Considering all the patients as a single group, the mean preoperative BCVA was 2.1 ± 0.8 logMAR, while the mean postoperative sixth-month control BCVA was 0.5 ± 0.4 logMAR, indicating a statistically significant difference between the two measurements ($P < 0.001$). The postoperative first-month and sixth-month BCVA results were 0.8 ± 0.5 and 0.5 ± 0.4 logMAR, respectively, and the increase in visual acuity was significant ($P < 0.001$). The mean preoperative corneal endothelial cell density was 2535 ± 388 cells/mm^2, and this value was found to decrease to 2260 ± 358 cells/mm^2 at the postoperative sixth month, resulting in a statistically significant difference ($P < 0.001$). At the postoperative sixth month, the mean spherical value was 0.3 ± 2.2 D (min-max, (−5.5)–(+6)), the mean of the cylindrical value was −1.7 ± 2.4 D (min-max, (−9.25)–(+4)), and the mean spherical equivalent value was −0.5 ± 2.3 D (min-max, (−6.5)–(+6)).

As shown in Table 2, there was no statistically significant difference between Groups 1 and 2 in terms of the mean postoperative IOP increase, endothelial cell density, BCVA, and spherical equivalent value ($P = 0.818$, 0.601, 0.368, and 0.675, respectively).

Table 1: Patient characteristics.

Characteristics	Group 1	Group 2	P value
Number of eyes	40	68	
Age (years, mean ± SD)	63.1 ± 10.7	61.9 ± 8.8	0.534
Gender (male/female)	23/17	36/32	
Diagnosis			
Dislocated PC IOL	7	15	
Subluxated PC IOL	6	10	
Opacified PC IOL	2	2	
Aphakia	18	21	
Subluxated cataract	3	11	
Dislocated nucleus	4	9	
Follow-up (months)			
Mean ± SD	15.2 ± 6.3	13.8 ± 6.8	0.282
Range	6–36	6–36	

SD, standard deviation; PC, posterior chamber; IOL, intraocular lens.

3.1. Complications. The distribution of intraoperative and postoperative complications is shown in Table 3. Intraoperatively, three patients in Group 1 and one patient in Group 2 developed retinal breaks due to the 27-gauge needle entry. Cases with a retinal break were successfully given laser treatment. Furthermore, two patients in Group 2 developed hemorrhage at the sclerotomy site, and two patients in Group 1 developed small choroidal hemorrhage.

Early postoperative complications were defined as those that developed within the first month after surgery. An IOP increase was observed in five patients in Group 1 and one patient in Group 2. A topical anti-glaucomatous agent was given to all of these patients, and they responded to this treatment. Two of the patients with increased IOP continued anti-glaucomatous treatment after the first month. Hypotonia was observed in two patients in Group 1 and three patients in Group 2 within the first week of surgery. There was no need for a second intervention in these patients, and it was observed that hypotonia improved in their follow-up. Vitreous hemorrhage was observed in two patients in each group and resolved during the follow-up. In Group 1, two patients had retinal detachment during their second-week follow-up. Both underwent pars plana vitrectomy and 360-degree retinal laser treatment within the same week. Dislocation was observed on one side of the intrascleral haptics in one patient in each group. A haptic correction operation was performed in these patients on the same day, and no problem was observed in their follow-up. Transient corneal edema was not observed in Group 1 but was present in two patients in Group 2.

One patient in each group who had macular edema due to late postoperative complications was prescribed topical nepafenac drops four times a day. In the follow-up, macular edema was improved in both patients. In our study, the development of RPB, uveal tissue inflammation, or endophthalmitis was not recorded.

4. Discussion

According to our review of the literature, this study evaluated the largest number of cases to date in terms of the outcomes of the flanged transconjunctival SIS IOL fixation

Table 2: Comparison of parameters between Groups 1 and 2.

Parameter	Group 1	Group 2	P value
Mean postoperative IOP (mmHg)	16.3 ± 5.9	16.8 ± 13.1	0.818
Mean postoperative endothelial cell count (cells/mm^2)	2390 ± 389	2430 ± 368	0.601
Mean postoperative BCVA (logMAR)	0.63 ± 0.40	0.56 ± 0.43	0.368
Mean postoperative spherical equivalent (diopters)	−0.3 ± 2.3	−0.5 ± 2.3	0.675

IOP, intraocular pressure; BCVA, best-corrected visual acuity.

Table 3: Intraoperative, early, and late complications of the two groups.

	Group 1	Group 2
Intraoperative		
Retinal break (iatrogenic)	3	1
Hemorrhage from sclerotomy	0	2
Small choroidal hemorrhage	2	0
Early		
Increased IOP (>25 mmHg)	5	1
Hypotony (IOP ≤ 5 mmHg)	2	3
Vitreous hemorrhage	2	2
Transient corneal edema	0	2
Retinal detachment	2	0
IOL dislocation	1	1
Late		
Increased IOP	2	0
Cystoid macular edema	1	1
Iris capture of IOL	1	1

IOP, intraocular pressure; IOL, intraocular lens.

and provided important data from an average follow-up period exceeding 12 months with no short-term follow-up, comparing the results of two groups undergoing PPV and anterior vitrectomy.

The flanged transconjunctival SIS fixation technique of the haptic of a three-piece IOL described by Yamane et al. [8] has many advantages over sutured SIS IOL fixation techniques reported by Gabor [5] and Agarwal [6]. Advantages are that there is no need for an intrascleral pouch, adhesive use, such as fibrin glue, or conjunctival dissection. In addition, another advantage can be considered as the much lower risk of hypotonia in this technique that allows for the use of 27- and 30-gauge needles compared to 23- and 24-gauge needles required by the other techniques. In all cases in our study, we used 27-gauge needles due to the problems in the accessibility of 30-gauge needles in Turkey. We observed hypotonia at a rate of 4.6% within the first week of the operation. All hypotonic eyes were observed normotonically in the following week. Abbey et al. [9] reported the rate of hypotonia as 13.3%. In another study conducted in 2019, Czajka et al. [10] determined the rate of postoperative hypotonia as 19.4%. In that study, the authors compared SIS IOL fixation techniques with and without the use of trocar and stated that hypotonia was more common in the trocar group. In the current study, the rate of postoperative hypotonia being higher in patients in Group 2 suggests that 25-gauge trocars used for the PPV entry may increase the development of this complication. The use of a smaller-gauge trocar for PPV can significantly reduce postoperative hypotonia.

In this study, the most frequently observed postoperative complication was the increase in IOP (5.6%), which we successfully resolved with topical treatment in all cases. Yamane et al. [8] determined the rate of increased IOP as 2%. In a 2018 study, Stem et al. [3] reported the rate of increased IOP as 23%, which they attributed to RPB developing postoperatively, and recommended performing intraoperative prophylactic iridotomy in these patients. RPB is a rare finding after the scleral fixation of IOL, but it may result in pigment dispersion or iris capture and therefore might require treatment with postoperative laser peripheral iridotomy to prevent these negative effects [11, 12]. In our study, RPB was not observed in any of the patients as a result of intraoperative prophylactic iridotomy being performed in all patients. Thus, our rate of increased IOP was also much smaller compared to the study of Stem et al. [3] Another important outcome of performing prophylactic iridotomy in our study was that no pigment dispersion occurred in any patient. However, the majority of our patients who had increased IOP postoperatively were in Group 1 (83.3%). In patients undergoing anterior vitrectomy, viscoelastic substance possibly remaining after the insufficient washing of the anterior chamber may have caused a temporary IOP increase.

IOL haptic dislocation being observed among the first cases operated in each group led us to consider two different reasons: the lack of complete flanging due to inadequate cauterization in the early stages of the learning curve and the vertical aspect being more than normal due to the insertion of the needle inside the sclera to the posterior of the iris without creating a complete parallel area of 2 mm from the intrascleral entry point. Although according to Czajka et al. [10], IOL haptic dislocation might be due to gas tamponade used in PPV and extra sutures might be required in the intrascleral region in which the haptic is placed, the absence of IOL dislocation in the later stages of our study does not support this idea. We consider that haptic dislocations can be prevented by sufficient flanging and forming intrascleral entry points 2 mm posterior to the limbus, running first parallel inside the sclera and then parallel to the iris with a 90-degree inclination to the entry point. In addition, when postoperative optical biometry measurements were reassessed in two patients with haptic dislocation, the diameter of the cornea was 12 mm in both eyes, which also suggests that there may be another reason for dislocation. In their 2015 study, Jacob et al. [13] stated that IOL should be placed vertically in eyes with a corneal diameter larger than 11.5 mm. In a more recent study, Czajka et al. [10] noted that the frequency of haptic dislocation increased in eyes with a corneal diameter greater than 12 mm. From this perspective, we think that the preoperative corneal diameter should be

measured in patients planned to undergo sutureless flanged SIS IOL fixation, and if this diameter is above 12 mm, haptic entries should be at 6 and 12 o'clock positions.

In studies where flanged transconjunctival SIS IOL fixation was performed and the endothelial cell density was evaluated before and after surgery, Yamane et al. [8] found a significant decrease in endothelial cell density, while Kelkar et al. [14] reported this difference as not significant. In our study, a significant decrease was observed in the corneal endothelial cell density in the postoperative period compared to the preoperative period, which is consistent with the findings of Yamane et al. However, when we compared the postoperative endothelial cell density between Groups 1 and 2, there was no significant difference.

Mora et al. [4] performed a comparative analysis of the safety and functional results of anterior and retropupillary iris-claw IOL fixation in their study published in 2018. In this study, BCDVA significantly improved after surgery in both groups, without significant difference between the two groups. Again, according to the results of this study, compared with the preoperative assessments, the endothelial cell counts were significantly reduced in both groups after surgery, without a significant intergroup difference [4]. The increase in postoperative visual acuity and decrease in the number of endothelial cells in our study were consistent with the study of Mora et al. In the needle-guided retropupillary fixation of iris-claw IOL technique proposed by Frisina et al., it is noteworthy that despite the increase in postoperative visual acuity, the postoperative endothelial cell density did not decrease [15]. However, the relatively high cost of iris-claw IOLs and the difficulty in supplying these lenses to patients forced us to choose the sutureless flanged transconjunctival scleral fixation technique.

In our study, the incidence of postoperative retinal detachment was 1.9%, which is in agreement with other studies. Retinal detachment is a rare complication after SIS IOL fixation, and its frequency varies between 0% and 3.8% [10, 16, 17]. Two retinal detachments occurred postoperatively among the first 20 cases in our study, suggesting that surgeons should take care in the first stages of the learning curve of the SIS technique. In addition, both cases being in Group 1 indicates that the vitreous base was not properly cleaned at the haptic entry points during anterior vitrectomy, causing retinal detachment by creating a stretching force between IOL and the vitreous body. Therefore, in patients who only underwent anterior vitrectomy before flanged transconjunctival SIS IOL fixation, complete intraoperative cleaning of the vitreous body in the scleral entry areas may prevent the development of postoperative retinal detachment.

The development of cystoid macular edema after flanged SIS IOL implantation has been reported with very variable rates in different studies. Stem et al. [3] determined the frequency of macular edema as 21% and achieved response to treatment in seven of 11 patients. Yamane et al. [8] found that 1% of cases developed cystoid macular edema. In our study, the incidence of cystoid macular edema was 1.9%. Topical non-steroidal anti-inflammatory drops were started in both patients, and it was observed that edema was resolved during the follow-up. Khan et al. [18], who used Gore-Tex sutures, calculated the incidence of cystoid macular edema as 4.8% while Yeung et al. [19], using 10/0 nylon sutures, reported this rate to be 8%. Based on these results, the use of sutures in the scleral fixation of IOL implants seems to increase the frequency of cystoid macular edema. However, when you have more than one surgical procedure, you have a higher risk of developing CME due to inflammation of the choroid and retina and breakage of the blood-retinal barrier [20]. Postoperative CME may result from an inflammatory process due to disruption of the blood-retina barrier, similar to what is known as the "Irvine–Gass syndrome" that occurs after any intraocular surgery [20].

In this study, the total postoperative spherical equivalent value of all patients was -0.5 ± 2.3 diopters. In addition, when the two groups were evaluated separately, although there was a higher myopic shift in Group 2 than in Group 1, the difference was not statistically significant. In our study, the causes of myopic shift may be the anterior location of IOL due to its short diameter and excessive cauterization of the haptic tip during flanging. Yamane et al. [8] compared four different types of IOL in their study and observed myopic shift in three IOLs and hyperopic shift in one IOL. However, there are no studies comparing the spherical equivalent value of patients that have undergone anterior vitrectomy to those having undergone pars plana vitrectomy before flanged transconjunctival SIS IOL fixation.

The limitations of our study include its retrospective nature and the lack of an evaluation of the IOL tilt level. However, our study also had certain strengths, such as the number of patients evaluated, the mean follow-up time exceeding 12 months in both groups, and being the first to compare the results of the flanged transconjunctival SIS IOL technique between two vitrectomy groups.

In conclusion, according to our clinical observation and the results of this study, the flanged transconjunctival SIS IOL fixation technique using a 27-gauge needle is safe and effective in patient groups with aphakia and lens/IOL dislocation or subluxation. However, in patients planned to undergo flanged transconjunctival SIS IOL implantation, performing pars plana vitrectomy seems to be a more suitable option than anterior vitrectomy to reduce complications.

Data Availability

The dataset used for analyses may be requested from the corresponding author for use in scholarly work related to the field.

Ethical Approval

Approval was obtained from the Antalya Training and Research Hospital ethical review committee (May 07, 2020, and decision number: 6/1).

Consent

Written informed consent was obtained from the patients and their families before any examination or treatment was performed.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Authors' Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; gave final approval of the version to be published; and agree to be accountable for all aspects of the work. All authors attest that they meet the current ICMJE criteria for authorship.

References

[1] Y. M. Por and M. J. Lavin, "Techniques of intraocular lens suspension in the absence of capsular/zonular support," *Survey of Ophthalmology*, vol. 50, no. 5, pp. 429–462, 2005.

[2] R. Fernández-Buenaga, J. L. Alio, and A. L. Pérez-Ardoy, "Late in-the-bag intraocular lens dislocation requiring explantation: risk factors and outcomes," *Eye*, vol. 27, no. 7, pp. 795–802, 2013.

