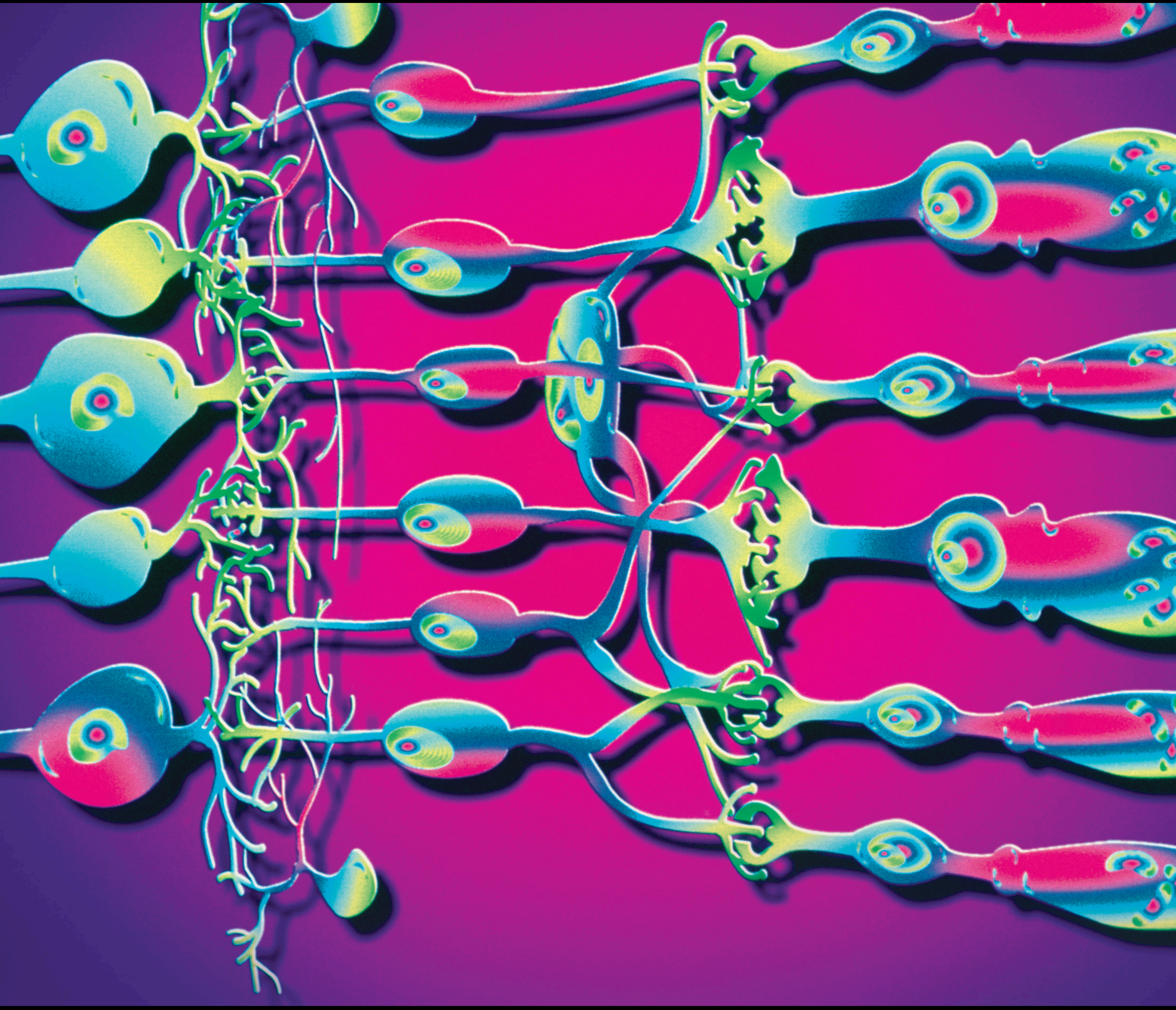
Journal of Ophthalmology

Advances in the Management of Aphakia

Lead Guest Editor: Georgios Panos
Guest Editors: Craig Wilde, Paris Tranos, and Zisis Gatzioufas



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Editorial

Advances in the Management of Aphakia

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Aphakia is a condition in which the crystalline lens of the eye is not present in its normal position following surgical removal, perforating injury, congenital anomaly, or dislocation of the lens. It causes loss of accommodation, high hyperopia, and anisometropia.

The management of aphakia can be either conservative (spectacles or contact lenses) or surgical [1]. Surgical management of aphakia concerns both anterior and posterior segment surgeons and can be a real challenge, especially in paediatric patients where the visual system is still immature; because the child's eye continues to grow during childhood, certain complications are not acceptable [2–4].

In this Special Issue published in the *Journal of Ophthalmology*, Sidiropoulos et al. presented a new sutureless scleral fixation technique using a single-piece foldable acrylic Carlevale intraocular lens which they inserted in 27 eyes of 27 patients with poor capsular support [5]. The mean postoperative refraction at 6 months was $-0.5 \pm 0.99\ D$, while the postoperative complications were either resolved spontaneously or treated medically without the need for further surgery.

Massa and colleagues from the Geneva University Hospitals presented the SWISS IOL, a new minimally invasive technique for the scleral fixation of intraocular lenses (IOLs) in eyes without capsular support [6]. The postoperative spherical equivalent refraction ranged between −0.75 and −2.25, and no perioperative or postoperative complications were recorded while all IOLs were well centered postoperatively without any dislocation or tilt.

Finally, Karasavvidou and colleagues from the Nottingham University Hospitals provided a literature review on the surgical management of paediatric aphakia in the absence of sufficient capsular support presenting the advantages and disadvantages of each surgical technique [7].

Conflicts of Interest

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

Georgios D. Panos
Craig Wilde
Paris Tranos
Zisis Gatzioufas

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Research Article

Novel Sutureless Scleral Fixated IOL for Inadequate or Absent Capsular Support

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Purpose. To evaluate the clinical outcome and safety profile of a new sutureless scleral fixation (SSF) technique using a single-piece foldable acrylic Carlevale intraocular lens. *Methods*. In this case study, 27 eyes of 27 patients were implanted with an SSF single-piece IOL because of inadequate or absent capsular support. The hand-shake technique used during surgery was combined with the creation of scleral pockets in order to secure the IOL haptics. The BCVA was evaluated in the 1st and 6th month in every patient and in the 12th and 24th months, when possible. Also, we evaluated the improvement achieved in spherical equivalent values from baseline to the 6th month after the procedure. Intraoperative and postoperative complications were assessed. *Results*. The mean age was 69.1 ± 14.9 years, and the mean follow-up was 13.6 ± 4.8 months. Indications of scleral-fixated IOL included dislocated posterior chamber IOL (40.7%), dislocated anterior chamber IOL (11.1%), subluxated traumatic cataract (18.5%), subluxated nontraumatic cataract (18.5%), and aphakia (11.1%). Concurrent PPV was performed on eight of the eyes (32%). The mean preoperative logMAR BCVA increased from 0.85 ± 0.59 baseline to 0.44 ± 0.30 one month after surgery ($p < 0.01$) and 0.36 ± 0.34 ($p < 0.003$) six months after surgery. The baseline refractive status expressed in SE was 4.3 ± 6.4 D, and the postoperative status was -0.5 ± 0.99 D. Postoperative complications included vitreous hemorrhage (7.4%), hypotony (7.4%), transient IOP elevation (3.7%), and postoperative cystoid macular oedema (3.7%). The IOL was very well centered and stable in every case during the follow-up period. *Conclusion*. The use of the SSF technique with implantation of a single-piece foldable acrylic Carlevale IOL seems to be a safe and effective alternative method that provides good preliminary results in cases where capsular support is inadequate or absent. Long-term stability results would be required to evaluate the benefit of this novel surgical approach in order to compare it with other existing methods.

