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ORIGINAL RESEARCH

Evaluating the Efficacy of a Novel Triangle Suture Technique in Scleral-Fixation of Intraocular Lens

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Purpose: The study aims to evaluate the efficacy and safety of a novel Triangle Suture Technique in the surgical placement of Scleral-Fixated Intraocular Lenses (SFIOLs). The research seeks to address the challenges in cases associated with inadequate capsular support for Intraocular Lens (IOL) implantation, offering an alternative to traditional methods.

Methods: This A pilot retrospective case series evaluated the efficacy and safety of a novel Triangle Suture Technique for scleral-fixation of intraocular lenses (SFIOL) using 10–0 Polypropylene suture (Prolene; Ethicon, Inc) in patients with dislocated IOLs. Visual acuity outcomes, intraocular pressure control, and post-operative complications were assessed.

Results: The study comprised 52 eyes from 49 patients (mean age 80.3±10.3 years). Mean pre-operative uncorrected visual acuity (UCVA) significantly improved from 1.14±0.84 to 0.61±0.56 logMAR at 3 months (P=0.001). Best-corrected visual acuity (BCVA) also improved from 0.84±0.65 to 0.54±0.56 logMAR at 3 months (P=0.048). Glaucoma drop usage decreased from 0.67±1.09 to 0.25 ±0.62 types at 6 months (P=0.018). Peri-operative complications included anterior segment complications in 4 eyes (7.54%) and posterior segment complications in 1 eye (1.9%). While non-recurrent IOL dislocation occurred in 45 eyes (86.5%), recurrent dislocation was noted in 7 eyes (13.5%), with one eye experiencing twice recurrent dislocation (1.9%).

Conclusion: The triangle suture technique is a versatile and accessible option for scleral fixation of various IOL designs. While these preliminary results demonstrate anatomical efficacy, the study's retrospective nature, small cohort, and single-surgeon experience necessitate a cautious interpretation. Further large-scale, comparative studies are required to establish long-term stability and clinical efficacy relative to current gold-standard methods.

Plain Language Summary:

- Recently, a novel triangular suture technique has been introduced for the scleral fixation of dislocated intraocular lenses (IOLs).
- This method involves creating a distinctive triangular suture support positioned posterior to the IOL.
- The primary objective of this study was to evaluate the efficacy and safety of this new IOL fixation approach.
- We followed 52 eyes of 49 patients for an average of 17 months, reporting good visual outcomes and a positive safety profile.
- The novel triangular suture scleral IOL fixation offers good efficacy and safety, warranting further investigation to determine its broader applicability.

Keywords: scleral fixation, triangular suture, intra-ocular lens, IOL, dislocation

Introduction

Intraocular lens (IOL) implantation is fundamental in managing various ophthalmic conditions, including cataracts and ocular trauma. However, significant challenges arise in cases with inadequate capsular support for IOL placement,

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a common issue stemming from ocular trauma, metabolic or inherited conditions, or complications during cataract surgery.[1–4] The prevalence of such conditions makes addressing this a crucial concern in ophthalmic surgery.

Over the years, the surgical landscape for IOL placement has evolved, offering alternatives when capsular support is compromised, including anterior chamber placement, iris fixation, and notably, scleral fixation. Scleral-fixated intraocular lenses (SFIOLs) have gained prominence due to advancements in surgical techniques, leading to improved visual and ocular outcomes.[5–7]

SFIOLs are primarily indicated when capsular or iris support is absent and the patient opts against aphakia.[2,3] Preoperative scenarios necessitating SFIOLs include IOL repositioning, exchange of an un-repositionable IOL, or secondary IOL placement in aphakic patients. Special populations, such as children, present unique considerations, making IOL fixation method a nuanced decision.[2–4]

Surgical techniques for SFIOLs have undergone significant refinements, with both sutured and sutureless approaches available, each carrying distinct advantages and potential complications.[5–7] The choice of IOL and surgical method is highly dependent on the specific clinical context, emphasizing the need for individualized treatment plans.[5–7]

While this study focuses on a novel triangular suture technique for SFIOLs, it is important to acknowledge other innovative methodologies for IOL fixation. The Yamane technique, for instance, offers a relevant sutureless approach to scleral fixation, known for its less invasive nature and reduced surgical time.[8,9] This method uses a cauterized flanged haptic for stable lens positioning, potentially lowering risks like suture erosion or knot exposure.[8,9] However, it demands high surgical skill and carries risks of tilt/dislocation, iris chafe, retinal detachment, and intraocular hemorrhage.[10,11]