[3] M. S. Stem, C. A. Wa, B. Todorich, M. A. Woodward, M. K. Walsh, and J. D. Wolfe, "27-GAUGE sutureless intrascleral fixation OF intraocular lenses with haptic flanging," *Retina*, vol. 39, no. 11, pp. 2149–2154, 2019.

[4] P. Mora, G. Calzetti, and S. Favilla, "Comparative analysis of the safety and functional outcomes of anterior versus retropupillary iris-claw IOL fixation," *Journal of Ophthalmology*, vol. 2018, Article ID 8463569, 8 pages, 2018.

[5] S. G. B. Gabor and M. M. Pavlidis, "Sutureless intrascleral posterior chamber intraocular lens fixation," *Journal of Cataract and Refractive Surgery*, vol. 33, no. 11, pp. 1851–1854, 2007.

[6] A. Agarwal, D. A. Kumar, S. Jacob, C. Baid, A. Agarwal, and S. Srinivasan, "Fibrin glue-assisted sutureless posterior chamber intraocular lens implantation in eyes with deficient posterior capsules," *Journal of Cataract and Refractive Surgery*, vol. 34, no. 9, pp. 1433–1438, 2008.

[7] S. Yamane, M. Inoue, A. Arakawa, and K. Kadonosono, "Sutureless 27-gauge needle-guided intrascleral intraocular lens implantation with lamellar scleral dissection," *Ophthalmology*, vol. 121, no. 1, pp. 61–66, 2014.

[8] S. Yamane, S. Sato, M. Maruyama-Inoue, and K. Kadonosono, "Flanged intrascleral intraocular lens fixation with double-needle technique," *Ophthalmology*, vol. 124, no. 8, pp. 1136–1142, 2017.

[9] A. M. Abbey, R. M. Hussain, A. R. Shah, L. J. Faia, J. D. Wolfe, and G. A. Williams, "Sutureless scleral fixation of intraocular lenses: outcomes of two approaches. The 2014 Yasuo Tano Memorial Lecture," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 253, no. 1, pp. 1–5, 2015.

[10] M. P. Czajka, A. Frajdenberg, M. Stopa, T. Pabin, B. Johansson, and G. Jakobsson, "Sutureless intrascleral fixation using different three-piece posterior chamber intraocular lenses: a literature review of surgical techniques in cases of insufficient capsular support and a retrospective multicentre study," *Acta Ophthalmologica*, vol. 98, pp. 224–236, 2019.

[11] S. P. Bang, C.-K. Joo, and J. H. Jun, "Reverse pupillary block after implantation of a scleral-sutured posterior chamber intraocular lens: a retrospective, open study," *BMC Ophthalmology*, vol. 17, no. 1, p. 35, 2017.

[12] T. Higashide, F. Shimizu, A. Nishimura, and K. Sugiyama, "Anterior segment optical coherence tomography findings of reverse pupillary block after scleral-fixated sutured posterior chamber intraocular lens implantation," *Journal of Cataract and Refractive Surgery*, vol. 35, no. 9, pp. 1540–1547, 2009.

[13] S. Jacob, A. Agarwal, A. Agarwal, and S. Narasimhan, "Closed-chamber haptic reexternalization for posteriorly displaced sclerotomy and inadequate haptic tuck in glued posterior chamber intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 41, no. 2, pp. 268–271, 2015.

[14] A. Kelkar, R. Fogla, J. Kelkar, A. Kothari, H. Mehta, and W. Amoaku, "Sutureless 27-gauge needle-assisted transconjunctival intrascleral intraocular lens fixation: initial experience," *Indian Journal of Ophthalmology*, vol. 65, no. 12, p. 1450, 2017.

[15] R. Frisina, E. Pilotto, L. Tozzi, R. Parrozzani, and E. Midena, "A new technique of needle-guided retropupillary fixation of iris-claw intraocular lens," *Journal of Cataract and Refractive Surgery*, vol. 45, no. 3, pp. 267–271, 2019.

[16] D. A. Kumar, A. Agarwal, S. Packiyalakshmi, S. Jacob, and A. Agarwal, "Complications and visual outcomes after glued foldable intraocular lens implantation in eyes with inadequate capsules," *Journal of Cataract and Refractive Surgery*, vol. 39, no. 8, pp. 1211–1218, 2013.

[17] B. Todorich, M. S. Stem, and K. Kooragayala, "Structural analysis and comprehensive surgical outcomes of the sutureless intrascleral fixation of secondary intraocular lenses in human eyes," *Retina*, vol. 38, pp. S31–40, 2018.

[18] M. A. Khan, W. A. Samara, and A. T. Gerstenblith, "Combined pars plana vitrectomy and scleral fixation OF an intraocular lens using gore-tex suture," *Retina*, vol. 38, no. 7, pp. 1377–1384, 2018.

[19] L. Yeung, N.-K. Wang, W.-C. Wu, and K.-J. Chen, "Combined 23-gauge transconjunctival vitrectomy and scleral fixation of intraocular lens without conjunctival dissection in managing lens complications," *BMC Ophthalmology*, vol. 18, no. 1, p. 108, 2018.

[20] R. Frisina, S. J. Pinackatt, and M. Sartore, "Cystoid macular edema after pars plana vitrectomy for idiopathic epiretinal membrane," *Graefes Archive for Clinical and Experimental Ophthalmology*, vol. 253, no. 1, pp. 47–56, 2015.

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Research Article

One Year Outcomes and Stability of a Novel Scleral Anchored Intraocular Lens

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Purpose. To assess one year results and stability of the implantation of a scleral anchored intraocular lens (IOL). *Design*. Interventional prospective case series. *Methods*. Sixty eyes of 60 patients affected by either aphakia or IOL dislocation were included in this study. Patients underwent vitrectomy, scleral fixation of the IOL, and, if present, dislocated IOL removal. Patients were evaluated preoperatively and at 1, 3, 6, and 12 months after surgery by best-corrected distance visual acuity (BCVA) assessment, intraocular pressure (IOP) measurement, corneal specular microscopy, and optical coherence tomography (OCT) of both the macula and anterior segment. *Results*. At twelve months, mean BCVA significantly improved ($p < 0.0001$), and none of the patients experienced a decrease of visual acuity. A 10% decrease of endothelial cell count occurred after surgery. Cystoid macular edema occurred in three patients (5%). A transient increase of intraocular pressure was noted in 7 cases (12%). At one month, horizontal and vertical IOL tilt was 1.04 ± 0.87 and 0.74 ± 0.71 degrees, respectively, and did not significantly change in the follow-up ($p > 0.05$). None of the patients had decentration or dislocation of scleral-fixated IOL during the follow-up. *Conclusion*. Implantations of scleral plug fixated IOL provide good visual results, low complication rate, and excellent stability of the lens until one-year follow-up.

1. Introduction

Intraocular lens implantation (IOL) in the capsular bag represents the gold standard in cataract surgery and provides excellent anatomical and functional outcomes [1]. However, lesions of the capsular bag including zonular dehiscence, posterior capsule rupture (PCR), and capsular bag luxation may occur due to cataract surgery complications [2], ocular trauma [3], high myopia [4], or pseudoexfoliation syndrome [5]. In these cases, capsular support is inadequate to allow standard in bag IOL implantation, and other surgical approaches should be adopted including anterior chamber IOL (ACIOL) implantation [6, 7], iris-fixated IOL [8, 9], and scleral-fixated IOL (SFIOL) [10, 11].

ACIOL and iris claw IOL are easy and fast to implant but might be associated with persistent inflammation, cystoid macular edema, and progressive endothelial cell loss with corneal decompensation [12, 13]. Various techniques have been proposed for scleral fixation of IOL. Classically, a rigid PMMA IOL is fixated to the sclera with prolene sutures. However, this procedure requires a large corneal incision, long operating times, and might be associated with late IOL dislocation due to loosening of sutures or erosion [10]. Furthermore, sutured scleral IOL is associated with significant optic tilt in over 50% of cases [14]. In the last few years, other techniques have been proposed for sutureless scleral fixation of a three-piece IOL with either fibrin glue [15–17] or by tucking the haptics into scleral tunnels [18, 19] or pockets [20]. Scleral gluing fixation technique has also been successfully combined with iris repair surgery [21]. Recently, a novel specially designed IOL with scleral plugs (Carlevale IOL) has been introduced as an option to correct aphakia

without residual capsular support with good short-term outcomes [22] and low degree of decentration and tilt [23]. However, the long-term outcomes and stability of this implant have still not been explored.

The aim of this study is to evaluate the one-year outcomes and stability of the implantation of the scleral tucking Carlevale IOL.

2. Materials and Methods

2.1. Patients and Examination Protocol. Sixty eyes of 60 patients who underwent SFIOL implantation between 1 November 2017 and 30 November 2019 at the Ophthalmology Department of Morgagni-Pierantoni Hospital and of San Marino State Hospital were enrolled in this prospective case series. The study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Ethics Committee. A written informed consent was obtained from all patients. The trial was registered at ISRCTN (trial number: ISRCTN10015880). Inclusion criteria were postoperative or posttraumatic aphakia or late dislocation of IOL and/or capsular bag due to pseudoexfoliation syndrome (PEX). Patients with corneal opacities, visually significant macular diseases, retinal detachment, optic disk atrophy, advanced glaucoma, and any other ocular condition that was likely to compromise the functional outcome were excluded from the study. All patients underwent a complete ophthalmological examination including best-corrected visual acuity (BCVA) assessment, intraocular pressure (IOP) measurement with noncontact tonometry, slit-lamp biomicroscopy, and indirect ophthalmoscopy before surgery, seven days postoperatively, and at 1, 3, 6, and 12 months after surgery. Spectral-domain optical coherence tomography (SD-OCT) (Heidelberg Spectralis, Heidelberg, Germany) scans of the macular region were acquired at 1, 6, and 12 months postoperatively to assess the presence of cystoid macular edema. Specular microscopy (SP-1P; Topcon, Japan) was done at baseline and at 1, 6, and 12 months follow-up to assess postoperative endothelial cells loss. Anterior segment OCT (AS-OCT) (Heidelberg Spectralis, Heidelberg, Germany) was performed at 1 and 12 months after surgery to assess IOL tilt. A horizontal and a vertical 12 mm scans centered at the pupil were performed. Images were then exported in TIFF format and processed with ImageJ software. IOL tilting in the horizontal and vertical axis was assessed by measuring the angle between the IOL optic and the posterior iris surface plane (Figure 1). A horizontal or vertical tilt exceeding 5° was considered significant.

2.2. Surgical Procedure. Surgical steps of FILSSF IOL scleral fixation are summarized in Figure 2. Operations were carried out by three vitreoretinal surgeons (A.E., C.G., and M.F.) under peribulbar anesthesia. First, localized conjunctival limbal peritomy at nasal and temporal side and coagulation of bleeding vessel by bipolar cautery application were performed. Two limbal-based 3×3 mm scleral flaps of about one half of scleral thickness are then made in the nasal and temporal sides exactly 180° apart. Subsequently, a standard three-port, transconjunctival 23 or 25 gauge pars plana vitrectomy (PPV) (Constellation Vision System, Alcon Laboratories Inc., Fort Worth, Tex., USA) was performed. Posterior vitreous detachment was induced, and careful inspection of the periphery with scleral depression was made to detect retinal breaks. A noncontact wide-angle viewing system (BIOM, Oculus Inc., Wetzlar, Germany) was used during PPV for visualization. Two 23-gauge sclerotomies were then performed under the scleral flaps at 1.5 mm from the limbus by using the trocars. In case of 25-gauge vitrectomy, the sclerotomies were slightly enlarged. The following surgical steps slightly differed depending on the presence of an IOL dislocated in the vitreous chamber. In case of dislocation of a previously implanted IOL, the implant was first luxated in the anterior chamber with the cutter in aspiration-only mode or with vitreous serrated forceps and then removed through a 5.4 mm corneal incision performed in the superotemporal cornea. Conversely, in the absence of a dislocated IOL, a 2.2 mm keratotomy is framed in the temporal clear cornea for IOL introduction. Before IOL implantation, the anterior chamber is filled with ophthalmic viscosurgical device (OVD) (Viscotech, SIFI, Italy), and a paracentesis is performed in the nasal cornea. While the IOL is slowly introduced and unfolded in the anterior chamber with the injector, a 25-gauge vitreous serrated or end-gripping forceps are inserted through the nasal sclerotomy and used to grasp the center of the anchor-shaped tip of the leading IOL haptic. The haptic is then carefully pulled when the IOL is completely unfolded and externalized from the nasal sclerotomy.

Thereafter, the 25-gauge forceps are introduced from the temporal sclerotomy to grasp and externalize the IOL trailing haptic tip. In order to approach the trailing haptic to the pupil and allow its grasp with the forceps, a Sinskey hook is used from the nasal paracentesis.

At this point, the IOL is already centered and fixed without the need of further intrascleral tucking or suturing. If IOL vertical tilt is noticed, it may be easily corrected by gently rotating the anchor tips outside the sclerotomies. Scleral flaps and the conjunctiva are then sealed with Vicryl 7.0 suture. Trocar sclerotomies were carefully massaged and left unsutured unless leakage was observed. Corneal incision is sutured with Nylon 10.0 sutures only if a 5.4 mm tunnel was performed. If a 2.2 mm tunnel was performed, the incision is closed by wound hydration.

2.3. Statistical Analysis. Continuous variables were described as mean ± standard deviation and categorical variables as percentages. Pre- and postoperative values of BCVA, IOP, endothelial cell count, and the degree of IOL tilting at each follow-up were compared. For this purpose, analysis of variance for repeated measures and Sidak post hoc test were performed in order to avoid family-wise errors for multiple comparisons. For statistical purposes, Snellen BCVA was converted into logarithm of the minimum angle of resolution (logMAR). For all analyses, a p value <0.05 was considered statistically significant.