1. Introduction

Cataract surgery with intraocular lens (IOL) implantation is currently one of the most frequent and successful surgical procedures [1]. However, when capsular support is inadequate or absent, IOL may be challenging even for experienced surgeons. Several techniques have been employed over the years to deal with zonular dehiscence or dialysis. Among the most common of these techniques are iris fixation suturing or iris-claw [2–6], anterior chamber IOL implantation [7], scleral fixation IOL with suturing [8], and the most recent: sutureless intrascleral IOL fixation [9–12], and glued IOL.

Sutureless intrascleral fixation was initially introduced by Maggi et al. in 1997, followed by the tunnel fixation method, proposed by Gabor Scharioth, and later modified as glued transscleral fixation by Agarwal et al. [9]. Recently, Yamane proposed "flanged fixation" [8–12]. This so-called Yamane technique externalizes the haptics of a three-piece IOL using a thin-walled 30- or 27-gauge needle inserted through two transconjunctival sclerotomies. Each haptic of the IOL is carefully placed into the lumen of the needle using intraocular forceps. Then, the needle is used to externalize each haptic on the conjunctival surface, followed by low-temperature cautery to make a flange or bulb at the edge of the haptics. This flange prevents the haptics from prolapsing back into the posterior chamber. Thus, the IOL is fixated efficiently in the posterior segment in the absence of capsular support.

Moreover, scleral-fixated IOL implantation is considered to be a safe procedure, in that the results show a reduction in suture-related complications [13] and in induced astigmatism. However, when 3-piece IOLs are used for scleral fixation, their long-term stability is debatable, since such IOLs are not specifically designed for this purpose. [8–12].

In this prospective analysis, we present a novel surgical technique for sutureless scleral-fixated IOL using a single piece SSF - IOL Carlevale Lens® (Soleko IOL Division, Italy, Figure 1). The Carlevale IOL is a foldable, one-piece, acrylic, monofocal, scleral fixating IOL that has a flexible anchorlike plug on the end of each haptic (Figure 1: demonstration of the single-piece SSF-IOL Carlevale lens). The current technique used during IOL implantation is the hand-shake technique, followed by the creation of scleral pockets in which the IOL haptics are secured afterward.

2. Patients and Methods

A novel surgical technique of sutureless scleral-fixated IOL implantation was performed on 27 eyes of 27 patients at the Ophthalmic Eye Institute between February 2019 and September 2020. All the surgeries were conducted by a single surgeon.

Inclusion criteria: patients had to be over 18 years old; BCVA > finger counting; patients had to have dislocated posterior or anterior chamber IOL, aphakia, and traumatic cataract with weak capsular support. Exclusion criteria: patients could not have extended glaucomatous or macular damage.

All patients provided written consent prior to surgery and the tenets of the Declaration of Helsinki were fully respected. The clinic's ethics committee approved the study, and the approved number was 01/2019/003_OPH_Aphakia. Baseline characteristics are summarized in Table 1 (baseline characteristics). The mean follow-up was 13.6 ± 4.8 months. Twenty-one patients received at least 12 months of follow-up and the other six, six months. Eleven of them went on to receive 24 months of follow-up.

The patients underwent a full preoperative examination including best corrected visual acuity (BCVA) in Snellen decimals, which were converted to the logarithm of the minimum angle of the resolution equivalents (LogMar), refraction, slit-lamp biomicroscopy of the anterior and posterior segment, Goldmann applanation tonometry (GAT IOP mmHg), fundus examination, and endothelial cell count density (Tomey EM -3000). A follow-up was scheduled on the 1st day, and also for the1st, 3rd, 6th, 12th, and 24th months.

During the follow-up, BCVA, GAT-IOP, and intra or postoperative complications were noted and evaluated. Refraction was also evaluated as spherical equivalent (SE) for the 1st and 6th months and compared to the baseline values. The IOL power was calculated using optical biometry (Lenstar, Haag-Streit). Whenever optical biometry was not possible, a standard conventional A-Scan biometry was employed to measure the axial length (AL mm), which was then fed into Lenstar to calculate the IOL power. All IOLs were calculated with the SRK-T, Barret universal, and Haigis formula.

Hypotony was defined when IOP was less or equal to 5 mmHg, while transient ocular hypertension was defined when IOP was equal to or more than 22 mmHg at any visit.

When pars plana vitrectomy (PPV) was employed (8 eyes), the data were analyzed and reported separately.

Statistical analysis was performed using MedCalc® 16.2.1 and IBM SPSS® statistics version 22. Parametrical or non-parametrical tests were used according to distribution. A $p < 0.05$ was considered statistically significant.

3. Surgical Technique

All surgeries were performed under retrobulbar anesthesia. Following anesthesia, corneal markings on the 10–190° axis were performed to ensure the correct centration of the IOL. A nasal and temporal conjunctival peritomy was then performed, followed by cauterization of the sclera under based saline solution (BSS) irrigation. Two spots were marked 1.5 mm behind the limbus to correspond to the corneal markings on the 10°–190° axis. A nasal and temporal sclerotomy was then performed at this location using an MVR 23 gauge knife (Alcon Grieshaber DSP Sterile Disposable) at a vertical orientation.

With each sclerotomy, two lateral midscleral 1.0 mm tunnels were created by dissecting the sclera perpendicularly to the incision. In this manner, two opposite self-sealing pockets were fashioned to position the two ends of the transscleral plug. This step was a modification of the technique proposed by Veronese et al. [14] (Figure 2).

In cases of the subluxated crystalline lens, phacoemulsification was performed with Stellaris Elite™ (Bausch and Lomb, USA) via a 2.2 mm corneal one-step incision using capsule hooks to support the weak zonules. Displaced IOLs were extracted from a 2.75 mm corneal three-step incision. After the removal of the IOL or the crystalline lens, an anterior and core vitrectomy was executed.

When required, a 25G or 27G PPV was performed. A 25G PPV was executed with Stellaris Elite™ (Bausch and Lomb, USA) when there was a loss of IOL or nucleus in the vitreous cavity. When macular pathology coexisted, a 27G PPV was preferred.