Recently, our group successfully treated three pseudoexfoliation patients with dislocated IOLs using this novel triangular suture technique.[12] The broader field of IOL fixation, particularly SFIOLs, has seen remarkable advancements. As surgical techniques continue to evolve, the emphasis remains on improving patient outcomes and expanding the range of treatable conditions. Understanding the nuances and outcomes of various methods is crucial for guiding individualized treatment plans.[8,9]

Therefore, the purpose of the current study was to assess the efficacy and safety of IOL fixation using this novel triangular suture technique.

Methods

Ethics

This study received approval from The Medical Center Institutional Review Board (IRB, number 0067–23-HMO) and was conducted in strict accordance with their guidelines and the Declaration of Helsinki. Patient informed consent for publication was waived by the IRB due to the anonymous and retrospective nature of the study. No patient-identifying information is included in this study.

Study Design and Setting

This pilot retrospective case series study reviewed clinical data from 49 patients who underwent intraocular lens (IOL) dislocation repair using the novel triangular suture technique between 2017 and 2022. All procedures were performed at Hadassah Medical Center in Jerusalem, Israel (Figure 1).

Data Collection and Sources

Clinical data were systematically extracted from Hadassah Medical Center's "Mahar" Electronic Medical Records (EMR) system. Patient identification was facilitated by targeted EMR searches conducted by the center's Business Intelligence (BI) unit. Supplementary imaging data were obtained from the Optical Coherence Tomography (OCT) Spectralis and Picture Archiving and Communication System (PACS) databases, integral to Hadassah's ophthalmic care infrastructure (Figure 1).

Study Variables

A comprehensive set of variables was collected, including patient demographics, medical and ocular history, and pre-operative measures. Details of the surgical procedures for IOL fixation were recorded, alongside post-operative visual acuity

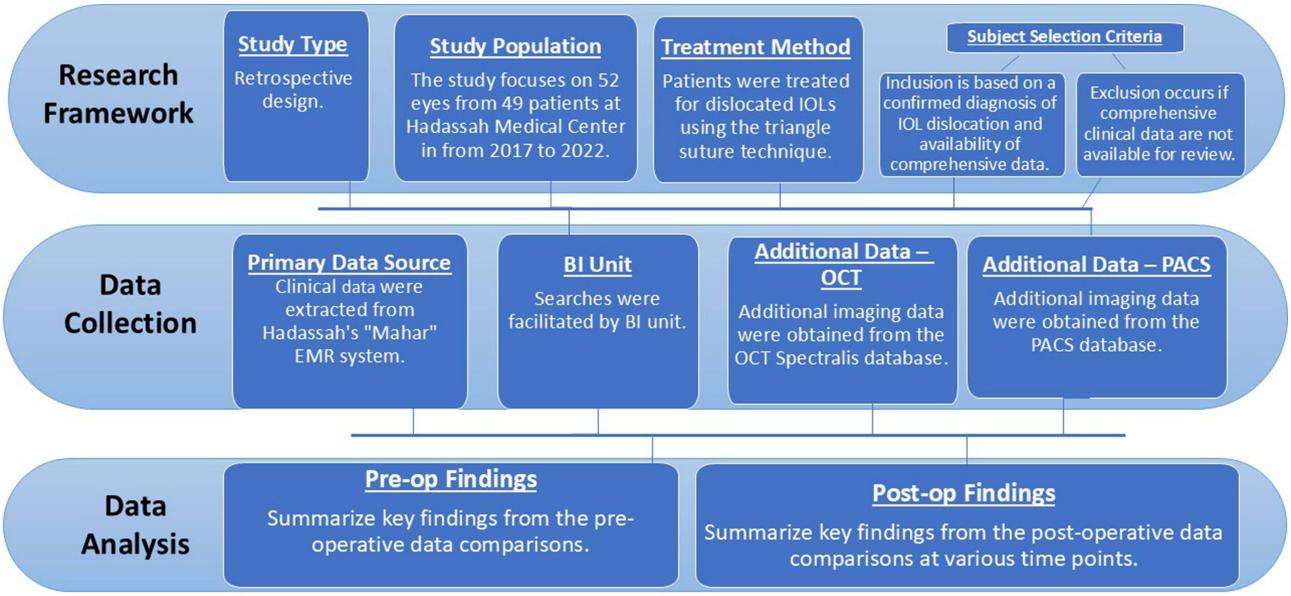

Figure 1 Flowchart of Methodological Framework for Study Data Analysis.

measurements, intraocular pressures (IOPs), slit lamp examination findings, and prescribed medications. OCT scans were utilized to detail the location of IOL subluxation or dislocation and to confirm the type of surgical intervention. Additionally, the number of glaucoma drop types used was measured, complications from original lensectomies were noted, and follow-up data, including total observation time and any subsequent IOL fixations, were included.