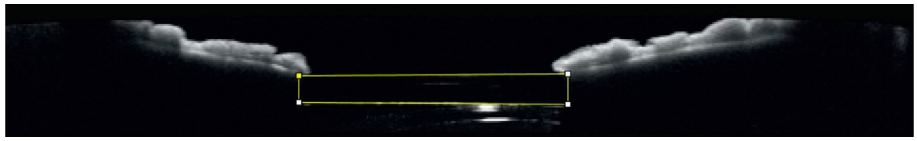

Figure 1: AS-OCT of a patient one month after FILSSF IOL implantation. Yellow boundary lines are drawn to calculate the angle between the implant and iris plane.

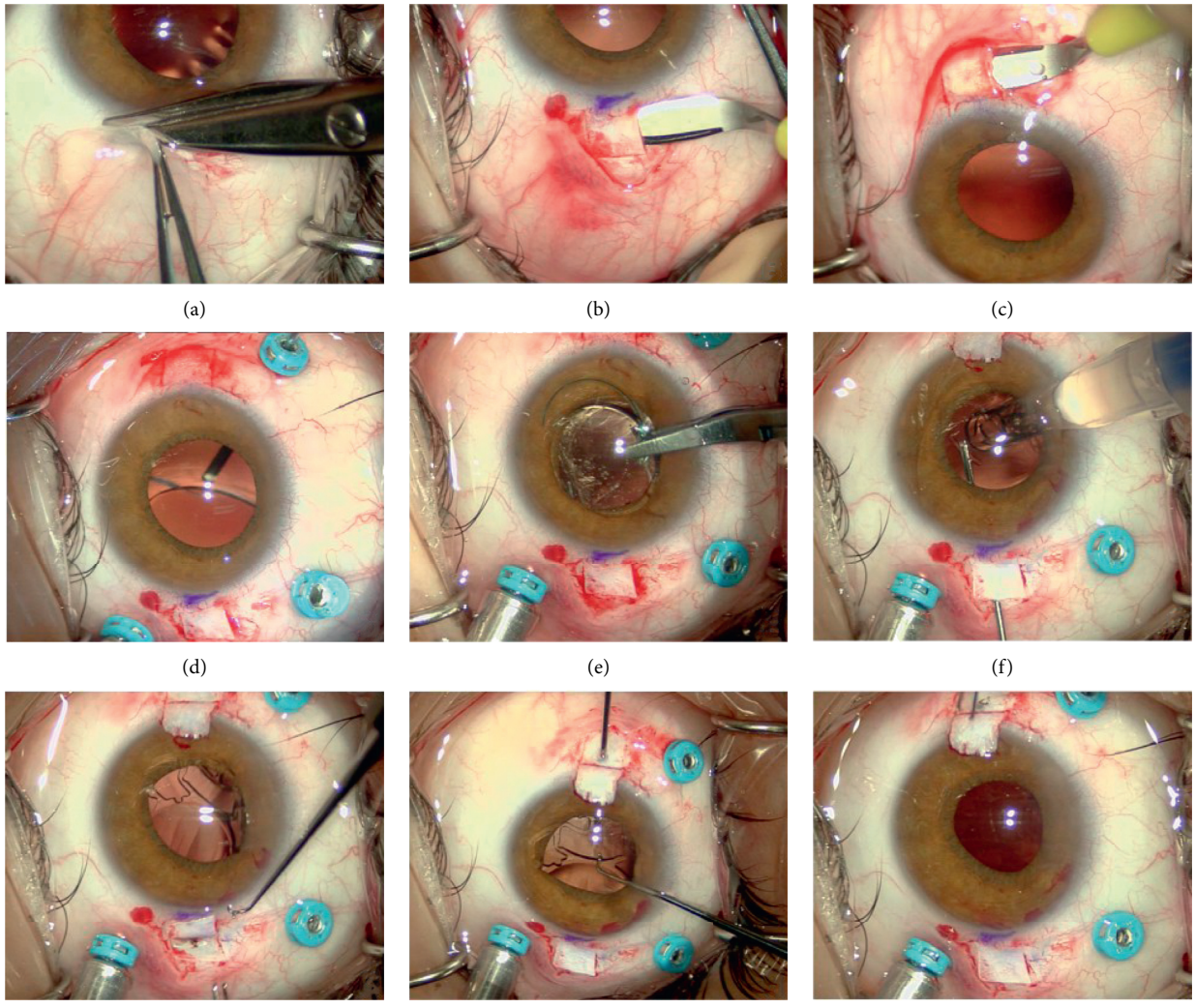

Figure 2: FILSSF IOL implant procedure: conjunctival peritomy (a), scleral flaps creation (b, c), vitrectomy (d), dilocated IOL removal (e), haptics grasping (f, h), and externalization (g, i).

3. Results

Sixty eyes of 60 patients met the inclusion criteria and were enrolled in the study. Forty-one patients (68%) were females and 19 were males (32%). The mean age was 79.3 ± 8.8 years. Preoperatively, thirty-three patients (55%) had late dislocation of a posterior chamber IOL which was due to progressive zonular laxity related to PEX in twenty-three cases (70%), trauma in three cases (9%), and high myopia in two cases (6%). In 20 patients (42%), aphakia was related to previous complicated cataract surgery. In three cases (5%), grasping the IOL with the end gripping forceps leads to haptic break. In such cases, the IOL was explanted trough the corneal incision and replaced with a FILSSF IOL with the same power. Three patients (5%) had intraoperative vitreous hemorrhage that spontaneously resolved at 1-month follow-up. No other intraoperative complications such as retinal breaks or detachment were noticed. BCVA was 0.58 ± 0.26 at baseline, increased to 0.26 ± 0.14 at 1 month ($p < 0.001$), and further improved to 0.19 ± 0.12 ($p < 0.01$) at three months

after surgery. Afterwards, BCVA remained stable reaching 0.17 ± 0.11 at final follow-up (Figure 3). None of the patients experienced a decrease of BCVA after surgery.

Preoperatively, mean intraocular pressure (IOP) was 17.8 ± 6.7 mmHg and 10 patients (16%) had ocular hypertension (IOP > 21 mmHg) associated with PEX in 6 cases (60%) and with vitreous prolapse in the anterior chamber in the remaining four eyes (40%).

A postoperative increase of IOP, probably related to retained OVD, occurred in 5 patients (8%) and was successfully managed with topic hypotensive drugs. Persistent elevated IOP rise was noted in 2 cases (3%) who were already affected by pseudoexfoliative glaucoma.

At twelve-month follow-up, mean IOP significantly decreased to 14.2 ± 3.6 mmHg ($p = 0.01$).

Before surgery, endothelial cell count was 1615 ± 502 cells/mm^2 and dropped to 1481 ± 471 cells/mm^2 one month after surgery. The difference reached statistical significance ($p < 0.001$). The density of endothelial cells further decreased to 1451 ± 457 cells/mm^2 at final follow-up. Cornea was clear in all patients at one month after surgery (Figure 4), and none of the patients developed corneal edema or decompensation during the one-year follow-up.

The amount of horizontal and vertical SSF IOL tilt is summarized in Figures 5(a) and 5(b), respectively.

Horizontal IOL tilt was $1.04 \pm 0.87^\circ$ 30 days after surgery (range 0.1–3.4°) and remained unchanged at one-year follow-up ($1.11 \pm 0.86^\circ$ $p = 0.20$). Vertical tilt was $0.74 \pm 0.71^\circ$ one month postoperatively and $0.79 \pm 0.65^\circ$ at final examination ($p = 0.47$). None of the patients had postoperative IOL dislocation, decentration, or significant vertical or horizontal tilt.

Postoperative retinal breaks and/or detachment were not observed in any of the patients included. Cystoid macular edema developed in three eyes (5%) at one-month follow-up and was successfully managed with topical and oral indomethacin in two cases and with dexamethasone implant in the remaining patient.

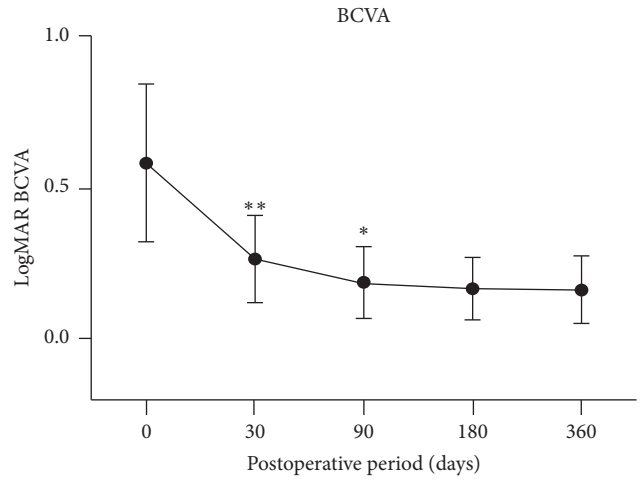

Figure 3: Graph showing the progressive postoperative improvement of BCVA. Visual acuity largely increased at 1 month, further improved at 3 months, and remained stable until the end of follow-up.

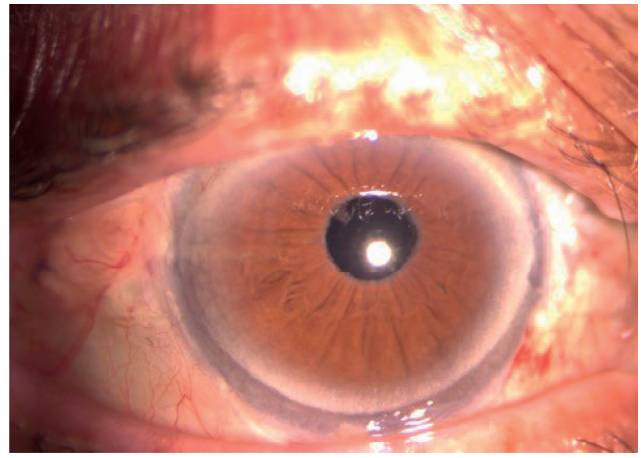

Figure 4: Slit lamp examination of a patient 1 month after surgery showing clear cornea, quiet anterior chamber, and perfect SSF IOL centration.

4. Discussion

Intraocular implantation in eyes with deficient capsular support is a therapeutic challenge for cataract surgeons, and multiple approaches have been proposed to manage these complicated cases. Placement of ACIOL or iris-fixated IOL is an easy and fast procedure but is associated with a large number of complications related to angle and iris tissue stimulation including endothelial cell loss, corneal decompensation, pigment dispersion, hyphema, secondary glaucoma, anterior uveitis, and cystoid macular edema [7–9]. To reduce the incidence of postoperative complications, particularly endothelial cell loss, retropupillary placement of iris-claw IOL has been proposed. However, a comparative case series by Toro et al. [24] did not show a significant difference between anterior and posterior iris claw IOL in terms of endothelial cells count. Intraocular lens fixation to the scleral wall provides a more physiological location of the implant, which lies near the ciliary body avoiding trauma and stimulation of the uveal tissue and thereby reducing inflammation-related ocular complications. The classical technique consists of rigid PMMA IOL suturing to the scleral wall with nonabsorbable prolene sutures. However, this technique requires a large corneal incision to introduce the IOL. Furthermore, an asymmetrical tension of prolene sutures may lead to significant IOL decentration and tilt which may cause significant astigmatism that may reduce visual recovery. In addition, erosion of progressive sutures may cause increasing IOL tilt and decentration or late dislocation of the IOL in the vitreous cavity.

In this study, we report the one-year functional and anatomical outcomes of the implant of FILSSF Carlevale IOL, a recently developed IOL specially designed for scleral sutureless fixation.

In three cases, intraoperative vitreous hemorrhage occurred but spontaneously resolved at one-month follow-up. No other major intraoperative complications were observed. In three cases, IOL leading to haptic break occurred after grasping it with end-gripping ILM forceps. This

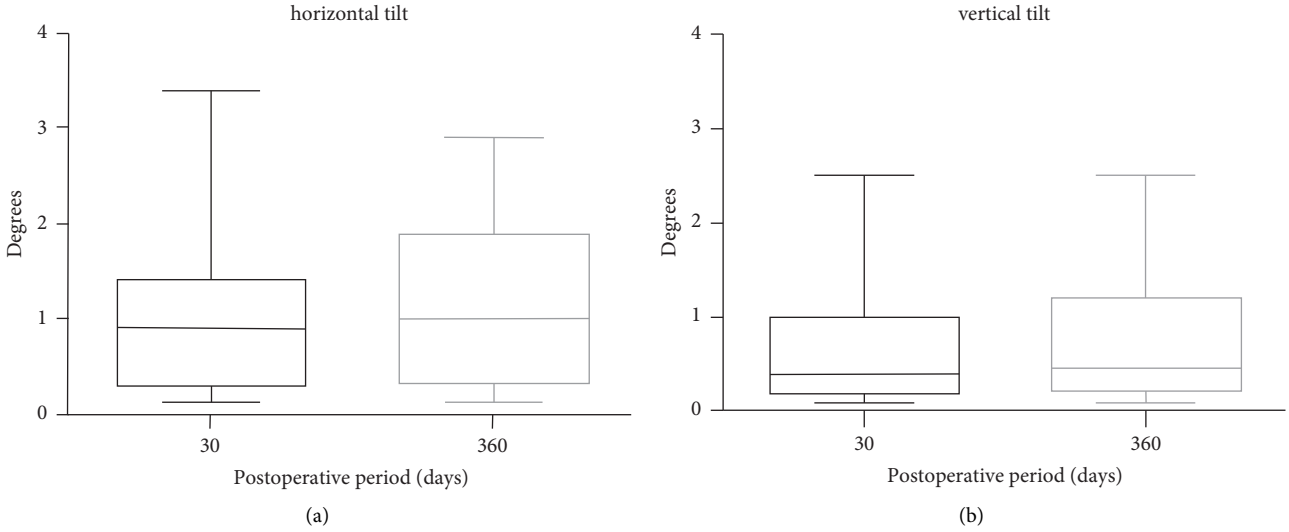

Figure 5: Box plot showing the stability of horizontal (a) and vertical (b) tilt of FILSSF IOL at 1 and 12 months after surgery.

complication is related to the softness of IOL hydrophilic material and to the sharpness of the tip of ILM-forceps. For this reason, to reduce the risk of haptic break, we suggest using vitreous serrated forceps to manipulate the IOL.