A single-piece hydrophilic Carlevale IOL was inserted into the anterior chamber with the IOL injector. Micro-intraocular forceps were employed through the sclerotomy to grasp the plug of the IOL haptic to prevent the IOL from falling into the vitreous cavity (Figure 3). Two notches on the IOL body (one on the lower left side and one on the upper right) helped the surgeon check the IOL's orientation (Figure 1). Then, the forceps were slowly withdrawn, dragging the plug through the sclerotomy. The trailing plug was grasped and externalized with the hand-shake

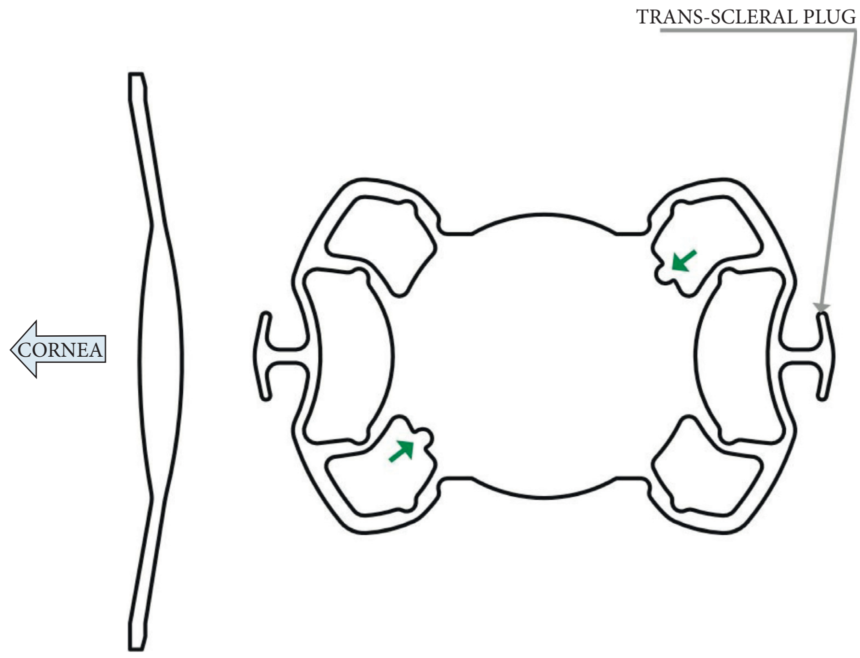

Figure 1: Demonstration of the single-piece SSF-IOL Carlevale Lens.

Table 1: Baseline characteristics.

		Total	PPV group	Non PPV group
Total patient		27	8	19
Age ± SD		69.12 ± 14.9 years (range 44–91)	61.25 ± 17.5 years (range 45–91)	72.6 ± 12.5 years (range 44–90)
Gender	Male	18 (66.6%)	14	4
	Female	9 (33.3%)	5	4
Follow up		13.6 ± 4.08 months (range 26–6)	14 ± 6.2 months (range 26–6)	13.5 ± 4.4 months (range 20–6)

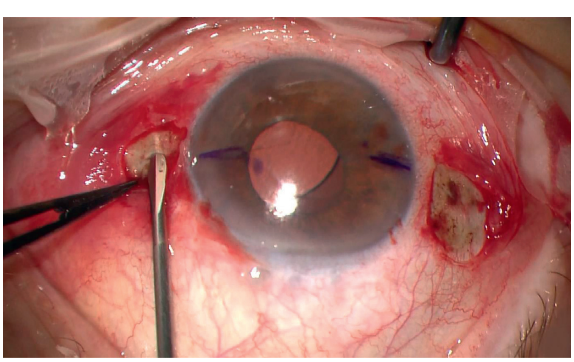

Figure 2: Creation of scleral pockets bilateral of the scleral tunnel.

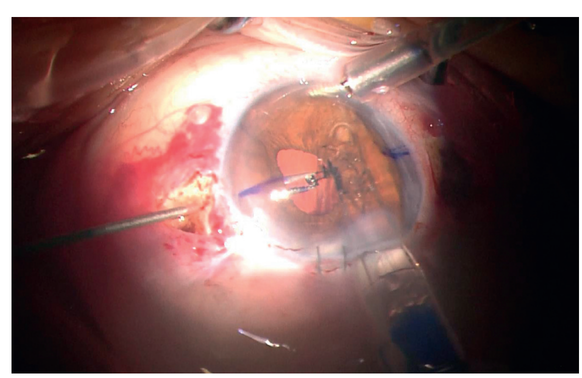

Figure 3: Leading plug grasped by crocodile tip forceps.

technique using two 25G intraocular forceps. Lastly, the two ends of each plug were positioned inside the scleral pockets that had been created for this purpose (Figure 4). The dimensions of the anchorlike "transscleral plugs" were 2 mm in width and 1 mm in length. Following the IOL centration, the sclerotomies were tested for leaks and the conjunctiva was closed, if needed, with an 8/0 absorbable polyglactin (vicryl suture). In three cases (all myopic eyes), the sclerotomies displayed leakage and the sclera was sealed with a 9/0 polypropylene suture to correct the problem.

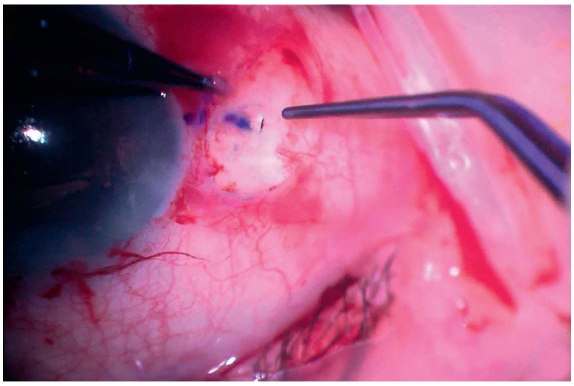

Figure 4: Transscleral plug placed in the scleral pocket.

4. Results

A preoperative evaluation gave evidence of weak capsular support due to trauma in six eyes (22.2%), pseudoexfoliation syndrome in two eyes (7.4%), and Marfan and Weill-Marchesani syndrome in two eyes (7.4%). In the cases, 40.7% presented posterior chamber IOL dislocation; 11.1% presented anterior chamber IOL dislocation; 18.5% had pre-existing subluxated traumatic cataracts, and 18.5% displayed subluxated nontraumatic cataracts. Lastly, 11.1% of the cases presented preoperative aphakia (from a previous operation). Eight eyes (29.6%) underwent concurrent 25 or 27 G pars plana vitrectomy (PPV). The mean axial length was 22.5 ± 0.68 mm (range 21.5 to 24.2 mm) and the mean IOL power was 19.3 ± 2.97 D (range 12 to 26 D) (Table 2).

The mean BCVA increased from 0.85 ± 0.59 LogMar baseline to 0.44 ± 0.30 at one month (Wilcoxon test, $p < 0.01$) and to 0.36 ± 0.34 (Wilcoxon test, $p < 0.003$) at six months. The refractive spherical equivalent also changed significantly from 4.3 ± 6.4 D to -0.5 ± 0.99 D at six months ($p < 0.01$ paired samples t-test). No change in the BCVA was observed at the 12-month follow-up. The mean corneal endothelial cell density had decreased from 2472 ± 202 cells/mm^2 to 2387 ± 197 cells/mm^2 (paired samples t-test, $p < 0.01$) (Table 2.)