Follow-Up Assessment

A structured follow-up protocol was implemented to evaluate the long-term efficacy of the surgical intervention. Post-operative assessments were conducted at one day (1D), two weeks (2W), three months (3M), six months (6M), and seventeen months (17M), serving as the final follow-up for this study. Each time point allowed for the comprehensive capture of various dimensions of surgical outcomes.

Study Objectives and Outcome Measures

The primary aim of this research was to assess the surgical outcomes and complication rates associated with the novel triangular suture technique. The primary endpoint was Best Corrected Visual Acuity (BCVA) in LogMAR. Secondary endpoints encompassed complication rates and intraocular pressures.

Subject Selection Criteria

Patients were included if they had a confirmed diagnosis of IOL dislocation followed by IOL fixation surgery at Hadassah Medical Center, and if complete baseline and follow-up clinical information, including OCT scans, were available in their electronic medical record. Exclusion criteria included the unavailability of comprehensive clinical data.

Surgical Technique

The surgical technique for intraocular lens fixation began with preoperative administration of 0.4% Oxybuprocain (Localin®; Fischer Pharmaceuticals, Israel) at two 15-minute intervals for topical anesthesia. Aseptic conditions were maintained with a 10% povidone-iodine solution applied to the periocular area and a 5% instillation into the eye. Surgery commenced with a peritomy performed in all three thirds of the eye, forming a triangular configuration 3.0 mm from the limbus. Concurrently, three 23G port sclerotomies were created, trocar positions verified, and an infusion inserted to maintain intraocular pressure.

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Suture configuration and placement followed. A double-armed 10–0 Polypropylene suture (Prolene®; Ethicon, Inc., Raritan, New Jersey, USA) with a 16-mm straight needle was inserted into the anterior chamber. A 25-gauge needle, positioned 180° away in the contralateral groove, served as a docking guide. The Prolene 10 suture was strategically placed behind the IOL, forming a triangular configuration between the 6, 10, and 2 o'clock positions (Video S1 and Figure 2). This suture was then passed through the docking guide, exiting on the opposite side, and secured within the initial groove to prevent conjunctival erosion.

Subsequently, a 23G limbal opening was made, and the IOL was centered and positioned atop the pre-formed suture structure, facilitating straightforward centration and eliminating lens tilt. A core vitrectomy was then performed, accompanied by a comprehensive 360-degree examination of the posterior pole. The surgical procedure concluded with the removal of all trocars, ensuring no leakage. Subconjunctival Cefuroxime (1mg) was administered for infection prevention. Finally, the eye was patched with a combined Neomycin, Polymyxin B, and Dexamethasone ointment (Maxitrol®, Novartis, Southfield, Michigan, USA) and shielded for protection.

Sample Size

Sample size calculation was based on a previous meta-analysis of 1935 eyes that underwent sutured SFIOL implantation.[13] That analysis demonstrated an average improvement in LogMAR Best Corrected Visual Acuity (BCVA) from 0.99±0.76 pre-operatively to 0.46±0.52 post-operatively (a 54% improvement).

Based on these results, the minimally calculated sample size was determined to be 23 eyes. To ensure adequate statistical power and to account for potential loss to follow-up and unexpected variability in outcomes, we increased the final sample size to 60 eyes.

Statistical Analysis

Statistical analysis for comparing pre- and post-operative measures was performed using a paired *t*-test with a two-tailed distribution and One-way Analysis of Variance (ANOVA) tests. All analyses were conducted using Statistical Package for Social Sciences software 26.0 (SPSS Inc., Chicago, Illinois, USA). A P-value <0.05 was considered statistically significant.