Similar to glueing [14] or flanged intrascleral fixation [17] of three-piece IOL, FILSSF implantation requires a small corneal incision that can be left unsutured allowing low postoperative astigmatism and fast visual recovery. Accordingly, in this study, the vast majority of BCVA improvement was obtained at one month after surgery. Visual acuity slightly further improved at three-month follow-up probably due to the resolution of the three cases of cystoid macular edema and to corneal suture removal in patients who had removal of previously implanted dislocated IOL.

The anchor-shaped design of SSF IOL allowed in all cases a precise centration of the lens after haptic externalization without the need of further IOL manipulation by the surgeon. In case of IOL vertical tilt, IOL positioning was easily optimized by carefully rotating the anchors outside the sclerotomies. Furthermore, once externalized, the anchor of the leading haptic prevented posterior dislocation of the IOL, while the surgeon was fixating the trailing haptic that may occur with scleral glueing or scleral tucking techniques. Hence, implantation of SSF IOL allows a reduction of IOL fixation maneuvers in the vitreous cavity which may explain the absence of postoperative retinal break and/or detachment in our group. The accuracy of lens positioning was demonstrated by the low degree and the marked stability of horizontal and vertical tilt. Horizontal tilt was slightly greater than vertical tilt, probably due to mild asymmetry of the sclerotomies under the scleral flaps. None of the patients had a vertical or horizontal tilt exceeding 5°. Furthermore, no cases of IOL decentration or dislocation occurred during the whole follow-up. These results apparently compare favorably with those previously reported for sutured [25] and glued [26] scleral-fixated IOL. However, comparative studies are warranted to assess whether SSF IOL stability is superior to other techniques of IOL scleral fixation.

5. Conclusions

In conclusion, implantation of FILSSF is a safe and repeatable technique and provides good clinical outcomes with good visual outcomes, excellent IOL stability, and low complication rate. Limitations of this study include the relative low number of patients enrolled and short follow-up. Larger, long-term prospective studies are warranted to better assess the outcomes of this technique. Finally, prospective studies comparing FILSSF IOL with other scleral fixation techniques would be of interest.

Data Availability

The data used to support the findings of this study are included within the article.

Conflicts of Interest

None of the authors have any conflicts of interest to disclose.

References

[1] M. Popovic, X. Campos-Möller, M. B. Schlenker, and I. I. K. Ahmed, "Efficacy and safety of femtosecond laser-assisted cataract surgery compared with manual cataract surgery," *Ophthalmology*, vol. 123, no. 10, pp. 2113–2126, 2016.

[2] S. Akkach, H. Yip, and R. Meusemann, "Ten-year audit of posterior capsule tear complication rates and visual outcomes following phacoemulsification," *Clinical and Experimental Ophthalmology*, vol. 47, no. 6, pp. 805-806, 2019.

[3] Y. M. Por and M. J. Lavin, "Techniques of intraocular lens suspension in the absence of capsular/zonular support," *Survey of Ophthalmology*, vol. 50, no. 5, pp. 429–462, 2005.

[4] F. J. Ascaso, V. Huerva, and A. Grzybowski, "Epidemiology, etiology, and prevention of late IOL-capsular bag complex dislocation: review of the literature," *Journal of Ophthalmology*, vol. 2015, Article ID 805706, 7 pages, 2015.

[5] R. Joshi and S. Singanwad, "Frequency and surgical difficulties associated with pseudoexfoliation syndrome among Indian rural population scheduled for cataract surgery: hospital-based data," *Indian Journal of Ophthalmology*, vol. 67, no. 2, pp. 221–226, 2019.

[6] M. Bergman and L. Laatikainen, "Long-term evaluation of primary anterior chamber intraocular lens implantation in complicated cataract surgery," *International Ophthalmology*, vol. 20, no. 6, pp. 295–299, 1997.

[7] K. E. Donaldson, J. J. Gorscak, D. L. Budenz, W. J. Feuer, M. S. Benz, and R. K. Forster, "Anterior chamber and sutured posterior chamber intraocular lenses in eyes with poor capsular support," *Journal of Cataract & Refractive Surgery*, vol. 31, no. 5, pp. 903–909, 2005.

[8] W. G. Zeh and F. W. Price, "Iris fixation of posterior chamber intraocular lenses," *Journal of Cataract & Refractive Surgery*, vol. 26, no. 7, pp. 1028–1034, 2000.

[9] V. Lorencova, P. Rozsival, and J. Urminsky, "Clinical results of the aphakia correction by means of secondary implantation of the iris fixated anterior chamber intraocular lens," *Ceská a Slovenská Oftalmologie*, vol. 63, no. 4, pp. 285–291, 2007.

[10] K. Solomon, J. R. Gussler, C. Gussler, and W. S. Van Meter, "Incidence and management of complications of transsclerally sutured posterior chamber lenses," *Journal of Cataract & Refractive Surgery*, vol. 19, no. 4, pp. 488–493, 1993.

[11] R. Asadi and A. Kheirkhah, "Long-term results of scleral fixation of posterior chamber intraocular lenses in children," *Ophthalmology*, vol. 115, no. 1, pp. 67–72, 2008.

[12] D. J. Apple, R. N. Brems, R. B. Park et al., "Anterior chamber lenses. Part I: complications and pathology and a review of designs," *Journal of Cataract & Refractive Surgery*, vol. 13, no. 2, pp. 157–174, 1987.

[13] S. R. Patel, D. S. Chu, B. D. Ayres, and P. S. Hersh, "Corneal edema and penetrating keratoplasty after anterior chamber phakic intraocular lens implantation," *Journal of Cataract & Refractive Surgery*, vol. 31, no. 11, pp. 2212–2215, 2005.

[14] N. Loya, H. Lichter, N. Goldenberg-Cohen, E. Strassmann, and D. Weinberger, "Posterior chamber intraocular lens implantation after capsular tear: ultrasound biomicroscopy evaluation," *Journal of Cataract & Refractive Surgery*, vol. 27, no. 9, pp. 1423–1427, 2001.

[15] A. Agarwal, D. A. Kumar, S. Jacob, C. Baid, A. Agarwal, and S. Srinivasan, "Fibrin glue-assisted sutureless posterior chamber intraocular lens implantation in eyes with deficient posterior capsules," *Journal of Cataract & Refractive Surgery*, vol. 34, no. 9, pp. 1433–1438, 2008.

[16] A. Agarwal, D. A. Kumar, S. Jacob, G. Prakash, and A. Agarwal, "Reply: fibrin glue-assisted sutureless scleral fixation," *Journal of Cataract & Refractive Surgery*, vol. 35, no. 5, pp. 795-796, 2009.

[17] D. A. Kumar, A. Agarwal, G. Prakash, S. Jacob, Y. Saravanan, and A. Agarwal, "Glued posterior chamber IOL in eyes with deficient capsular support: a retrospective analysis of 1-year post-operative outcomes," *Eye*, vol. 24, no. 7, pp. 1143–1148, 2010.

[18] S. Yamane, S. Sato, M. Maruyama-Inoue, and K. Kadonosono, "Flanged intrascleral intraocular lens fixation with double-needle technique," *Ophthalmology*, vol. 124, no. 8, pp. 1136–1142, 2017.

[19] A. Kelkar, R. Fogla, J. Kelkar, A. Kothari, H. Mehta, and W. Amoaku, "Sutureless 27-gauge needle-assisted transconjunctival intrascleral intraocular lens fixation: initial experience," *Indian Journal of Ophthalmology*, vol. 65, no. 12, pp. 1450–1453, 2017.

[20] M. Postorino, A. Meduri, L. Inferrera et al., "Scleral pockets for an innovative technique of intrascleral fixation of intraocular lens," *European Journal of Ophthalmology*, vol. 30, no. 5, pp. 985–990, 2020.

[21] D. A. Kumar, A. Agarwal, S. Jacob, M. Lamba, S. Packialakshmi, and A. Meduri, "Combined surgical management of capsular and iris deficiency with glued intraocular lens technique," *Journal of Refractive Surgery*, vol. 29, no. 5, pp. 342–347, 2013.

[22] C. Veronese, C. Maiolo, G. W. Armstrong et al., "New surgical approach for sutureless scleral fixation," *European Journal of Ophthalmology*, vol. 30, no. 3, pp. 612–615, 2020.

[23] T. Rossi, D. Iannetta, V. Romano et al., "A novel intraocular lens designed for sutureless scleral fixation: surgical series," *Graefes Archive for Clinical and Experimental Ophthalmology*, vol. 259, no. 1, pp. 257–262, 2021.

[24] M. D. Toro, A. Longo, T. Avitabile et al., "Five-year follow-up of secondary iris-claw intraocular lens implantation for the treatment of aphakia: anterior chamber versus retropupillary implantation," *PLoS One*, vol. 14, no. 4, Article ID e0214140, 2019.

[25] B. F. Marianelli, T. S. Mendes, R. P. de Almeida Manzano, P. N. Garcia, and I. C. Teixeira, "Observational study of intraocular lens tilt in sutureless intrascleral fixation versus standard transscleral suture fixation determined by ultrasound biomicroscopy," *International Journal of Retina and Vitreous*, vol. 5, no. 1, p. 33, 2019.

[26] D. A. Kumar, D. A. Agarwal, D. Dhawan et al., "Glued intraocular lens in eyes with deficient capsules: a retrospective analysis of long term effects," *Journal of Cataract & Refractive Surgery*, vol. 47, no. 4, pp. 496–503, 2020.

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Research Article

Outcomes and Complications of Sutured Scleral-Fixated Foldable Intraocular Lens Implantation: A Retrospective Study of 5-Year Follow-Up

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Purpose. To evaluate long-term outcomes and complications of sutured scleral-fixated foldable intraocular lens (IOL) implantation. *Design*. Retrospective study. *Methods*. Patients who underwent sutured scleral-fixated foldable IOL implantation using 10-0 polypropylene suture were followed up for at least 5 years at one Chinese tertiary hospital and two primary hospitals. *Results*. 52 eyes among 48 patients (35 male and 13 female) were evaluated. The mean age (years) was 50.27 ± 20.08 (range: 6 to 81). The mean postoperative follow-up time (months) was 79.70 ± 18.84 (range: 60 to 121). The mean best-corrected visual acuity (BCVA) improved from 0.83 ± 0.69 logarithm of the minimum angle of resolution (logMAR) at baseline to 0.50 ± 0.45 logMAR at the last follow-up visit. There was improved or unchanged BCVA in 44 eyes (84.62%) and reduced BCVA in 8 eyes (15.38%). Mild intraoperative intravitreal hemorrhage was observed in 3 eyes (5.77%). Early postoperative complications included transient elevated intraocular pressure (IOP) in 5 eyes (9.62%) and hypotony in 1 eye (1.92%). Secondary epimacular membrane occurred in 5 eyes (9.62%) and retinal detachment (RD; 3 years postsurgery), subconjunctival suture knot exposure (5 years postsurgery), and persistent elevated IOP (in a GRAVES patient) occurred in 1 eye (1.92%) each. No suture erosion or breakage nor IOL dislocation was observed. No visually threatening IOL tilt or decentration was reported in any patient. *Conclusion*. Sutured scleral-fixated foldable IOL implantation demonstrated satisfactory long-term outcomes and rare suture-related complications. This technology was safe and did not require complicated equipment and is of considerable interest in the setting of aphakia without adequate capsule support.

1. Introduction

There are several mainstream surgical approaches to correct aphakia without adequate capsular support. Current choices include implantation of an iris-fixated intraocular lens (IOL) (pre- or retropupillary), sutureless intrascleral posterior chamber IOL fixation, and scleral-fixated IOL [1–8]. Although angle-supported anterior chamber IOL (AC-IOL) was adopted in 1952, its use today is limited due to high long-term risks of bullous keratopathy and glaucoma [5, 6]. Scleral-fixated IOL (SF-IOL), including sutureless and sutured fixated IOL (SSF-IOL), continues to gain acceptance among surgeons [4, 9].

Sutureless ciliary sulcus-fixation technique, as proposed by Gabor and Pavlidis [2] in 2007, attempted to avoid suture-related complications. However, most reports of implantation of sutureless intrascleral posterior chamber IOL had short (1–55 months) follow-up periods [4, 9–11] and subconjunctival IOL haptic exposure, IOL dislocation (as early as 1 day postsurgery), and pupil capture have been reported [10, 12, 13]. Additionally, the need for complicated equipment/instruments and specialized surgical skills

challenge the use of such techniques in developing and underdeveloped countries, especially in primary hospitals and eye centers.

Considering these obstacles, SSF-IOL implantation remains an effective procedure. Its long-term outcomes and safety profile have been widely reported [14–24]. The most concerning late complication was IOL dislocation due to suture breakage, occurring on average at approximately 50 months postsurgery, with differences between studies and ethnic groups [15–17]. For example, suture breakage in Caucasians varied from 0% to 57.69% [21–23, 25–28] at 12–294 months of follow-up, whereas in more darkly pigmented groups such as Asians and Africans, it varied from 0% to 4.65% [14, 19, 20, 29–31] at 12–180 months of follow-up. Other reported adverse events (AEs) included lens tilt, suprachoroidal or vitreous hemorrhage, retinal detachment (RD), and endophthalmitis, which varied among studies [14, 15, 18, 32].

Several studies have retrospectively evaluated long-term outcomes and complications of SSF-IOL implantation in Asian and African patients [14, 19, 20, 29–31]. Of note, reports by Kim et al. [20] and Yang and Chao [19] were based on relatively small cohorts (15 and 29 cases, respectively), and those by Zhao et al. [24] and Rogers et al. [29] were based on follow-up periods from 6 to 99 months and from 0 to 54 months, respectively. In one large retrospective review by Luk et al. [14] with follow-up ranging from 12 to 180 months, procedures were performed by four different surgeons. The study reviewed postoperative AEs, but lacked detail regarding time of occurrence. The purpose of our study was to evaluate the long-term safety, efficacy, and clinical outcomes of SSF-IOL implantation over a 5-year period in China. Special emphasis was placed on AEs including suture-related complications, IOL dislocation, hypotony, elevated intraocular pressure (IOP), and RD.

2. Materials and Methods

SSF-IOL implantation was performed by the same surgeon at three sites: Fujian Provincial Hospital (tertiary referral site) and Guangze County Hospital and Xiapu County Hospital (primary hospital sites). The study was conducted in compliance with the guidelines of the Declaration of Helsinki and was approved by the ethics committees of all participating hospitals.