In the PPV group, mean BCVA increased from 1.02 ± 0.60 LogMar baseline to 0.65 ± 0.37 within the first month (Wilcoxon test, $p < 0.01$) and to 0.47 ± 0.30 (Wilcoxon test, $p < 0.005$) within six months. The refractive spherical equivalent also changed significantly from 3.6 ± 12 D to -0.59 ± 0.98 D within six months ($p < 0.01$ paired samples t-test). The mean corneal endothelial cell density decreased from 2553 ± 205 cells/mm^2 to 2453 ± 200 cells/mm^2 (paired samples t-test, $p < 0.01$) (Table 2).

Postoperative complications included vitreous hemorrhage in two eyes (7.4%), which resolved without intervention; hypotony in two eyes (7.4%), which resolved automatically after three days; and transient hypertony in one eye (3.7%) on the 1st day, which was treated medically (Table 3). There were no signs of uveitis. Postoperative optical coherence tomography was performed on every patient (SPECTRALIS OCT, Heidelberg Engineering, Heidelberg, Germany), revealing one case of postoperative cystoid macular oedema (CMO). During the follow-up period, there was neither haptic exposure nor scleral or conjunctival erosion. Hypotony in one eye (12.5%) was the only postoperative complication in the PPV group.

5. Discussion

Poor capsular support may be observed in many ocular conditions such as trauma or pseudoexfoliation syndrome, or as an ophthalmic manifestation in systemic pathologies such as Marfan and Weill-Marchesani syndrome. Many surgical procedures have been proposed over the years to address IOL support in the absence of an intact capsule. The three options surgeons have been anterior chamber IOL, iris fixated IOL, and scleral fixated IOL. The percentages of complications vary among different studies. A report by the American Academy of Ophthalmology in 2003 compared the efficacy of secondary IOLs and concluded that there is insufficient evidence to demonstrate the superiority of one lens type or fixation site [15]. Each of these methods has advantages and disadvantages that should be taken into consideration.

The new technique of sutureless scleral fixation using the single-piece foldable Carlevale IOL, which is designed specifically for this purpose, offers considerable advantages for the surgeon. Its specially designed sclero-corneal plugs prevent the reinsertion of the haptic into the vitreous cavity. Placement of the plugs in the scleral pockets offers good IOL stability [14, 16]. The 13.5 mm total length and 6.5 mm large optic improve the centration and function of the lens. The Carlevale IOL's specially-designed soft haptics can be stretched, increasing the total length for severe myopia and Marfan cases [17]. The learning curve of this method is relatively steep, meaning that extensive surgical exposure to a significant number of cases is required in order to gather the experience that is necessary for mastering this technique. One possible disadvantage is the haptic and plug fragility. Compared to the conventional 3-piece IOLs, IOL haptics can be torn with negligible force during manipulation. Therefore, it is very important for the IOL to be well-centered with minimal effort.

In this study, overall visual acuity showed a statistically significant improvement, and the refractive outcome was acceptable in all cases. Several studies evaluating alternative methods for secondary IOLs placement, such as the iris-fixated [18], sutureless scleral-fixated [19–22], and anterior chamber [23] methods, reported rates of transient ocular hypertension ranging from 4% to 12.4% [18–24], IOL dislocation in 0–12% [18–24], hyphema in 4.0–9.7% [18–20, 23], vitreous hemorrhage in 0–12.2% [18–23], serous choroidal detachment in 1.3–2.7% [18, 19, 23], IOL capture within uveal tissue in 0–8.6% [19, 21, 23], cystoid macular oedema in 0–6.9% [18–24], retinal detachment in 0–2% [19–24], and anterior uveitis in 1.1–5.4% [18] cases. In the present study, the most common complications were vitreous hemorrhage (9.5%) and transient hypotony (9.5%). Similar results were shown in the study by Barca et al. [16] Regarding the IOL stability, there were no dislocations during the examined period. The corneal endothelium

Table 2: Results.

	Total	PPV group	Non PPV group
Preoperative logMAR BCVA	0.85 ± 0.59 (range 0.05–2.3)	1.02 ± 0.60 (range 0.05–1.8)	0.83 ± 0.61 (range 0.15–2.3)
1-month postoperative logMAR BCVA	0.44 ± 0.30 (range 0.05–1)	0.65 ± 0.37 (range 0.15–1)	0.37 ± 0.35 (range 0.05–0.95)
6 months postoperative logMAR BCVA	0.36 ± 0.34 (range 0.05–1)	0.47 ± 0.30 (range 0.05–1)	0.32 ± 0.33 (range 0.05–0.95)
12 months postoperative logMAR BCVA	0.35 ± 0.32 (range 0.05–1)	0.50 ± 0.30 (range 0.05–1)	0.33 ± 0.32 (range 0.05–0.95)
24 months postoperative logMAR BCVA	0.33 ± 0.32 (range 0.05–0.9)	0.45 ± 0.27 (range 0.05–0.9)	0.30 ± 0.31 (range 0.05–0.6)
Endothelial cell count	Preoperative	2472 ± 202 cells/mm^2	2553 ± 205 cells/mm^2
	Postoperative	2387 ± 197 cells/mm^2	2453 ± 200 cells/mm^2
Indication	Dislocated PC IOL (40.7%) AC IOL complication (11.1%) Subluxated traumatic cataract (18.5%) Subluxated nontraumatic cataract (18.5%) Aphakia (11.1%)		

Table 3: Postoperative complications.

Postoperative complications	Eyes (%)
Vitreous hemorrhage	2 (7.4%)
Hypotony	2 (7.4%)
Hypertony	1 (3.7%)
CMO	1 (3.7%)

remained intact and there were no noticeable signs of inflammation in the postoperative anterior chamber. Altering the classic technique minimized the risk of scleral or conjunctival erosion since no portion of the lens was exposed during the examined period.

In summary, we have reported our clinical results of using sutureless scleral fixation of the Carlevale IOL, which seems to be a safe and effective method, providing good visual outcomes in situations where capsular support is inadequate or absent. The Carlevale IOL's main advantage is its special design for scleral fixation, which offers unique characteristics, one of which is good stability with minimum need of intraoperative manipulation to achieve perfect centration. Long-term results and evaluation of outcomes are needed to determine the superiority of this procedure compared with other, more well-established ones.

One limitation of our study is the small sample size. However, we propose a longer follow-up time for this new approach to SFIOL using this novel IOL.