Results

Study Participants

This retrospective study evaluated the preoperative characteristics of 52 eyes from 49 patients who underwent the novel triangular suture IOL fixation technique between 2017 and 2020 by the same surgeon (E.A). The participants' average age was 80.31 years, and 54% were male. On average, 4.98 years (range 0–25 years) elapsed from the original lensectomy to the planned IOL fixation. Table 1 details the primary ocular history and surgical approach (IOL fixation vs exchange) for these patients.

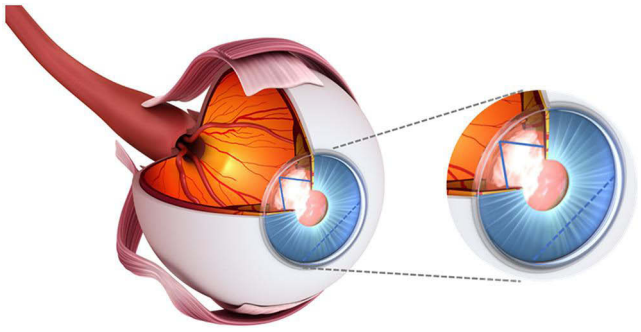

Figure 2 Illustration of the scleral sutured triangular formation, situated behind the IOL (blue lines). The scleral entrance points are at a distance of 3.0 mm from the limbus.

Table 1 Preoperative Characteristics and Surgical Plans for Patients Undergoing IOL Fixation or Exchange

Ocular History	Secondary Ocular History	Complications in Original Lensectomy	Diagnosis (IOL)	Current Surgery (Fixation vs Exchange)
Only Lensectomy: 24 (46%); PXF: 21 (40%); Trauma: 2 (4%); Previous Vitrectomy: 2 (4%); Uveitis: 0 (0%); Previous IOL Fixation Sx: 3 (6%)	Glaucoma: 22 (44%); AMD: 4 (8%); Retinal Detachment: 2 (4%); Retinitis Pigmentosa (Usher1): 2 (4%); High Myopia: 2 (4%); Corneal Edema: 2 (4%); Other[a]: 12 (24%)	None: 51 (98%); IFIS: 0 (0%); Malignant Glaucoma: 1 (2%)	IOL Subluxation: 45 (86.5%); IOL Dislocation: 7 (13.5%)	Fixation: 51 (98%); Exchange: 1 (2%)

Notes: [a]Macular Puckering of Retina; Posterior Subcapsular Fibrinous Glaucoma (PSFG); Neovascular Primary Open-Angle Glaucoma (NPDS); Phacodonesis; Intraocular Neoplasm (ION), Glaucoma, Retinopathy; Non Exudative Macular Degeneration Retinopathy (MDR); Cataract; Dacryocystorhinostomy (DCR); Corneal Graft Due to Bullous Keratopathy; Central Retinal Vein Occlusion (CRVO); Ocular Surgery in Childhood Due to Chemical Burn; Dermatochalasis, Blepharoptosis; Macular Degeneration of Retina; Arrested Proliferative Diabetic Retinopathy (PDR); Optic Atrophy.
Abbreviations: IOL, Intraocular Lens; PXF, Pseudoexfoliation; AMD, Age-Related Macular Degeneration; IFIS, Intraoperative Floppy Iris Syndrome; Sx, Surgery.

Longitudinal Analysis of Visual and Intraocular Changes

Significant improvements in visual acuity (VA) and intraocular pressure (IOP) control were observed post-operatively. However, a transient IOP increase at three months necessitated close monitoring. Central Macular Thickness (CMT) showed a decreasing trend over the follow-up.

Mean pre-operative uncorrected VA (UCVA) was 1.11±0.84 logMAR, improving significantly to 0.60±0.46 logMAR at 3 months (P=0.008). Mean pre-operative best-corrected VA (BCVA) was 0.91±0.67 logMAR, improving significantly to 0.62±0.62 logMAR at 3 months (P=0.031). At 6 months, UCVA was 0.74±0.65 logMAR (P=0.048) and BCVA was 0.59±0.67 logMAR (showing an improvement trend vs pre-op). At last follow-up, average UCVA and BCVA showed a non-significant improvement trend compared to the pre-operative visual acuities (Figure 3). The percentage of eyes with UCVA better than 6/18 improved from 32.5% pre-op to 52.4% at last follow-up (P=0.008). The percentage of eyes with BCVA better than 6/18 showed a non-significant trend from 53.3% pre-op to 72.0% at last follow-up (P=0.46).