To evaluate long-term outcomes, we conducted a retrospective investigation of patients with at least 5 years of follow-up data between December 2009 and November 2015. In total, 101 patients (27 female and 74 male) underwent surgery during this period. We excluded 6 patients who had incomplete medical records. Among the remaining 95 patients, 46 were excluded for the following: 8 died, 4 were unable to visit clinic due to disability, and 34 were lost to follow-up. Finally, we studied 52 eyes (3 in Guangze County Hospital, 2 in Xiapu County Hospital, and 47 in Fujian Provincial Hospital) among 48 patients (35 male and 13 female). Preoperative data included demographics, best-corrected visual acuity (BCVA), IOP, lens status, previous surgeries, preexisting ocular pathologies, and history of ocular trauma. Axial length (AL) was measured by using a partial coherence interferometer (IOL Master, Carl Zeiss AG, Jena, Germany) or A-scan ultrasound biometry (AL-4000 Pachymeter, Japan) prior to surgery. The refractive power of the IOL was calculated using the SRK/T formula for AL between 21 and 26 mm and the Haigis formula for AL exceeding this interval.

Visual outcomes were measured by the distance Snellen chart preoperatively and at the last clinic visit. Pre- and postoperative BCVA were measured. Snellen acuity was converted to the logarithm of minimal angle of resolution (logMAR) VA for analysis. We used a logMAR VA of 2 and 3, respectively, to represent counting fingers and hand movement vision [33]. The spherical equivalent (SE) value was calculated as the sum of the spherical power with half of the cylindrical power. The refractive prediction error (RPE) was calculated by subtracting the estimated preoperative SE from the postoperative SE. Considering that developing AL might interfere with RPE, we excluded subjects who were less than 18 years of age.

Early postoperative complications were defined as AEs occurring within 1 month postsurgery. Any AE occurring after 1 month was considered a late complication. We observed the 10-0 polypropylene suture/suture knot with a slit-lamp and, when the suture/suture knot was visible under the conjunctival, we used bulbar conjunctival fluoresce staining to determine whether the suture/suture knot was exposed beyond the conjunctival epithelium.

2.1. Surgical Technique. Procedures were performed by the same surgeon using a similar technique (video and supplemental digital content are available at https://drive.google.com/file/d/1Ff5wC1Uf1pqohpw1j-S3kiiTwfMbbjhp/view?usp=sharing). Retrobulbar or general anesthesia (2 children) was administered. A three-piece (ZA9003, Tecnis, AMO) or one-piece (ZCB00, Tecnis, AMO) IOL was implanted. Two opposing limbus-based triangle scleral flaps were prepared 1.5 mm from the limbus at 4-5 o'clock and 10-11 o'clock in 48 eyes. In 4 eyes with a partial residual capsule, a single-suture scleral fixation was used to position the IOL haptic at the absent capsular position. The ab externo technique was used as described below. A straight needle carrying a 10-0 polypropylene suture was inserted into the posterior chamber through one scleral flap. A 26-gauge needle was then inserted through the opposite scleral flap to pull the straight needle out of the eye within its barrel. Then, a 2.4 or 3.0 mm corneal incision was made at 9 o'clock and the suture was pulled out through the corneal incision and cut off. A foldable IOL was loaded in the injector, part of the foregoing (leading) haptic was pushed out of the cartridge, and the suture was tied with at least 5 knots to the maximum radian of the IOL haptic to prevent suture slippage (Figure 1(a)). For the three-piece IOL (38 subjects), the haptic end was heated to create a mushroom-shaped flange of about 0.16 mm. For the one-piece IOL (10 subjects), the end was not heated, but the haptic was slightly depressed by the suture to reduce suture movement. Then, after tying the suture to the leading haptic, the plunger was withdrawn

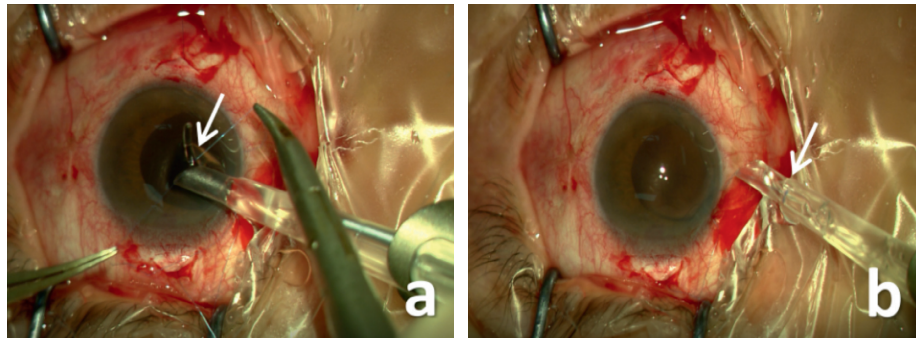

Figure 1: Sutured scleral-fixated implantation with a one-piece foldable IOL. (a) The suture was tied to the maximum radian of the IOL haptic with at least 5 knots. (b) After withdrawing the plunger, the haptic drew back into the cartridge.

(Figure 1(b)), so that the IOL could be implanted into the posterior chamber through a smaller (2.4 mm) corneal incision. Subsequently, the cartridge was inserted into the corneal incision and the posterior (trailing) haptic was left outside the incision for suture fixation as aforementioned. Then, the sutured posterior haptic was carefully inserted into the posterior chamber through the corneal incision using microforceps. After tensioning the sutures, the IOL was placed in a central position and the corneal incision was closed using a 10-0 nylon suture followed by suturing of the scleral flaps and conjunctiva. For secondary lens implantation in eyes without coexistent vitreoretinal disorders, no vitrectomy was performed and infusion or AC maintainer was not applied. For those with minor vitreous incarceration in the pupil area/corneal incision, a scissors was used to excise it. In 4 eyes with prior pars plana vitrectomy (PPV), vitreous infusion was used to maintain intraocular stability. In 5 eyes with RD, PPV with SSF-IOL implantation was performed at the same time.

2.2. Statistical Analysis. Means and standard deviations (SDs) of the quantitative variables were calculated. A paired *t*-test was used to detect differences in quantitative variables when data obeyed normal distribution; otherwise, the Wilcoxon matched-pairs signed ranks sum test was used. Differences were considered statistically significant if the *P* value was <0.05. All calculations were performed using SPSS software (version 24, SPSS, Inc.).

3. Results

In the present study, 52 eyes among 48 patients (35 male and 13 female) were evaluated. The characteristics of the study population are shown in Table 1. The mean age was 50.27 ± 20.08 (range: 6–81) years. The mean follow-up time was 79.7 ± 18.84 (range: 60–121) months.

3.1. Refractive and Visual Outcomes. The mean preoperative BCVA was 0.83 ± 0.69 logMAR; the mean postoperative BCVA was 0.50 ± 0.45 logMAR at the last follow-up $p < 0.05$. In 44 eyes (84.62%), BCVA improved or remained unchanged; in 8 eyes (7.2%), it worsened (Figure 2). Reasons for BCVA decline included secondary epimacular membrane (3 eyes), progressive epimacular membrane (1 eye), optic atrophy (1 eye), and retinitis pigmentosa (3 eyes).

At the last follow-up visit, the mean SE was -1.00 ± 1.74 diopters, and the mean RPE was -0.67 ± 1.31 diopters. RPEs in 32 eyes (61.54%) were within 1.00 diopters and in 15 eyes (28.85%) were within 2.00 diopters. In 2 eyes (3.85%), RPE exceeded 4.00 diopters; both had high axial myopia (27.31 mm and 29.08 mm) and posterior scleral staphyloma, and their ALs had been measured by A-ultrasound in a county hospital, which might explain the unexpectedly large postoperative RPEs.

3.2. Complications

3.2.1. Intraoperative. In 3 eyes (2 patients), vitreous hemorrhage occurred in association with passing the 10-0 polypropylene suture through the sclera 1.5 mm posterior to the limbus. In 1 eye, the hemorrhage appeared to arise from extraocular blood wicked into the eye through the puncture; it was mild and stopped after hemostasis. In the other 2 eyes, the patient had Marfan syndrome and took an oral anticoagulant (Warfarin) after cardiac surgery; the hemorrhage may have come from the ciliary body. Surgery proceeded and the vitreous hemorrhage resolved within 2 weeks. There was no other case of intraoperative complications such as choroidal detachment or suprachoroidal hemorrhage.

3.2.2. Postoperative. As shown in Table 2, early complications included transient elevated IOP in 5 eyes (9.62%) and hypotony in 1 eye (1.92%) that had previous PPV surgery. Late complications included retinal detachment, subconjunctival suture knot exposure, and persistent elevated IOP in 1 eye (1.92%) each; the latter occurred in an eye with GRAVES. Epimacular membrane occurred in 5 eyes (9.62%). In the eye with RD, the 1/5 PD round hole was located near the 9 : 30 o'clock 20G trocar position, away from the suture-fixation position. We observed few complications associated with sutures; in most patients, suture knots could be seen in the subconjunctiva (Figure 3(a)), but staining was negative (Figure 3(b)). Only in 1 eye (1.92%), one suture knot exposure occurred 5 years after surgery with positive staining, but no suture knot erosion was observed (Figure 3(c)). We performed a conjunctival separation and

Table 1: Patient characteristics.

Parameter	
Male : female	35 : 13
Age (years, mean ± SD)	50.27 ± 20.08
Follow-up time (months, mean ± SD)	79.7 ± 18.84
Right eye : left eye	27 : 25
Preoperative comorbidities, *n* (%)	
Trauma	12 (23.08%)
Postglaucoma surgery	2 (3.85%)
Glaucoma with vitreous incarceration	4 (7.69%)
History of retinal detachment	5 (9.62%)
Marfan syndrome	3 (5.77%)
Myopic degeneration	2 (3.85%)
Surgical indication, *n* (%)	
Aphakia after complicated cataract surgery	29 (55.77%)
Aphakia after traumatic cataract surgery	10 (19.23%)
Aphakia resulting from previous pars plana vitrectomy (PPV) for RD or trauma	4 (7.69%)
Dislocated crystalline lens	6 (11.54%)
Dislocated IOL	3 (5.77%)

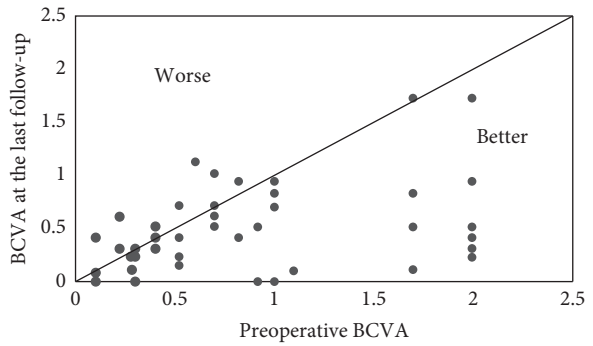

Figure 2: Scattergram of BCVA in 52 eyes that underwent SSF-IOL implantation. BCVA is represented in logMAR values. BCVA: best-corrected visual acuity; SSF-IOL: sutured scleral-fixated intraocular lens.

Table 2: Distribution and management of postoperative complications in eyes undergoing SSF-IOL.

	Complication			
Early (≤1 month)	*n* (%)	Mean duration postsurgery	Range	Management
Increased IOP	5 (9.62)	1.6 ± 0.8 days	1–3 days	Medical management
Transient vitreous hemorrhage	3 (5.77)	1 day	1 day	Medical management; resolved within 2 weeks
Transient hypotony	1 (1.92)	1 day	1 day	Suture the incision
Late (>1 month)	*n* (%)	—	—	—
Suture knot exposure	1 (1.92)	5 years	5 years	Surgical management
Retinal detachment	1 (1.92)	3 years	3 years	Surgical management
Increased IOP	1 (1.92)	6 years	6 years	Medical management

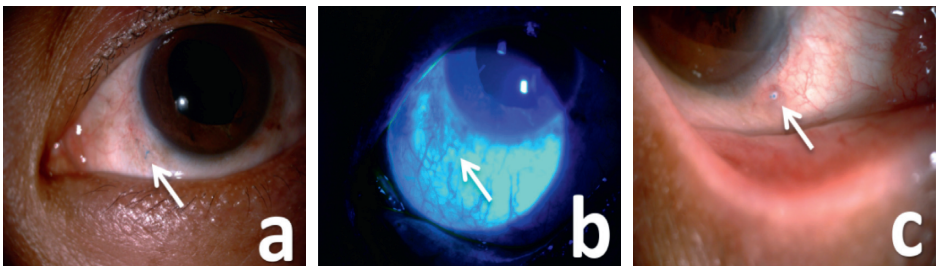

Figure 3: Slit-lamp microscopy images of the suture knot. (a) Suture knot visible under the conjunctiva. (b) Negative bulbar conjunctival fluoresce staining. (c) Suture exposure 5 years postsurgery.

coverage to rescue it. No optical disturbing IOL tilt or decentration was observed (Figure 4).

It is notable that no suture breakage or IOL displacement was observed during follow-up of any patient in this study.

4. Discussion

Compared to iris-fixed IOL and AC-IOL, SF-IOL is superior in protecting the integrity of the anterior chamber, minimizing uveal contact, and independence of the presence of iris tissue [3, 8]. However, due to the need for vitrectomy equipment and specialized surgical skill, sutureless SF-IOL is not likely to be widely used in primary hospitals and eye centers, especially in undeveloped/developing countries. There are few reports of sutureless SF-IOL with extended follow-up [4, 9–11]. In contrast, the SSF-IOL is a time-tested method initially described in 1986 by Malbran et al. [34]. Its long-term track record and independence from vitrectomy equipment has made it a primary implant technique worldwide in patients without sufficient capsular support [14–24].