Data Availability

The SPSS file which contains the data used to support the findings of this study is available from the corresponding author upon request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Review Article

Surgical Management of Paediatric Aphakia in the Absence of Sufficient Capsular Support

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There are several available options for the demanding surgical correction of paediatric aphakia without sufficient capsular support. The literature suggests the implantation of a transscleral fixated posterior chamber-intraocular lens (PCIOL), an intrascleral fixated PCIOL, an iris-sutured intraocular lens (IOL), or an anterior chamber iris-claw IOL. We searched for reports on the management of paediatric aphakia in case of inadequate capsular support that delineated the diverse surgical approaches and their postoperative results. Analysis demonstrated that different complications can be encountered depending on IOL placement technique, such as suture rupture, IOL dislocation, secondary glaucoma, endophthalmitis, vitreous hemorrhage, and endothelial cell loss. However, it was shown that various IOL designs have similar visual outcomes. Taking into consideration the advantages and disadvantages of each surgical technique, ophthalmic surgeons can determine the safest and most efficient approach for paediatric aphakic patients.

1. Introduction

Paediatric aphakia with the absence of adequate capsular support may occur after lens removal for congenital cataract, after trauma or lens subluxation associated with systemic disorders. Refractive error can be temporarily managed with spectacles or contact lenses; however, secondary implantation of an intraocular lens (IOL) provides better visual outcomes in children with aphakia or lens subluxation [1, 2].

Various alternatives have been proposed for IOL secondary implantation through the years, but the research for the optimal surgical approach and IOL design is still in progress. To date, available options include the use of an anterior chamber IOL, a scleral fixated (SF) sutured posterior chamber IOL (PCIOL), an intrascleral fixated PCIOL, an iris-sutured PCIOL, or iris-claw lens [3]. Glued sutureless intrascleral fixation techniques as well as the creation of scleral pockets for intrascleral fixation of IOL haptics have shown good results in adults [4, 5]. On the other hand, the implantation of anterior chamber IOLs has been related to several postoperative complications, such as corneal endothelial cell loss (ECL), glaucoma, intraocular inflammation, hyphema, and cystoid macular oedema. Thus, anterior chamber IOLs are not recommended for use in the paediatric population [6].

This review aims to present the different surgical methods used in cases of paediatric aphakia without adequate capsular support and give a full description of their complications and visual outcomes.

2. Transscleral Fixation with Sutures

Over the past years, transscleral-sutured fixation of a single- or three-piece IOL has been considered an effective approach in the management of aphakia in paediatric eyes with no capsular support [7, 8]. Nevertheless, various studies have reported significant late complications related to the sutures. These complications involve suture erosion and dislocation of the IOL due to suture breakage [2, 9]. Moreover, ocular inflammation and discomfort may develop in the eyes with protruding suture ends. Close observation is required in these cases, as the risk for delayed onset endophthalmitis is increased [10, 11].

Asadi et al. showed a relatively high percentage of IOL dislocation resulting from suture rupture, a complication that was recorded in six of twenty-five paediatric eyes that underwent transscleral PCIOL [12]. Another study that evaluated the long-term outcomes of this surgical technique in children found that suture breakage was present approximately five years after surgery. They also observed that 10-0 polypropylene sutures had been used in all the cases complicated by suture rupture and that this rupture was mostly spontaneous [7]. Their results were supported by Price et al., who found degradation of the ruptured 10-0 polypropylene sutures after microscopic examination in patients with late dislocation of scleral-sutured IOLs [13]. It appears that long-term reliability of transscleral IOL fixation depends on the size and sturdiness of the suture material. Therefore, alternative suture size and materials such as 9-0 polypropylene or Gore-Tex have been suggested, considering the major concerns about the stability and safety of 10-0 polypropylene sutures used for IOL scleral fixation [7]. It is presumed that the 9-0 polypropylene suture has higher tensile strength and can better resist biodegradation and trauma [13]. Vasavada et al. observed that the 9-0 polypropylene sutures were broken clinically; however, histopathological analysis of the broken sutures was not indicative of any degenerative changes [14]. Apart from biodegradation, a clinicopathologic study concluded that polypropylene suture breakage and subsequent transscleral fixated IOL subluxation may result from the positioning IOL holes cutting the sutures and chronic inflammation that accelerates degradation process [15].

The use of alternate suture materials for IOL fixation to the paediatric sclera, including 10-0 mersilene and CV-8 Gore-Tex, has been investigated in a few studies. Although results have been encouraging, longer follow-up periods are required in order to reach safe conclusions about the stability of these materials [2].

Taking into consideration the results from published studies that investigated the use of scleral-sutured PCIOLs in children, satisfying visual outcomes have been demonstrated, with the mean postoperative best corrected visual acuity (BCVA) ranging from 0.69 ± 0.69 to 0.12 ± 0.13 logMAR at follow-up from 3 to 200 months (Table 1).

3. Intrascleral Fixation without Sutures

Long term side effects related to sutures led to the development of novel surgical methods for scleral IOL fixation in children. Kumar et al. presented a sutureless glued intrascleral single- or three-piece IOL fixation in 41 eyes [16]. The technique they used included externalisation of the haptics through 20G sclerotomies under partial thickness scleral flaps, which were then closed with fibrin glue. One case of postoperative optic capture and two cases of IOL decentration were reported. Similar results were demonstrated by Kannan and colleagues, who described a method of intrascleral IOL fixation without flaps, sutures, or glue in 40 eyes of 25 children with ectopia lentis [17]. The haptics were externalised through a scleral tunnel with the use of a 24G needle and buried in an adjacent scleral pocket. Four eyes developed early hyphema, five eyes developed intraocular haemorrhage, and there was one case of hypotony and one case of late IOL subluxation. Shuaib et al. compared sutureless transscleral technique for IOL fixation to retropupillary iris-claw IOLs in 30 paediatric eyes with aphakia [18]. For the IOL fixation to the sclera, they exteriorised the haptics through 23G sclerotomies under a scleral flap without glue usage. Postoperatively, hypotony due to subconjunctival leakage ($n = 1$), high intraocular pressure ($n = 2$), subconjunctival haptic exposure without erosion ($n = 3$), and IOL dislocation ($n = 2$) were mainly observed in the sutureless transscleral IOL fixation group. In a case series presented by Sternfeld et al., the flanged intrascleral IOL fixation (known as Yamane technique) was performed in order to correct aphakia in 12 eyes of 10 children [3]. In this technique adapted for paediatric patients, the haptics were externalised using a 30G thin-walled needle. Afterwards, the end of each haptic was broadened into a flange with low-temperature cautery and haptics were depressed back into the intrascleral tunnel. There was one case of postoperative IOL subluxation that also developed mild hypotony and choroidal effusion with no clinical leakage. Mild IOL decentration ($n = 2$), pigmentary deposits on the IOL ($n = 3$), irregular peaked pupil due to a vitreous strand ($n = 1$) and visible haptic through the conjunctiva in a child with Marfan syndrome were reported. Finally, a recent study retrospectively evaluated the use of Carlevale IOL in five paediatric eyes with aphakia and insufficient capsular support [19]. The Carlevale IOL is a novel foldable, acrylic, one-piece lens with T-shaped haptics, specifically designed for scleral fixation without sutures [20]. In the technique presented by Gotzaridis et al., the Carlevale IOL was inserted into the anterior chamber after three-port pars-plana vitrectomy [19]. The leading T-shaped haptic was then grabbed with 25G intraocular forceps under the scleral flaps and expressed through the sclerotomy. Identically, the trailing haptic was expressed through the other sclerotomy. No significant complications were reported after the surgery, and in all cases, IOL was well centered without IOL capture.