Average pre-operative IOP was 16.4 mmHg, showing a trend of increase (P=0.07) to 20.2 mmHg at 3 months post-op (Figure 4). At 6 months and last follow-up, IOP non-significantly decreased to 14.3 mmHg and 14.2 mmHg, respectively (Figure 4).

Pre-operatively, patients used 0.67±1.09 types of glaucoma drops. This remained stable at 0.66 types at 3 months. However, a significant decrease to 0.23 types was observed at 6 months (P=0.007), with 0.36 types at last follow-up (P=0.08) (Figure 4).

Pre-operative CMT was 286.7±81.3μ. It non-significantly decreased at 3 and 6 months post-op (Figure 4). CMT showed a trend of reduction (P=0.15) to 221.6±89.2μ at last follow-up.

Recurrent Dislocation Patterns

Non-recurrent dislocation of the IOL was observed in 86.5% (n=45) of eyes, indicating a stable postoperative course. Recurrent dislocation occurred in 13.5% (n=7) of eyes, necessitating further intervention. The average time for another IOL fixation in these eyes was 23±26 months, ranging from 1 to 68 months post-initial surgery. A small subset, 1.9% (n=1) of eyes, experienced twice recurrent dislocation, requiring multiple interventions with re-fixation times ranging between 5 and 13 months.

Distribution of Anterior Segment Complications

Out of 52 eyes analyzed, 92.3% (n=48) experienced no anterior segment complications. Specific complications observed included suture exposure in 1 eye (1.9%) and corneal edema in 2 eyes (3.8%). An acute IOP increase due to forward IOL displacement with angle closure and a flat chamber was noted in one eye (1.9%). This resolved with hypotensive topical treatment within one day. Notably, complications such as pupillary block, IOL capture, prolonged inflammation (>1 month), toxic anterior segment syndrome (TASS), and synechia were not observed.