We report the long-term outcomes of SSF-IOL implantation via a small (≤3 mm) corneal incision using 10-0 polypropylene suture. Included are cases performed at the beginning of the learning phase and those performed in two primary hospitals. Short- and long-term complications were infrequent and clinical outcomes were favorable. The SSF foldable IOL technique is less traumatic as fewer manipulations inside the eyeball are needed: suture presetting, suture out-pulling, and IOL inserting, with puncture performed when the eyeball was intact and the other procedures were finished under a small (≤3 mm) incision. For eyes having secondary lens implantation without coexistent vitreoretinal disorders, 38 eyes (73.08%) at the tertiary hospital and 5 eyes (9.62%) at the primary county hospitals did not require vitrectomy. When there was minor vitreous incarceration in the pupil area/corneal incision, the vitreous can be excised using scissors and then using a miotic agent. The use of a thinner 10-0 polypropylene suture preset through the ciliary sulcus with ab externo technique and smaller suture puncture were associated with minimal vitreous fluid outflow and only minor change in IOP. Little disturbance of the intraocular environment helps maintain the integrity and stability of the eyeball, such that infusion or AC maintainer is not needed.

Short-term complications included vitreous hemorrhage (5.77%), transient elevated IOP (9.62%), and hypotony (1.92%). Mild transient intravitreal hemorrhage was observed in 3 eyes (2 patients); one of these patients had Marfan syndrome and the AE might be attributable to Warfarin after cardiac surgery. In these patients, hemorrhage resolved within 2 weeks. In another case, extraocular blood may have wicked into the eye through the puncture; however, it was mild and resolved with well hemostasis. The incidence of vitreous hemorrhage was comparable to previous reports by Yeung et al. [35] and Zhao et al. [24] (5% and 6.6%, respectively). Transient elevated IOP was observed within 3 days postoperatively in 5 eyes. All eyes were stabilized with topical medication within a few days

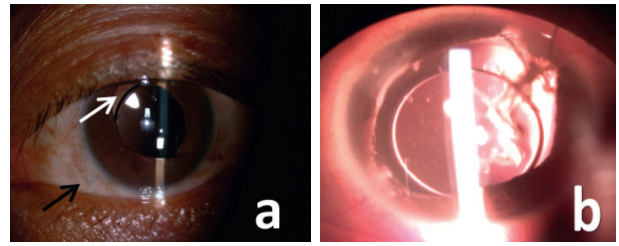

Figure 4: Slit-lamp microscopy images of well-centered IOLs. (a) Stable IOL position 97 months postsurgery. The black arrow points to the suture knot seen under conjunctiva. The white arrow points to the iris defect and pupil distortion due to previous trauma. (b) Well-placed IOL in a traumatic eye with atrophic iris 120 months postsurgery.

postsurgery. The supposed reasons of ocular hypertension included postoperative inflammation, retained viscoelastic agents, and temporary dysfunction of the trabecular meshwork [25]. Our study implanted a foldable SSF-IOL through a small corneal incision, using only a small amount of viscoelastic agents with minimal manipulation and vitreous disturbance. Even in the 4 cases with previous ocular hypertension resulting from vitreous incarcerate in the pupil area, IOP returned to normal after excising vitreous and implanting IOL. The ocular hypertension rate in our study was significantly lower than those in SSF-IOL studies with methyl methacrylate (PMMA) material (range: 10%–44%) [16, 25–27] and comparable to others with foldable material (range: 7%–11.5%) [20, 36, 37]. Hypotony caused by incision leakage was observed in 1 eye post-PPV 1 day postsurgery. Thereafter, the main incision was sutured at the end of surgery to prevent postoperative hypotony, especially in vitrectomized eyes, and no further hypotony occurred. Consequently, the hypotony rate in this study is in stark contrast to studies (range: 4.3%–9.4%) [16, 24, 37].

IOL dislocation due to suture breakage was a late complication and is considered by surgeons to be the greatest challenge of this technique. The incidence of this complication, typically observed 3–5 years postprocedure [14–24], is estimated to be 0%–57.69% in Caucasians [23–28] and 0% to 4.65% in Asians and Africans [14, 19, 20, 29–31]. In our study, there was no suture breakage with a mean follow-up of 79.7 months. The role of pigment is unclear and requires further randomized, multicenter prospective study. Furthermore, according to some reports, the risk of postoperative suture breakage was greater in younger patients (range: 12%–24%) [17, 18]; however, in our study, there was no breakage in 13 patients who are <40 years old. An Indian report by Bhojwani et al. [31] including 12 children (under 16 years old) also found no suture breakage. Thus, we consider suture breakage in younger Asian patients is worth further investigation.

Although 9-0 polypropylene suture has been widely used recently [32, 38, 39], our study revealed no suture breakage, perhaps demonstrating the stability of 10-0 polypropylene scleral fixation sutures. This result was consistent with Luk et al. [14], with a mean follow-up of 73.4 months. We consider 10-0 polypropylene suture to have some advantages. First, a 10-0 polypropylene suture knot is smaller than

a 9-0 knot and may produce fewer complications such as scleral atrophy above the knot and erosion of the stiff cutting ends [14, 26]. In most patients in our study, suture knots were seen in the subconjunctiva, but bulbar conjunctival fluorescein staining was negative (Figures 3(a) and 3(b)). Among 100 suture knots in 52 eyes, only 1 exposure was observed 5 years postsurgery with positive staining (Figure 3(c)), which was rescued by conjunctival separation and coverage. Smaller knots and softer thread arms of the 10-0 suture might produce less suture exposure and erosion. Second, when presetting sutures, the thicker and stiffer texture of a 9-0 or 8-0 suture may result in larger puncture allowing more intravitreous fluid leakage. What is more, there are several reports of a 10-0 polypropylene suture knotless *Z*-suture technique that demonstrate promising clinical results with follow-up from 6 to 135 months and that might further enhance SSF-IOL implantation [22, 23].

Other long-term AEs, including RD and significant lens tilt or decentration, were also infrequent in our study. RD was seen in 1 eye (1.92%) 3 years postsurgery with the retinal hole located away from the suture-fixation position (11 o'clock). We ascribe the detachment to the vitreous traction around the trocar rather than suture-fixation surgery. The retina was reattached successfully with no negative sequelae. Lens tilt and decentration are well-documented complications in SSF-IOL implantation. Durak et al. [40] reported a 16.7% rate of lens tilt or decentration. Lens tilt develops due to asymmetric suture placement, and decentration occurs due to the asymmetric attachment of suture haptics on the scleral bed, loose suture, suture breakage, or other causes [40]. We identified no significant IOL decentration or tilt in our study at a mean follow-up of 79.7 months.

After IOL implantation, all patients had improved vision. In 44 eyes (84.62%), BCVA improved or remained unchanged and worsened in 8 eyes (7.2%) at the last follow-up visit. Most previous studies showed increased or unchanged BCVA after SF-IOL implantation in 86.2%–92.8% of cases [24, 32, 35]. Visual outcomes in our study were impressive and comparable to the previous study with a high rate of BCVA improvement, demonstrating long-term stability of SSF foldable IOL. Those eyes with worsening BCVA over the follow-up period resulted from epimacular membrane, optic atrophy, and retinitis pigmentosa, which were inextricable. At the last follow-up, RPEs in 32 eyes (61.54%) were within 1.00 diopters and in 15 eyes (28.85%) were within 2.00 diopters. There is no consensus on the target spherical equivalent when implanting an SF-IOL. Because sulcus-fixated IOL is located more anteriorly than in-the-bag fixation, postoperative refraction can lead to a myopic shift from the predicted value. In our study, an unexpected myopic shift occurred in 2 eyes (−4.22 diopters and −5.74 diopters), both at county hospitals, with high axial myopia (27.31 mm and 29.08 mm) and posterior scleral staphyloma. Due to the lack of optical biometry there, ALs were measured by A-ultrasound, which could explain the large postoperative spherical equivalent deviation. Therefore, we strongly recommended taking careful repeated measures of AL and applying precise optical biometry in patients with high axial myopia and posterior scleral staphyloma.

There were some limitations to this study, primarily the retrospective design and the absence of a control group. However, its greatest strength was the long (>5 years) follow-up period. Another limitation was substantial (49%) loss to follow-up, which might introduce selection bias. Nevertheless, in our study, patient data were collected retrospectively for more than 5 years, and the loss to follow-up was a limitation inherent to the long-term retrospective design. Anterior segment optical coherence tomography or Scheimpflug images were not reported as a more accurate indication of IOL tilt or decentration; therefore, large, prospective, and long-term randomized clinical trials are required to further substantiate the therapeutic benefits demonstrated in this study.

5. Conclusions

Our study validated the beneficial long-term outcomes of SSF foldable IOL implantation in China via a small (≤3 mm) corneal incision using 10-0 polypropylene suture. This technology was safe, easy to master, and easily replicated. Both short- and long-term AEs (particularly suture-related complications) were rare and long-term visual outcomes were stable. Free from relying on complicated resources, such as expensive equipment and vitrectomy skills, SSF-IOL technology may be especially useful in primary hospitals and eye centers, and in underdeveloped or developing settings.

Data Availability

The dataset used for analyses may be requested from the corresponding author for use in scholarly work related to the field.

Disclosure

The sponsor or funding organization had no role in the design or conduct of this research.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Supplementary Materials

The supplementary materials are two videos which describe the surgical procedure in detail. (*Supplementary Materials*)

References

[1] R. T. Peralba, D. Lamas-Francis, T. Sarandeses-Diez, L. Martínez-Pérez, and T. Rodríguez-Ares, "Iris-claw

intraocular lens for aphakia: can location influence the final outcomes?" *Journal of Cataract and Refractive Surgery*, vol. 44, no. 7, pp. 818–826, 2018.

[2] S. G. B. Gabor and M. M. Pavlidis, "Sutureless intrascleral posterior chamber intraocular lens fixation," *Journal of Cataract and Refractive Surgery*, vol. 33, no. 11, pp. 1851–1854, 2007.

[3] M. D. Sindal, C. P. Nakhwa, and S. Sengupta, "Comparison of sutured versus sutureless scleral-fixated intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 1, pp. 27–34, 2016.

[4] J. Nehme, M. Sahyoun, M. Saad et al., "Secondary intraocular lens implantation with absence of capsular support: scleral versus iris fixation," *Journal Français d'Ophtalmologie*, vol. 41, no. 7, pp. 630–636, 2018.

[5] K. Droutsas, A. Lazaridis, G. Kymionis et al., "Endothelial keratoplasty in eyes with a retained angle-supported intraocular lens," *International Ophthalmology*, vol. 39, no. 5, pp. 1027–1035, 2019.

[6] R. Oltulu, I. Erşan, G. Şatırtav, M. Donbaloglu, H. Kerimoglu, and A. Ozkagnici, "Intraocular lens explantation or exchange: indications, postoperative interventions, and outcomes," *Arquivos Brasileiros de Oftalmologia*, vol. 78, no. 3, pp. 154–157, 2015.

[7] M. Schallenberg, D. Dekowski, A. Hahn, T. Laube, K. P. Steuhl, and D. Meller, "Aphakia correction with retropupillary fixated iris-claw lens (Artisan)-long-term results," *Clinical Ophthalmology*, vol. 8, pp. 137–141, 2014.

[8] N. Madhivanan, S. Sengupta, M. Sindal, P. Nivean, M. Kumar, and M. Ariga, "Comparative analysis of retropupillary iris claw versus scleral-fixated intraocular lens in the management of post-cataract aphakia," *Indian Journal of Ophthalmology*, vol. 67, no. 1, pp. 59–63, 2019.

[9] A. C. Bonnell, D. Mantopoulos, H. M. Wheatley, and J. L. Prenner, "Surgical technique for sutureless intrascleral fixation of a 3-piece intraocular lens using a 30-gauge needle," *Retina*, vol. 39, no. 1, pp. S13–S15, 2019.

[10] M. P. Czajka, A. Frajdenberg, M. Stopa, T. Pabin, B. Johansson, and G. Jakobsson, "Sutureless intrascleral fixation using different three-piece posterior chamber intraocular lenses: a literature review of surgical techniques in cases of insufficient capsular support and a retrospective multicentre study," *Acta Ophthalmologica*, vol. 98, no. 3, pp. 224–236, 2020.

[11] B. Todorich, M. S. Stem, K. Kooragayala et al., "Structural analysis and comprehensive surgical outcomes of the sutureless intrascleral fixation of secondary intraocular lenses in human eyes," *Retina*, vol. 38, no. 1, pp. S31–S40, 2018.

[12] Y. Matsui, H. Matsubara, T. Hanemoto, and M. Kondo, "Exposure of haptic of posterior chamber intraocular lens after sutureless intrascleral fixation," *BMC Ophthalmology*, vol. 15, no. 1, p. 104, 2015.

[13] A. M. Abbey, R. M. Hussain, A. R. Shah, L. J. Faia, J. D. Wolfe, and G. A. Williams, "Sutureless scleral fixation of intraocular lenses: outcomes of two approaches. the 2014 Yasuo Tano memorial lecture," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 253, no. 1, pp. 1–5, 2015.

[14] A. S. W. Luk, A. L. Young, and L. L. Cheng, "Long-term outcome of scleral-fixated intraocular lens implantation," *British Journal of Ophthalmology*, vol. 97, no. 10, pp. 1308–1311, 2013.

[15] B. J. Vote, P. Tranos, C. Bunce, D. G. Charteris, and L. Da Cruz, "Long-term outcome of combined pars plana vitrectomy and scleral fixated sutured posterior chamber intraocular lens implantation," *American Journal of Ophthalmology*, vol. 141, no. 2, pp. 308–312, 2006.

[16] A. S. McAllister and L. W. Hirst, "Visual outcomes and complications of scleral-fixated posterior chamber intraocular lenses," *Journal of Cataract and Refractive Surgery*, vol. 37, no. 7, pp. 1263–1269, 2011.

[17] E. G. Buckley, "Safety of transscleral-sutured intraocular lenses in children," *Journal of American Association for Pediatric Ophthalmology and Strabismus*, vol. 12, no. 5, pp. 431–439, 2008.

[18] R. Asadi and A. Kheirkhah, "Long-term results of scleral fixation of posterior chamber intraocular lenses in children," *Ophthalmology*, vol. 115, no. 1, pp. 67–72, 2008.

[19] C.-S. Yang and Y.-J. Chao, "Long-term outcome of combined vitrectomy and transscleral suture fixation of posterior chamber intraocular lenses in the management of posteriorly dislocated lenses," *Journal of the Chinese Medical Association*, vol. 79, no. 8, pp. 450–455, 2016.