Visual outcomes of intrascleral fixated PCIOLs without sutures in paediatric population are comparable to those that have been reported for scleral-sutured IOLs. Kumar et al. found that the mean postoperative BCVA for glued intrascleral fixated PCIOLs was 0.43 ± 0.33 at a follow-up period of 17.5 ± 8.5 months (range 12–36 months) [16]. They also noted that in 53.6% of the cases, BCVA improved by more than 1 line, with no BCVA loss in any other case. Similar BCVA improvement was reported in 47.5% of the eyes that had intrascleral fixation of IOL haptics with no sutures or glue [17]. Visual results of the flanged intrascleral IOL fixation (Yamane technique) agree with those presented above, since postoperative BCVA improved in 50% of the cases or remained stable. Significant visual acuity improvement has been reported with Carlevale IOLs as well,

Table 1: The most important studies of scleral-sutured IOLs in paediatric population.

Study	Design	Number of patients (eyes)	Key results
Sharpe et al. (1996)	Retrospective outcomes of scleral-sutured PCIOLs	7 (7)	(1) VA improvement in six of seven patients (average improvement of 4 lines) (2) Complications: scleral fixation suture exposure ($n = 1$), lens decentration ($n = 1$), and lens tilt ($n = 1$)
Lam et al. (1998)	Retrospective safety and efficacy of scleral fixated IOLs	3 (6)	(1) Good visual improvement (2) Stable and well-positioned PCIOL after surgery in all eyes (3) Complications: asymptomatic pupillary IOL capture in 3 eyes
Kumar et al. (1999)	Prospective case series evaluation of scleral fixated IOL implantation	11 (11)	(1) Postoperative BCVA: stable in 54.5%, improved by more than 1 Snellen line 27.2% and decreased by more than 1 Snellen line in 18.1% (2) Complications: suture erosion through the conjunctiva in 18.18%, marked postoperative anterior chamber reaction in 18.18%, IOL decentration in 9.09%, glaucoma in 9.09%, and cystoid macular edema in 9.09%
Zetterström et al. (1999)	Retrospective long-term outcomes of scleral-sutured PCIOLs	13 (21)	(1) Postoperative BCVA: stable or improved (2) Complications: posterior synechiae ($n = 4$), cells on the IOL surface ($n = 4$), and IOL subluxation ($n = 2$); no visual axis opacification, secondary glaucoma, or retinal complication was recorded
Vadalà et al. (2000)	Retrospective results of scleral fixated IOLs	3 (5)	(1) Postoperative VA: 20/20 to 20/40 (2) Complications: IOL dislocation ($n = 1$) and posterior capsular opacification ($n = 3$)
Jacobi et al. (2002)	Prospective evaluation of transscleral fixated IOLs	26 (26)	(1) Postoperatively, BCVA within one Snellen line was achieved by more than 80% of the patients (2) Complications: IOP increase in 11.5%, marked anterior chamber reaction in 15.4%, IOL decentration in 19.2%, and suture erosion through the conjunctiva in 7.4%
Sewelam et al. (2001)	Retrospective haptic position evaluation of transscleral fixated PC IOLs using UBM	20 (20)	IOL haptics located in the sulcus (55.0%), anterior to the sulcus (27.5%), and posterior to the sulcus (17.5%)
Ozmen et al. (2002)	Retrospective assessment of the visual outcome and complications of transscleral fixated IOLs	18 (21)	(1) Visual improvement of more than 2 Snellen lines in 9 eyes (42.8%) (2) Complications: the most severe were concurrent endophthalmitis and retinal detachment ($n = 1$); the most common were pupillary distortion, transient pupillary membrane, pupillary capture, and strabismus and anterior uveitis
Bardorf et al. (2004)	Retrospective long-term results of transscleral-sutured IOLs		(1) Postoperative VA: improved in 70%; in 51% improved by two lines or more; no patient suffered visual acuity loss (2) Complications: small hyphemas (7%), vitreous hemorrhage (5%), ocular hypertension or hypotony (5%) and iris capture of the IOL optic (5%); no retinal detachment or other retinal complications were reported
Buckley (2007)	Retrospective long-term outcomes of transscleral-sutured PCIOLs	26 (33)	(1) Postoperative VA: significantly improved ($P < 0.001$) (2) Complications: intraoperative and immediate postoperative minimal and not sight-threatening; IOL subluxation due to spontaneous 10-0 polypropylene suture breakage ($n = 3$) at 3.5, 8, and 9 years after surgery; 10 similar cases by a survey of paediatric ophthalmologists (mean, 5 years after surgery)

Table 1: Continued.

Study	Design	Number of patients (eyes)	Key results
Asadi and Kheirkhah (2008)	Case series long-term results of transscleral fixated PCIOLs	23 (25)	(1) Postoperative BCVA: improved in 48% by >1 Snellen line; the main cause of reduced vision was corneal and retinal pathologies and amblyopia (2) Complications: transient intraocular hemorrhage (52%), transient choroidal effusion (8%), late endophthalmitis (4%), retinal detachment (4%), and late IOL dislocation due to breakage of polypropylene sutures after 7 to 10 years (24%)
Olsen and Pribila (2011)	Retrospective sulcus fixated, sutured PCIOL using endoscopic guidance during PPV	20 (21)	(1) Most patients had visual function improvement (2) Complications: suture breakage ($n = 2$) due to repeat trauma (3) Advantages: excellent visualization and haptic localization, optimal lens centration, buried knots, broad scleral imbrication, and minimal vitreous- and hemorrhage-related complications (4) Disadvantages: learning curve, increased operative time, long-term suture stability issues, and limited availability of intraocular endoscopes
Burcu et al. (2014)	Retrospective evaluation of the outcomes of scleral fixated PCIOLs	14 (24)	Median postoperative BCVA: 0.2 (min: hand motion; max: 0.8) in decimal notation ($P = 0.017$); BCVA improved at least one Snellen line or remained unchanged in all eyes

PCIOL: posterior chamber-intraocular lens, VA: visual acuity, BCVA: best corrected visual acuity, IOP: intraocular pressure, UBM: ultrasound biomicroscopy, and PPV: pars-plana vitrectomy.

with a mean postoperative BCVA at 0.26 ± 0.32 logMAR after a median follow-up period of 9 months (range 7–13 months) [19]. Although all these sutureless methods appear promising, they have not been widely performed in children and their long-term results need to be investigated.