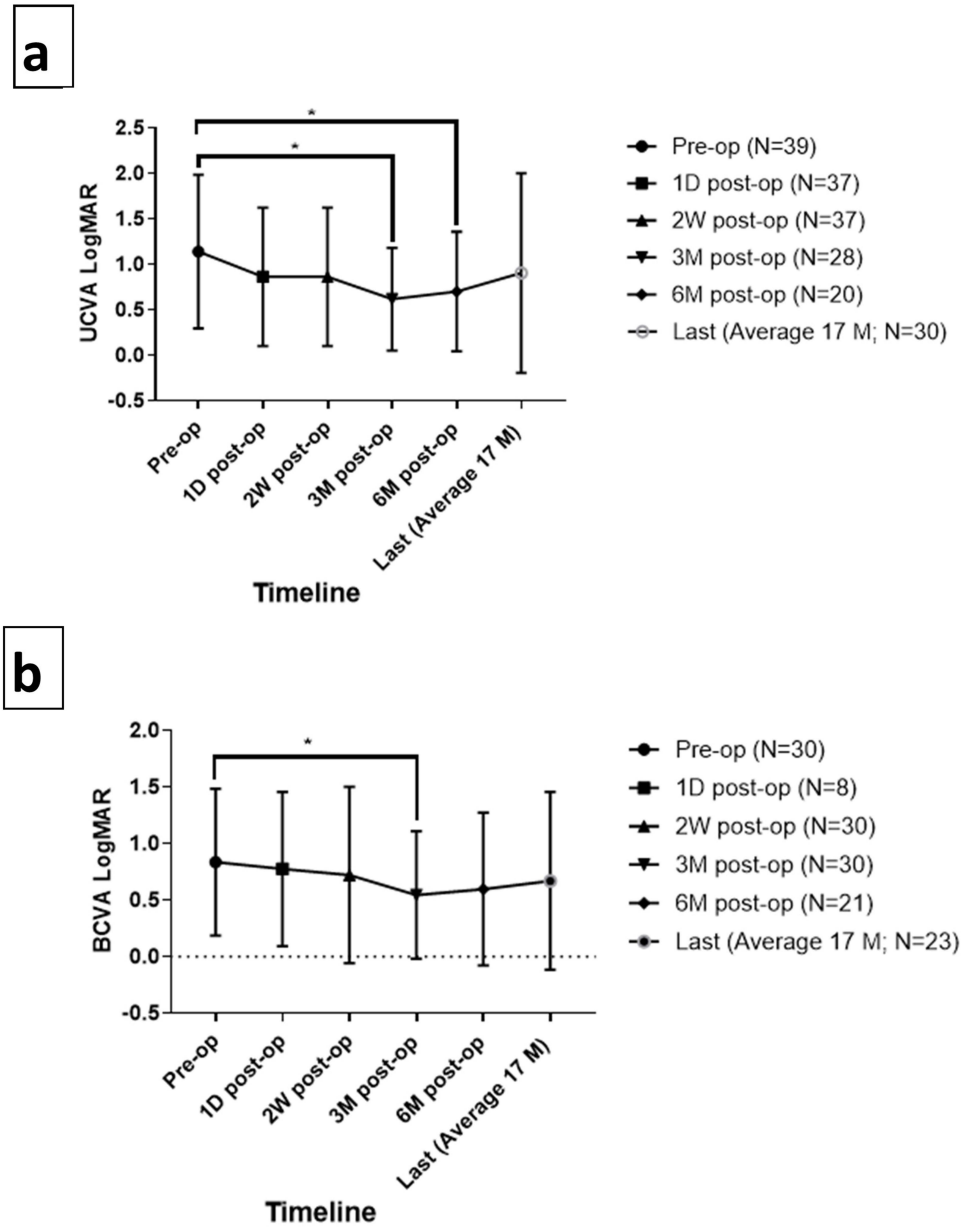

Figure 3 Variations in Uncorrected Visual Acuity (**a**) and Best-corrected Visual Acuity (**b**) Over Time Post-Operatively. Continuous data are presented as the mean ± standard deviation. Comparisons of pre-op and each post-op values were analyzed using Man-Whitney or *t*-test, depending on data normality. *P<0.05 is considered statistically significant.

Abbreviations: N, number of eyes; LogMAR, logarithm of the Minimum Angle of Resolution; UCVA, Uncorrected Visual Acuity; BCVA, Best-Corrected Visual Acuity; D post-op, Day post-op; M post-op, Month post-op.

Distribution of Posterior Segment Complications

Posterior segment complications were relatively uncommon. Only one eye (1.9%) experienced a posterior segment complication, identified as endophthalmitis. No instances of other commonly reported complications, such as retinal detachment or vitreous hemorrhage, were noted.

Discussion

The present study found significant improvements in uncorrected and best-corrected distance visual acuity at several timepoints during long-term follow-up. These visual gains suggest long-term stabilization of the intraocular lens (IOL) following the novel triangular suture scleral IOL fixation.