[20] S. J. Kim, S. J. Lee, C. H. Park, G. Y. Jung, and S. H. Park, "Long-term stability and visual outcomes of a single-piece, foldable, acrylic intraocular lens for scleral fixation," *Retina*, vol. 29, no. 1, pp. 91–97, 2009.

[21] G. M. Cavallini, V. Volante, M. De Maria et al., "Long-term analysis of IOL stability of the Lewis technique for scleral fixation," *European Journal of Ophthalmology*, vol. 25, no. 6, pp. 525–528, 2015.

[22] N. Kandemir Besek, N. Alagoz, G. Gumus et al., "Long-term results of aphakia management by scleral fixation intraocular lens placement with knotless transscleral *Z*-suture method," *International Ophthalmology*, vol. 40, no. 6, pp. 1449–1454, 2020.

[23] S. Dimopoulos, V. Dimopoulos, G. Blumenstock et al., "Long-term outcome of scleral-fixated posterior chamber intraocular lens implantation with the knotless *Z*-suture technique," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 2, pp. 182–185, 2018.

[24] H. Zhao, W. Wang, Z. Hu, and B. Chen, "Long-term outcome of scleral-fixated intraocular lens implantation without conjunctival peritomies and sclerotomy in ocular trauma patients," *BMC Ophthalmology*, vol. 19, no. 1, p. 164, 2019.

[25] D. Lockington, N. Q. Ali, R. Al-Taie, D. V. Patel, and C. N. J. McGhee, "Outcomes of scleral-sutured conventional and aniridia intraocular lens implantation performed in a university hospital setting," *Journal of Cataract and Refractive Surgery*, vol. 40, no. 4, pp. 609–617, 2014.

[26] G. Bading, J. Hillenkamp, H. G. Sachs, V.-P. Gabel, and C. Framme, "Long-term safety and functional outcome of combined pars plana vitrectomy and scleral-fixated sutured posterior chamber lens implantation," *American Journal of Ophthalmology*, vol. 144, no. 3, pp. 371–377, 2007.

[27] L. Krause, N. E. Bechrakis, H. Heimann, S. Salditt, and M. H. Foerster, "Implantation of scleral fixated sutured posterior chamber lenses: a retrospective analysis of 119 cases," *International Ophthalmology*, vol. 29, no. 4, pp. 207–212, 2009.

[28] G. T. Kokame, R. T. Yanagihara, J. G. Shantha, and K. N. Kaneko, "Long-term outcome of pars plana vitrectomy and sutured scleral-fixated posterior chamber intraocular lens implantation or repositioning," *American Journal of Ophthalmology*, vol. 189, pp. 10–16, 2018.

[29] G. Rogers, H. Mustak, M. Hann, D. Steven, and C. Cook, "Sutured posterior chamber intraocular lenses for traumatic cataract in Africa," *Journal of Cataract and Refractive Surgery*, vol. 40, no. 7, pp. 1097–1101, 2014.

[30] R. Mannan, R. Sinha, N. Sharma, A. Pruthi, J. S. Titiyal, and R. B. Vajpayee, "Intrascleral reverse pocket approach of transconjunctival transscleral sulcus fixation of intraocular lens in eyes with ocular trauma," *Eye & Contact Lens: Science & Clinical Practice*, vol. 37, no. 5, pp. 316–319, 2011.

[31] D. Bhojwani, A. R. Vasavada, V. Vasavada, S. Vasavada, M. R. Praveen, and S. Srivastava, "Intraoperative performance and long-term postoperative outcomes after scleral fixation of IOLs with polytetrafluoroethylene suture," *Journal of Cataract and Refractive Surgery*, vol. 46, no. 11, pp. 1480–1486, 2020.

[32] E. Wasiluk, P. Krasnicki, D. A. Dmuchowska, E. Proniewska-Skrętek, and Z. Mariak, "The implantation of the scleral-fixated posterior chamber intraocular lens with 9/0 polypropylene sutures-long-term visual outcomes and complications," *Advances in Medical Sciences*, vol. 64, no. 1, pp. 100–103, 2019.

[33] K. Schulze-Bonsel, N. Feltgen, H. Burau, L. Hansen, and M. Bach, "Visual acuities "hand motion" and "counting fingers" can be quantified with the freiburg visual acuity test," *Investigative Opthalmology & Visual Science*, vol. 47, no. 3, pp. 1236–1240, 2006.

[34] E. S. Malbran, E. Malbran Jr., and I. Negri, "Lens guide suture for transport and fixation in secondary IOL implantation after intracapsular extraction," *International Ophthalmology*, vol. 9, no. 2-3, pp. 151–60, 1986.

[35] L. Yeung, N.-K. Wang, W.-C. Wu, and K.-J. Chen, "Combined 23-gauge transconjunctival vitrectomy and scleral fixation of intraocular lens without conjunctival dissection in managing lens complications," *BMC Ophthalmology*, vol. 18, no. 1, p. 108, 2018.

[36] P. C. Jacobi, T. S. Dietlein, and F. K. Jacobi, "Scleral fixation of secondary foldable multifocal intraocular lens implants in children and young adults," *Ophthalmology*, vol. 109, no. 12, pp. 2315–2324, 2002.

[37] Y. Chantarasorn, S. Techalertsuwan, P. Siripanthong, and A. Tamerug, "Reinforced scleral fixation of foldable intraocular lens by double sutures: comparison with intrascleral intraocular lens fixation," *Japanese Journal of Ophthalmology*, vol. 62, no. 3, pp. 365–372, 2018.

[38] Y. U. Shin, M. Seong, H. Y. Cho, and M. H. Kang, "Novel technique to overcome the nonavailability of a long needle 9-0 polypropylene suture for sutured scleral fixation of the posterior chamber intraocular lens using a single fisherman's knot," *Journal of Ophthalmology*, vol. 2017, Article ID 2683415, 4 pages, 2017.

[39] D. C. Terveen, N. R. Fram, B. Ayres, and J. P. Berdahl, "Small-incision 4-point scleral suture fixation of a foldable hydrophilic acrylic intraocular lens in the absence of capsule support," *Journal of Cataract and Refractive Surgery*, vol. 42, no. 2, pp. 211–216, 2016.

[40] A. Durak, H. F. Oner, N. Koçak, and S. Kaynak, "Tilt and decentration after primary and secondary transsclerally sutured posterior chamber intraocular lens implantation," *Journal of Cataract and Refractive Surgery*, vol. 27, no. 2, pp. 227–232, 2001.

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Research Article

Standardized Flanged Intrascleral Intraocular Lens Fixation with the Double-Needle Technique for Cataract Luxation in the Vitreous Chamber during Phacoemulsification

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Purpose. To assess the visual and refractive outcome of immediate intraoperative vitrectomy and intrascleral intraocular lens implantation using a "standardized" sutureless Yamane technique during cataract luxation in the vitreous chamber as a complication of phacoemulsification. *Design*. A prospective, interventional, consecutive case series. *Materials and Methods*. Twelve patients underwent vitrectomy and intrascleral intraocular lens fixation using a standardized Yamane technique as the primary procedure during complicated phacoemulsification. Patients were evaluated preoperatively and 6 months postoperatively for best-corrected distance visual acuity, correspondence to the preoperative refractive target in the spherical equivalent, endothelial cell count, and complications. *Results*. Mean preoperative best-corrected visual acuity was 1.16 ± 0.3 logarithm of the minimum angle of resolution (logMAR), the endothelial cell count was 1910.5 ± 297.64, and target refraction at baseline was -0.197 ± 0.087. Postoperatively, best-corrected visual acuity was significantly improved; the mean value was 0.05 logMAR $\pm$ 0.06. Mean baseline target refraction in the spherical equivalent was -0.20 ± -0.09 (range: -0.08 to -0.37), and mean final refraction was -0.44 ± -0.14 (range: -0.25 to -0.75) with no significant difference ($p = 0.87$). No complication was registered intra- and postoperatively. *Conclusion*. Standardization of the Yamane technique seemed a valuable option for patients who had complicated phacoemulsification to achieve a predictable refractive outcome. *Synopsis*. The predictable refractive outcome could be achieved with the immediate standardized Yamane technique in patients with intraoperative cataract luxation in the vitreous chamber during phacoemulsification.

1. Introduction

The intraocular lens (IOL) scleral fixation using the Yamane technique was introduced in 2014. The technique was sutureless, with an intrascleral fixation and with a good wound closure [1]. There is currently no complete consensus on how to surgically treat aphakia without capsular support. Scleral fixation of a posterior chamber intraocular lens with sutures and retropupillary and anterior chamber fixation of an iris-claw IOL are the alternative surgical techniques for the treatment of aphakia [2–5].

Yamane technique, despite many advantages, is still challenging for many surgeons. First of all, threading the trailing haptic into the needle represented a crucial point for

a good scleral fixation. Furthermore, the material of the lens's haptic is an essential factor to be considered to prevent kinking or breakage and therefore failure of the technique [6, 7].

Finally, since it is difficult to insert the haptics into the scleral tunnel using this approach, scleral fixation of the IOL haptics is a significant issue [6–11]. The technique is often poorly standardized in terms of tunnel construction, position of the opposite tunnel, and length of the portion of the haptic that requires cauterization.

Standardization of this procedure may be crucial in achieving the desired refractive target since we must note that these patients were originally cataract patients. In this study, we propose a standardization of the original technique with the aim of improving the final visual outcome of our patients and to overcome all potential surgery challenges.

2. Materials and Methods

This is a prospective, interventional, nonrandomized case series. The study was conducted according to the principles defined in the Declaration of Helsinki and amendments. The study was approved by the institutional review board. All patients gave written informed consent after explanation of the nature and possible consequences of the surgery. We evaluated 12 eyes of 12 consecutive patients, who experienced cataract luxation in the vitreous chamber during phacoemulsification with a temporal 2.4 mm clear cornea incision performed by several surgeons. All the patients immediately underwent 23-gauge (g) three-port pars plana vitrectomy (PPV), removal of cataract remnants, and intrascleral fixation using a "standardized" Yamane technique performed by the same expert surgeon (GB).

We evaluated the preoperative data present in the routine cataract surgery charts, such as best-corrected visual acuity in logMAR (BCVA), slit-lamp biomicroscopy, Goldmann tonometry, endothelial cell count (ECC), biometry (IOL Master 700, Carl Zeiss Meditec, Germany), fundus examination after pupil dilation, and macular status assessed by optical coherence tomography (OCT) (Stratus OCT, Carl Zeiss Meditec). All patients completed 6-months of follow-up. We recorded intraoperative complications, and we postoperatively analyzed the correspondence between target refraction and final refraction in the spherical equivalent (SE), BCVA, ECC, and the presence of complications such as iris capture, early postoperative hypotony, anterior chamber or vitreous hemorrhage, CME, or IOL dislocations/decentration.

2.1. Surgical Technique. Immediately after cataract luxation in the vitreous chamber, a single experienced surgeon (GB) performed a standard 23 g three-port PPV (Constellation, Alcon, USA) with cataract fragment removal with core vitrectomy, posterior hyaloidectomy, peripheral vitreous shaving without indentation, anterior hyaloidectomy, removal of residual capsular and zonular remnants and scleral fixation IOL implant with "standardized" Yamane's technique, and peripheral retina check with indentation. A superior 2.75 mm clear cornea incision was performed at 11 o'clock, and a corneal paracentesis with a 20 g blade was made opposite to the primary temporal corneal incision. The anterior chamber was filled with dispersive viscoelastic (IAL F, Bausch & Lomb) in order to provide the best protection of the endothelium while also increasing the anterior chamber space. Furthermore, the intraocular pressure (IOP) control of the vitrectomy machine was set to 10 mmHg to prevent hypotony during surgical maneuvers. A dedicated surgical tool called Yamane double-needle stabilizer (Geuder AG, Germany) was used to guide the needle to create the transconjunctival sclerotomies. The stabilizer is designed with several "teeth" underneath the crown for 270 degrees in order to grab the limbal tissue; the remaining 90 degrees with no "teeth" must be applied in the projection of the 2.75 mm superior incision in order to exert no pressure on the main incision and not to lose the stability of the anterior chamber. Setting the IOP at 10 mmHg leads to no iris prolapse throughout the corneal wounds during the scleral tunnel construction. To create the "L-shaped" scleral tunnel, a 30 g ultrathin-wall (UTW) needle (TSK, Japan) was used, and it was bent 7 mm far from the tip in order to be locked into the Yamane stabilizer after creating a 2 mm intrascleral tunnel starting 2 mm far from the limbus. A second scleral tunnel was created in the same fashion. The Yamane stabilizer assures the insertion of the needle at 180 degrees one opposite to the other. At this point, the tip of both needles is free-floating in the vitreous chamber, and the peculiar shape of the tunnel does not allow the tips to get in contact with the retinal surface. A preloaded foldable 3-piece IOL (Kowa PU6AS, Japan) was slowly injected into the viscoelastic-filled anterior chamber through the superior tunnel. The power selected for the IOL implanted was the one measured by automated biometry planned to achieve the negative refraction nearest to 0 if the IOL was placed into the bag. The distal haptic of the IOL was gently placed on the anterior surface of the iris, while the proximal haptic was left outside the tunnel in order to avoid the IOL to fall in the vitreous chamber. Then, using a 23 g vitreoretinal forceps, the distal haptic is placed inside the lumen of the needle, and the same procedure was made for the proximal haptic; the haptics were then externalized through the scleral tunnels as it was previously described. 2 mm was measured using a common ruler from the end of the haptic. We heated 2 mm of the haptic because we previously measured with a professional ruler (Borletti, Italy) the external dimension of the 30 g UTW needle in order to measure the internal dimension of the scleral tunnel. We stuck the ruler at that value. We applied cauterization to the haptics of the IOL, putting the forceps at different distances from the tip in order to investigate the optimal dimension of the plug to be stuck into the scleral tunnel. We put the forceps at 1 mm and 2 mm from the tip and heated the tip from distance. So, we created 2 different dimensions of the plug. The plug created at 1 mm slipped into the ruler, while the plug created at 2 mm does not. It means, to us, that this was the optimal amount of the tip to be heated in order to create a plug that could be inserted into the scleral tunnel by applying a little of stretch