4. Iris-Sutured IOLs

The use of iris-sutured IOLs has also been proposed for the correction of aphakia in children with no adequate capsular support. Dureau et al. described a surgical method for iris fixation of foldable IOLs in 17 eyes of 9 paediatric patients with ectopia lentis [21]. Postoperatively, they found one case of hyphema and one case of aseptic endophthalmitis; however, in all cases, IOLs were centered and pupils were round [21]. Another study presented the outcomes of iris-sutured IOL implantation in 12 eyes of children with ectopia lentis. IOL dislocation without breakage of fixation sutures was detected in four eyes (33%). They hypothesised that these dislocations resulted from the rotation of the IOL haptic out of the suture loop [22]. Although a previous report claimed that using the remaining portion of the capsule with sufficient zonular support may be helpful in achieving better IOL stability [21], Kopel and colleagues supported that capsular remnants may be the cause of vitreous traction resulting in retinal tears and/or detachment [22]. In a similar research by Yen et al., dislocation of the iris-fixated IOL was observed in 41% of the cases [23]. Nevertheless, it was highlighted that all sutures were intact and in their appropriate iris position. Finally, researchers described the rare development of a secondary iris cyst after iris-sutured IOL insertion in two children with Marfan syndrome [24, 25].

Postoperative BCVA in paediatric cases that were corrected with iris-sutured IOLs varied from 0.24 to 0.35 logMAR at the last follow-up of 19.8 months to 4.7 years [2]. In a case series that compared the outcomes of pars-plana lensectomy-vitrectomy with and without iris-sutured IOL in paediatric eyes with ectopia lentis, no statistically significant difference in the fraction of eyes that achieved BCVA of 20/40 or better was found between the two groups [22]. In addition, no difference was observed in mean postoperative BCVA. On the other hand, Shah et al. noticed that mean visual acuity improved in 71% of the cases but decreased in another 24% after iris-sutured IOL placement [26].

5. Anterior-Fixated Iris-Claw IOLs

Another alternative solution for the correction of paediatric aphakia in case of insufficient capsular support has been the implantation of Artisan IOL [27]. The Artisan IOL, invented by Worst in 1986, was originally a biconcave iris-enclavated IOL used in phakic patients with high myopia [28]. Due to its different design, the current biconvex rigid acrylic three-piece IOL allows aqueous flow between the optic and the iris and decreases pigment dispersion. IOL haptics are fixated to the peripheral iris, at 3 and 9 o'clock, with the use of an enclavating needle [2].

Anterior-fixated Artisan IOLs prevail over scleral- or iris-sutured IOLs because their implantation is technically easier [29]. In addition, the risk of posterior segment complications is reduced as no surgical manipulation takes place behind the iris. Nevertheless, such complications have been reported, but their occurrence is attributed to multiple factors, including concomitant surgical procedures such as vitrectomy or a history of previous surgery. Long axial lengths or other structural ocular deformities seem to be equally significant. For instance, axial elongation and higher lens subluxation probability appear to increase the risk of retinal detachment in patients with Marfan syndrome [2].

Anterior chamber Artisan IOLs may be complicated by pupillary block, with a cited frequency ranging from 0% to 20%, and this complication can be detected from day 1 to 9 months postoperatively [2]. Hirashima et al. found that pupillary block can still be observed in pseudophakic eyes, even after laser iridotomy [29]. Surgical iridectomy was successfully performed for the inversion of pupillary block in all the reported cases. Therefore, the implantation of Artisan IOL should always involve a surgical peripheral iridectomy with sufficient size, in order to avoid this complication [2].

De-enclavation of Artisan IOLs has been recorded in up to 6.25% of cases [2]. In a study by Tychsen and Faron, repeated IOL de-enclavation led to the explantation of the Artisan IOL in one of the total 28 eyes that they were implanted [30]. Manning and colleagues reported spontaneous lens de-enclavation in one of the 16 eyes with ectopia lentis that had been treated with Artisan IOL implantation [31]. This complication occurred at the seventh postoperative year. A similar condition was described in a case series by Ong et al. [32].

The preservation of endothelial cell count (ECC) is a challenging issue for ophthalmic surgeons when performing cataract surgery and lens implantation [2]. Over the years, many studies have investigated ECL after lensectomy in children. In a prospective study by Kora et al., ECL was evaluated to be 6% three years after cataract surgery, using PCIOL and Hessberg-type anterior chamber IOLs [33]. They assumed that factors, such as age, indications for surgery, or technique, could change that result. The degree of ECL varied from 5.3% to 7.5% after extracapsular cataract surgery and PCIOL implantation in another long-term study on paediatric population [34]. Ramasubramanian and colleagues showed that mean ECC was decreased by 11% in paediatric eyes that had undergone cataract surgery [35].

Artisan IOLs concern specialists even more about ECL, because they were created for anterior chamber placement. In a number of studies that investigated the long-term results of Artisan IOLs in children with lens subluxation related to systemic disorders, the mean ECL was found to be higher, ranging from 14.2% to 18.5% [2]. Nonetheless, there are some reports that display conflicting results. Güell et al. discovered that mean ECC was not statistically different in eyes with Artisan IOL compared to eyes with any IOL-type placement [36]. Two other studies on children with lens subluxation concluded that there was no statistically significant difference in ECL between unoperated eyes and eyes that had undergone lensectomy and Artisan IOL implantation [27, 37].

It appears that prior ocular trauma may lead to even lower ECC. Odenthal and colleagues retrospectively assessed ECL after the implantation of Artisan IOL for congenital and traumatic cataract in children [38]. They observed that mean ECL was 41% in the traumatic cataract group after 10.5 years of follow-up and was strongly correlated with the original corneal scar length from trauma. Similarly, in a long-term study by Gawdat et al., a higher rate of ECC loss was noted in paediatric eyes that had undergone Artisan IOL implantation for the correction of aphakia after traumatic cataract surgery at 12-month follow-up [33]. It was assumed that original trauma and its surgical repair were liable for the greater ECL rate. However, they highlighted the necessity of longer follow-up, in order to evaluate ECL through adulthood.

Various factors are presumed to affect ECL, besides trauma. Different ECL rates have been presented among studies that explored the outcomes and complications related to Artisan IOLs and this diversity probably results from the wide variation in described surgical techniques, incisions, and follow-up durations. Considering the high heterogeneity of ECL results, researchers have not reached a safe conclusion about the correlation between ECL and the use of anterior-fixated Artisan IOLs [2].

Even though anterior Artisan IOLs have been associated with serious complications, encouraging visual outcomes have been published by multiple studies over the last two decades (Table 2). Research results showed that visual acuity was stable or improved in cases of lens subluxation that were managed with Artisan IOL placement. The mean postoperative BCVA varied from 0.36 ± 0.26 to 0.04 ± 0.09 logMAR at different follow-up durations [2].

6. Retropupillary-Fixated Iris-Claw IOLs

An alternative, retropupillary fixation of Artisan IOL has been recommended, in order to avoid ECC issues that result from anterior-fixated Artisan IOLs. Studies on the adult population have shown that, since retropupillary-fixated Artisan IOLs are located in the posterior chamber, the depth of the anterior chamber increases. Thus, the risk for ECL, which is the main concern when Artisan IOLs are used, is hypothetically lower [39, 40]. Gonnermann and colleagues presented the outcomes of retropupillary-fixated Artisan IOL use in seven paediatric eyes with lens subluxation and no capsular support [41]. A mean ECL of 6.4% was noted at the last postoperative follow-up, without spontaneous IOL dislocation or any other reported serious complication. Similar studies also revealed low complication rates with this technique [42, 43].