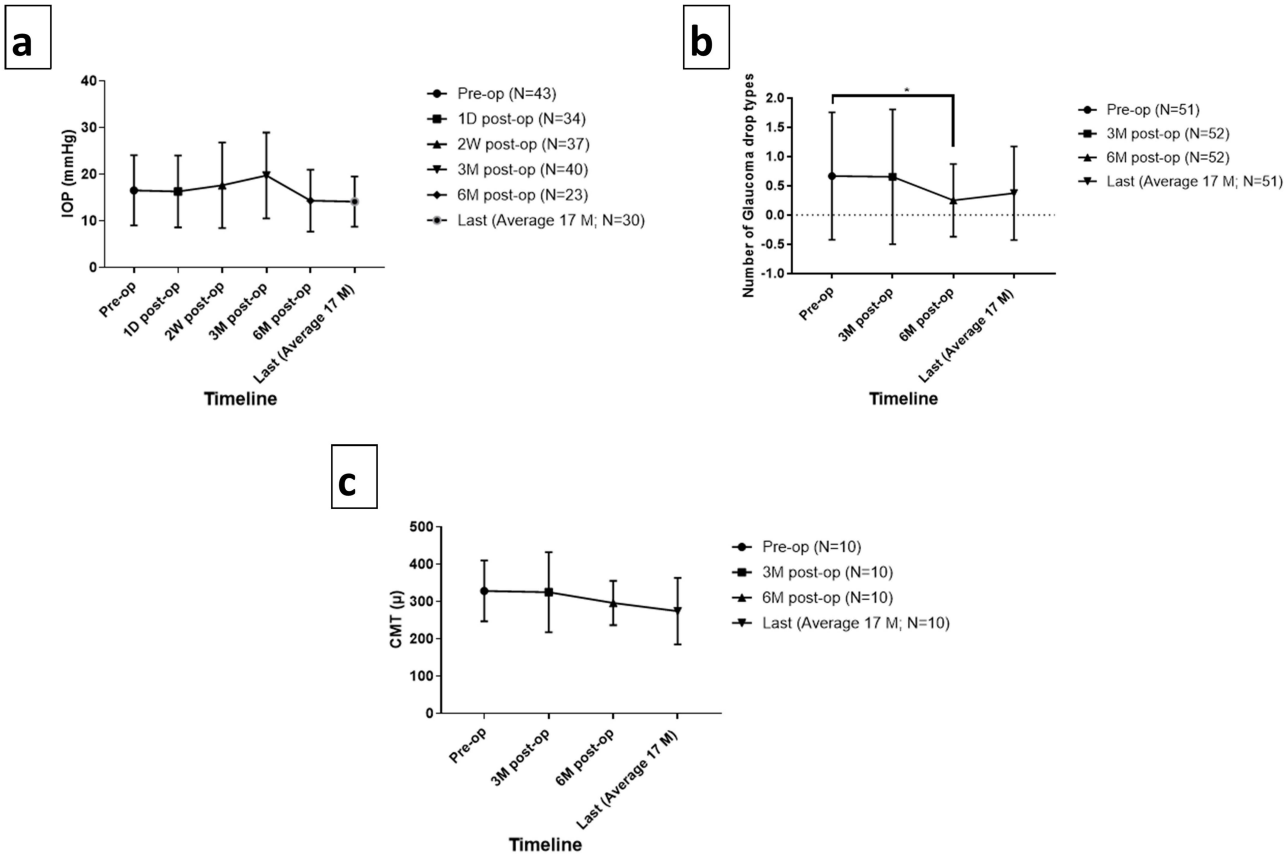

Figure 4 Temporal Variations in Intraocular Pressure (**a**), Number of Glaucoma Drop Types (**b**), and Central Macular Thickness (**c**) Following Surgery. Continuous data are presented as the mean ± standard deviation. Comparisons of pre-op and each post-op values were analyzed using Man-Whitney or *t*-test, depending on data normality. *P<0.05 is considered statistically significant.

Abbreviations: IOP, Intraocular Pressure; mm Hg, millimeters of Mercury; N, number of eyes; CMT, Central Macular Thickness; μ, Microns; D post-op, Day post-op; M post-op, Month post-op.

We also observed significant improvements in intraocular pressure (IOP) control post-operatively, though a transient IOP increase at the 3-month mark necessitated close monitoring. This temporary elevation may have stemmed from peri-operative steroid use. Our results align with a previous study of 91 scleral-fixated IOL (SFIOL) cases, which also showed a significant IOP reduction in glaucoma patients post-fixation.[14]

Possible mechanisms for improved IOP control after IOL fixation include decreased pseudoexfoliative material release in pseudoexfoliation (present in 40% of our cohort) and reduced pigment release and inflammation from improved IOL stability and minimized IOL-iris contact.

The central macular thickness (CMT) demonstrated a decreasing trend over the 17-month follow-up. We hypothesize that enhanced IOL stability, reduced iris touch, and the core vitrectomy performed during surgery contributed to this reduction in macular edema and thickness. This aligns with a study by Massa et al, who observed complete resolution of cystoid macular edema (CME) within three months in six patients with iris-fixated IOLs after IOL exchange to scleral fixation.[15] However, our findings contrast with a recent large meta-analysis of 737 SFIOL eyes, which reported a significant incidence of post-operative CME in 6.7% of cases, with no difference between sutured and sutureless (Yamane) techniques.[16]

Regarding recurrent dislocation, our study demonstrated an overall stable postoperative course, with 86.5% of eyes reporting no recurrence and only 1.9% of patients requiring a third IOL fixation. This is consistent with previous reports on other SFIOL techniques; for instance, a study on 176 SFIOL cases noted 14.8% underwent recurrent IOL fixation, and only 1.7% required a third surgery.[17]

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The data underscore the relative safety of our surgical procedure concerning anterior segment complications, with most patients experiencing none. One patient (1.9% of our cohort) experienced anterior IOL displacement with ocular hypertension. We observed this complication more frequently with tighter sutures placed 3mm from the limbus when performing the triangular suture SFIOL. After implementing looser tightening and placing sutures 3.5 mm from the limbus, this complication became rare in our experience. We speculate that an IOL-suture bed complex positioned too anteriorly can contact the iris diaphragm, promoting angle closure.