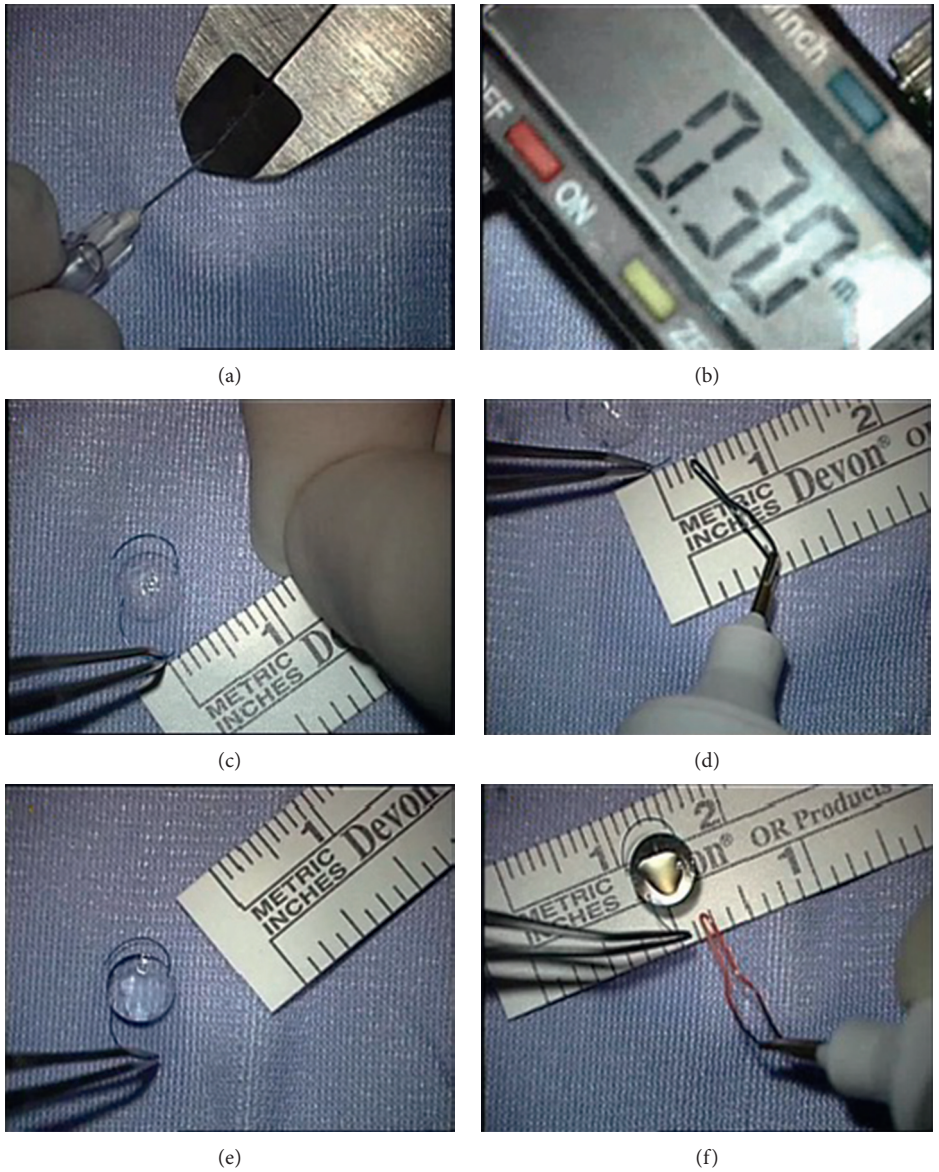

Figure 1: A professional ruler was used to measure the external dimension of the 30 g UTW needle and blocked in that position (a, b) in order to measure the internal dimension of the scleral tunnel. Forceps was put at 1 mm and 2 mm (c, d) from the tip, and the tip was heated from distance until the plug reached the forceps (e, f).

at the beginning of the tunnel, but since it is a little bigger than the tunnel, once inside, it will remain stable without slipping (Figure 1). Forceps held the haptic at 2 mm from the tip, and the plug was created by heating the end of the haptic, without touching the haptic. The plugs were gently inserted into the scleral tunnel, and the overlying conjunctiva was mobilized. The trocars were then removed, and the sclerotomies were sealed using wet-field diathermy. The corneal wounds were at the end hydrosutured.

2.2. Statistical Analysis. Data were organized in a Microsoft Excel XP table to perform statistical analysis. The Kolmogorov–Smirnov test was used to assess normality of the data. Changes at follow-up were calculated as the difference between follow-up and baseline measurements and were analyzed by Student's *T*-test for paired data assessing differences in mean values; when parametric analysis was not indicated, Wilcoxon signed-rank test was applied to assess the significance of differences between examinations. A p value <0.05 was considered statistically significant. Data were presented as mean + standard deviation. Analyses were performed using SPSS (version 21, IBM Corp).

3. Results

Twelve consecutive patients were prospectively enrolled and evaluated. Mean age of our patients was 76.42 ± 5.91; 8 were male and 4 were female.

Mean baseline target refraction (SE) was -0.20 ± -0.09 (range: -0.08 to -0.37), and mean final refraction was -0.44 ± -0.14 (range: -0.25 to -0.75). Figure 2 shows the

postoperative spherical equivalent relative to the intended target; we found no significant difference between mean preoperative target SE and mean postoperative SE ($p = 0.87$, not significant).

Best-corrected visual acuity increased significantly from 1.16 ± 0.3 logMAR to 0.05 ± 0.06 logMAR ($p < 0.05$).

Mean endothelial cell count at baseline was 1910.5 ± 297.64, and 6 months after IOL scleral fixation, it was 1508.8 ± 294.14 ($p < 0.05$).

All 12 patients had no intraoperative complications such as hemorrhages, haptic damage, or IOL luxation in the vitreous chamber. No hypotony was observed in early postoperative days. At six months, we observed no iris capture, early postoperative hypotony, anterior chamber or vitreous hemorrhage, cystoid macular edema (CME), or IOL dislocations/decentration.

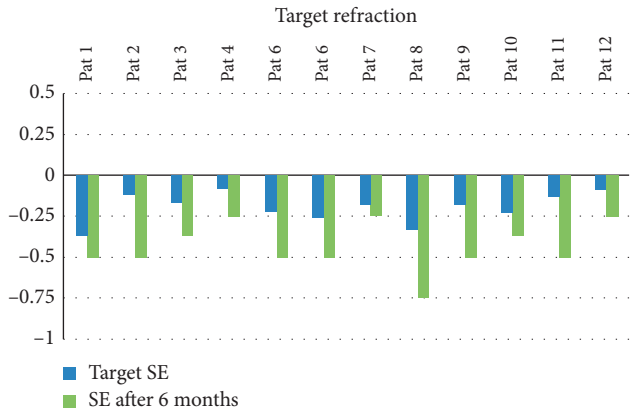

Figure 2: The spherical equivalent (SE) before and after IOL scleral fixation is shown. The difference between the mean preoperative target SE and the mean postoperative SE was not significant ($p = 0.87$).

4. Discussion

The aim of this prospective nonrandomized series was to demonstrate that an improved standardization of the Yamane technique could lead to a more predictable visual outcome in patients who needed this procedure to immediately repair an intraoperative complication during standard phacoemulsification.

The main and the new advantage related to this further standardization of the technique are related with the final position of the IOL, which did not interfere with the final refractive outcome.

Traditionally, IOL power calculations are based on IOL localization, but to date, there is no consensus on the target spherical equivalent to use when implanting a scleral-fixated intraocular lens [12, 13]. Yamane, in 2017, used four different models of IOLs, and the mean refractive difference from the predicted value differed significantly among the models. The difference from the predicted value was neither related with the tilting of the lens nor with iris capture [6]. However, transscleral fixation of the lens determined a mean myopic shift of −1 diopter because the lens is fixed forward in the eye [12–14].

In our series, we observed no statistically significant difference between the predicted SE for the bag fixation and the final target refraction after 6 months ($p > 0.05$). We speculate that the correspondence with the preoperative target refractive error and the final refractive error could be subsequent to an improvement of the standardization of the technique. The Yamane stabilizer provides a perfect 180° opposition between the scleral tunnel. Bending the 30 g UTW needle at 7 mm from the tip ensures that the surgeon will achieve a 2 mm intrascleral tunnel because the device itself is designed in order to stop the needle when a 2 mm tunnel is created. Another variable we standardized is the amount of the haptics that need to be heated. There are no guidelines about the amount of the material of the haptics that must be cauterized in order to achieve stability of the IOL. We highlight that heating 2 mm of the IOL haptics could be enough to prevent them from slipping out of the 2 mm scleral tunnel and that standardizing the amount of the heated haptic may lead to a predictable refractive outcome. It is important to underline that our findings could only be applied to the selected IOL, as different haptics, even if made of the same material, showed different behaviors if heated [9].

In terms of complications, a reduction in the mean central endothelial cell count after 6 months has been observed from 1910.5 ± 297.64 to 1508.8 ± 294.14. A mean reduction of 22% of endothelial cell count has been already described by other authors after six months [14], but compared with that obtained by Yamane is greater [6]. Nevertheless, in our series, the baseline endothelial cell count was lower, and this could explain the higher loss of endothelial cells after six months. Indeed, the reduction of endothelial cell count did not seem to negatively affect the visual outcome of our patients at all. Furthermore, we did not observe any cystoid macular edema at six months from surgery in contrast with other techniques, such as anterior or posterior iris-claw IOL fixation where CME was observed to be the most frequent complications at both one month and one year of follow-up [15].

Moreover, in our series, we did not observe iris capture, early postoperative hypotony, anterior chamber or vitreous hemorrhage, or IOL dislocations/decentration.

The main limitations of this prospective nonrandomized study are related with the small sample size.

5. Conclusion

In conclusion, we observed that the standardization of the Yamane technique using the Yamane stabilizer allows to create sclerotomies at exactly 180°, one opposite to the other, with a predictable geometry of the scleral tunnel. Furthermore, standardizing the type of the IOL and the amount of the haptic that should be heated may lead to a predictable and congruent refractive result in patients that need a sutureless scleral-fixated IOL as an immediate procedure when they experience a cataract luxation in the vitreous chamber during phacoemulsification.

Data Availability

The supporting data are not available since the data collection was only available on the paper and not electronically.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

References

[1] S. Yamane, M. Inoue, A. Arakawa, and K. Kadonosono, "Sutureless 27-gauge needle-guided intrascleral intraocular lens implantation with lamellar scleral dissection," *Ophthalmology*, vol. 121, no. 1, pp. 61–66, 2014.

[2] R. S. Hoffman, H. I. Fine, M. Packer, and I. Rozenberg, "Scleral fixation using suture retrieval through a scleral tunnel," *Journal of Cataract and Refractive Surgery*, vol. 32, no. 8, pp. 1259–1263, 2006.

[3] M. Monteiro, A. Marinho, S. Borges, L. Ribeiro, and C. Correia, "Scleral fixation in eyes with loss of capsule or zonule support," *Journal of Cataract and Refractive Surgery*, vol. 33, no. 4, pp. 573–576, 2007.

[4] R. Frisina, E. Pilotto, L. Tozzi, R. Parrozzani, and E. Midena, "A new technique of needle-guided retropupillary fixation of iris-claw intraocular lens," *Journal of Cataract and Refractive Surgery*, vol. 45, no. 3, pp. 267–271, 2019.

[5] I. J. van der Meulen, F. P. Gunning, M. G. Vermeulen, and M. D. de Smet, "Artisan lens implantation to correct aphakia after vitrectomy for retained nuclear lens fragments," *Journal of Cataract and Refractive Surgery*, vol. 30, no. 12, pp. 2585–2589, 2004.

[6] S. Yamane, S. Sato, M. Maruyama-Inoue, and K. Kadonosono, "Flanged intrascleral intraocular lens fixation with double-needle technique," *Ophthalmology*, vol. 124, no. 8, pp. 1136–1142, 2017.

[7] R. A. Gelman and S. Garg, "Novel yamane technique modification for haptic exposure after glued intrascleral haptic fixation," *American Journal of Ophthalmology Case Reports*, vol. 14, pp. 101–104, 2019.

[8] D. B. Kim, "Trailing-haptic-first modification of double-needle intrascleral haptic fixation technique," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 4, pp. 424–428, 2018.

[9] M. Kronschläger, S. Blouin, P. Roschger, R. Varsits, and O. Findl, "Attaining the optimal flange for intrascleral intraocular lens fixation," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 11, pp. 1303–1305, 2018.

[10] E. S. Hwang, C. C. Warren, and S. B. Koenig, "Flanged intrascleral intraocular lens fixation with a single needle," *Journal of Cataract and Refractive Surgery*, vol. 44, no. 12, pp. 1526-1527, 2018.

[11] P. Narang and A. Agarwal, "Handshake riveting flanged technique for Yamane method of intrascleral fixation of an intraocular lens," *Journal of Cataract & Refractive Surgery*, vol. 45, no. 12, pp. 1838-1839, 2019.

[12] J. K. Ahn, H. G. Yu, H. Chung, W. R. Wee, and J.-H. Lee, "Transscleral fixation of a foldable intraocular lens in aphakic vitrectomized eyes," *Journal of Cataract and Refractive Surgery*, vol. 29, no. 12, pp. 2390–2396, 2003.

[13] M. S. Stem, B. Todorich, M. A. Woodward, J. Hsu, and J. D. Wolfe, "Scleral-fixated intraocular lenses: past and present," *Journal of VitreoRetinal Diseases*, vol. 1, no. 2, pp. 144–152, 2017.

[14] A. M. Abbey, R. M. Hussain, A. R. Shah, L. J. Faia, J. D. Wolfe, and G. A. Williams, "Sutureless scleral fixation of intraocular lenses: outcomes of two approaches. The 2014 Yasuo Tano memorial lecture," *Graefe's Archive for Clinical and Experimental Ophthalmology*, vol. 253, no. 1, pp. 1–5, 2015.

[15] P. Mora, G. Calzetti, S. Favilla et al., "Comparative analysis of the safety and functional outcomes of anterior versus retropupillary iris-claw IOL fixation," *Journal of Ophthalmology*, vol. 2018, Article ID 8463569, 8 pages, 2018.