Suture exposure occurred in one eye (1.9%) in our study, a rate consistent with other research. Yu et al reported a 1.9% suture exposure rate after 5 years in 52 eyes undergoing sutured scleral IOL fixation, and Ganekal et al found a 6.7% suture erosion rate in 30 eyes followed for six months.[18,19]

Two eyes developed corneal edema in our study. While the literature often describes this as a more common complication following SFIOL (eg, Krause et al observed corneal edema in 29.4% of 119 SFIOL cases, primarily due to post-operative glaucoma, with 60% resolving within 3 months), our incidence was lower.[20]

We observed a low incidence of posterior segment complications, with only a single reported case of endophthalmitis and no instances of post-operative vitreous hemorrhage or retinal detachment. This contrasts with some studies that suggest an increased risk for vitreous hemorrhage and retinal detachment after sutured SFIOL procedures, although endophthalmitis remains generally rare across studies. Specifically, we did not identify vitreous hemorrhage as a post-operative complication, whereas a recent meta-analysis by Kanclerz et al[21] reviewing 497 eyes reported this in 8.5% of cases. Similarly, our retinal detachment results diverge from published data; Yu et al[18] described 5.7% (3 cases) in their 52-eye study (with a longer 79-month average follow-up), and Jakobsson et al[14] reported 3.3% (3 eyes) in 91 SFIOL cases. In contrast, the Kanclerz et al[21] meta-analysis found a lower 1.8% post-operative incidence of retinal detachment. Neither Yu et al nor Jakobsson et al reported cases of endophthalmitis.[14,18]

Polypropylene 10–0 fixation sutures (Prolene) were used for scleral fixation with the triangular suture technique in the present study. Prolen 10–0 sutures have a long-curved needle which offer convenient intraocular docking to an opposite docking guide needle. The issue of suture breakage over the long term is of importance. This is not described in the study due to a follow up of less than 4 years. The literature regarding Prolen 10–0 early degradation offer different findings. While one study[22] found 28% breakage over a mean of 50 months, mainly in younger patients (n=61 eyes), another more recent study[23] found a breakage of 0.5% over 6 years using Prolen 10–0 sutures (n=118 eyes). It should be noted that the patient population in the current study was relatively older (mean age of 80 years old), which allows for more liberty in choosing Prolen 10–0 for scleral fixation of IOLs.

Beyond an acceptable efficacy and safety profile, the novel triangular suture SFIOL offers additional benefits. Importantly, multi-point scleral fixation is well mentioned in the literature.[24–28] However, most use special design IOLs with loops or eyelets, while the advantage of the technique described in the present work is its compatibility with various IOL designs and lack of dependence on IOL loops. This technique is compatible with various IOL designs and does not necessitate IOL exchange. Furthermore, we hypothesize that the triangular configuration of the suture bed behind the IOL provides more balanced fixation with less chance of IOL tilt compared to the two-point hinge of the Yamane technique. Also, this fixation method is relatively technically simple and is not time consuming.

The limitations of our study include its retrospective nature, lack of a control group, absence of post-operative astigmatism measurements, single surgeon experience, and a small sample size. However, a key strength is the long follow-up period of over 12 months. Future research on this technique will aim to include more patients, multi-center prospective cohorts with comparison to other scleral IOL fixation techniques, a wider profile of lens dislocation causes, astigmatism documentation, and even longer follow-up durations.

Conclusion

In conclusion, the triangular suture technique provides a versatile and technically accessible option for scleral fixation of various IOL designs. Our preliminary results show promising anatomical outcomes; however, the limitations of this study —including its retrospective nature, small sample size, and single-surgeon bias—must be considered. While the technique offers distinct advantages in reducing tilt and simplifying docking, further large-scale, comparative studies are necessary to fully define its long-term stability and clinical efficacy compared to existing gold-standard methods.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Data Sharing Statement

The corresponding author has full access to all the data in the study and takes responsibility for the data's integrity, the data analysis's accuracy, and the decision to submit for publication. Data reported in this work are available upon request from the corresponding author.

Ethics Approval and Consent to Participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional (HMO-0067-23 Hadassah Medical Organization IRB approved the study) and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent for Publication

Not applicable. The study does not contain any patient-identifying information.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agreed to be accountable for all aspects of the work.

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Disclosure

The authors declare no competing interests in this work.

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