Retropupillary fixation of Artisan IOL has demonstrated good visual outcomes in aphakic children. In the study by Gonnermann et al., the mean postoperative BCVA was 0.13 ± 0.17 logMAR at a follow-up duration of 31 ± 21 months (range 10–64 months) [41]. These results are comparable to those reported for anterior-fixated Artisan IOLs and scleral fixated IOLs.

Table 2: The most important studies of Artisan IOL in paediatric aphakic patients.

Study	Design	Number of patients (eyes)	Key results
Lifshitz et al. (2004)	Retrospective Artisan IOL for idiopathic subluxated lenses	3 (4)	(1) Postoperative BCVA 6/12 or better in 3 cases that could be recorded (2) VA improved by 2 or more Snellen lines in all eyes (3) Complications: none
Odenthal et al. (2006)	Retrospective ECL evaluation after Artisan IOL for traumatic and congenital cataract	10 (10)	(1) ECL: 41% in the traumatic cataract group (2) ECL related to the original corneal scar length of the trauma (3) No statistical difference in ECC between operated and unoperated eye in the congenital cataract group
Sminia et al. (2007)	Retrospective Artisan IOL for aphakia after trauma	5 (5)	(1) Postoperative BCVA 20/40 or better in 4 eyes (2) Mean ECL: 40% (3) Complications: retinal detachment 19 months after primary injury in one eye
Hirashima et al. (2010)	Randomized controlled trial anterior vs. posterior chamber iris-claw IOL lens subluxation in Marfan	16 (31)	(1) Postoperative BCVA did not differ significantly between groups (2) Complications: IOL dislocation ($n = 3$) in the PCIOL group, retinal detachment ($n = 3$) in both groups (3) Mean postoperative foveal thickness decreased in 54.16% of the patients
Sminia et al. (2011)	Retrospective ECL evaluation after Artisan IOL for traumatic and congenital cataract	10 (20)	Postoperative mean ECC comparable to the mean normal ECC for this age group reported in the literature
Sminia et al. (2012)	Retrospective Artisan IOL for ectopia lentis in Marfan	2 (4)	Good postoperative visual outcome, no serious IOL-related complications, and ECC within the expected range for normal eyes
Cleary et al. (2012)	Retrospective Artisan iris-claw IOL for ectopia lentis	5 (8)	(1) Postoperative mean VA: 0.04 ± 0.09 logMAR ($P = 0.04$) (2) Mean postoperative ECL: 14.2% ($P < 0.001$) (3) Complications: none
Siddiqui et al. (2013) 23316948	Prospective evaluation of visual outcomes and ECC after Artisan IOL for lens subluxation	11 (18)	(1) Mean postoperative BCVA: 0.26 ± 0.13 logMAR ($P = 0.001$) (2) Mean postoperative ECL: 17.1%
Tychsen and Faron (2013)	Prospective outcomes of Artisan IOL for aphakia	17 (28)	(1) Postoperatively, BCVA improved an average 2 Snellen lines (0.18 logMAR) (2) Complications: pupillary block ($n = 4$) and de-enclavation ($n = 1$)
Gawdat et al. (2015)	Prospective outcomes of Artisan IOL for aphakia	18 (25)	(1) Postoperative BCVA for traumatic aphakia and lens subluxation improved to 0.38 ± 0.15 logMAR ($P < 0.002$) and 0.3 ± 0.2 logMAR ($P < 0.0001$), respectively (2) One year postoperative significant decrease of ECC (2892.64 ± 441.79 cells/mm^2) (3) Complications: traumatic dislocation ($n = 2$), pupillary block ($n = 1$)
Manning et al. (2016)	Retrospective outcomes after Artisan IOL for ectopia lentis in Marfan	8 (16)	(1) Mean postoperative BCVA: 0.12 ± 0.19 logMAR (2) Mean postoperative ECL: 15.4% (3) Complications: pupillary block ($n = 1$) and de-enclavation ($n = 1$)
Kavitha et al. (2016)	Retrospective outcomes of Artisan IOL vs. PCIOL for traumatic cataract	50 (50)	(1) BCVA improvement in both groups with no significant difference in BCVA logMAR between them (2) Complications in the Artisan IOL group: secondary glaucoma ($n = 1$), IOL de-enclavation ($n = 1$), and cystoid macular edema ($n = 1$)
Catala-Mora et al. (2017)	Prospective outcomes of Artisan IOL for ectopia lentis	12 (21)	(1) Mean BCVA improved from 0.91 ± 0.29 logMAR to 0.18 ± 0.23 logMAR at final follow-up ($P < 0.0001$) (2) Postoperative ECL: 5.04% ± 9.58% with an annual ECL rate of 3.16% ± 4.46% (3) Complications: traumatic IOL dislocation and retinal detachment ($n = 1$), cystoid macular oedema ($n = 1$)

IOL: intraocular lens, BCVA: best corrected visual acuity, VA: visual acuity, ECL: endothelial cell loss, and ECC: endothelial cell count.

7. Conclusions

Surgical correction of paediatric aphakia with inadequate capsular support represents a challenging task for ophthalmic surgeons. Several IOL designs and surgical techniques have been recommended, each one with benefits and risks. The literature has shown that scleral fixation provides good refractive and visual outcomes. Nevertheless, this method has demonstrated higher rates of complications associated with the sutures, such as suture erosion and IOL dislocation, as well as ocular inflammation and endophthalmitis. Similar complications have been described with iris-sutured IOLs, except suture breakage. Fewer cases of suture-related IOL decentration have been encountered with sutureless intrascleral IOL fixation, including the Yamane technique or the implantation of the novel Carlevale IOLs. These alternatives are potentially less complicated, but also faster. Finally, the placement of anterior Artisan IOLs is reportedly easier than that of the previous techniques; however, their long-term impact on ECL still needs to be determined.

The current literature for the correction of aphakia in children has several limitations. The majority of published reports are retrospective and noncomparative, and their sample size is small. Therefore, larger prospective studies are required in order to define which one is the optimal approach for the management of aphakia in the paediatric population.

Data Availability

No data were used to support this study.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Research Article

The SWISS IOL Technique (Small-Width Incision Scleral Suture): A Mini-Invasive Technique

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Purpose. To evaluate the outcomes and safety of a minimally invasive technique for sutured IOL scleral fixation in case of compromised capsular and iris support. *Materials and Methods*. In this retrospective study, we explain our mini-invasive technique and assess the outcomes in terms of visual acuity, pre- or postoperative complications, and IOL position (Sensar AR40e, AMO) in a case series of three patients. *Results*. The expected best corrected visual acuity could be achieved after one month. Surgeries were uneventful with a stable eye. No postoperative complications occurred except for one patient who had a conjunctival disinsertion. Neither postoperative hypotony nor raised IOP was found. Additionally, no patient experienced corneal edema at one week control, IOL dislocation, vitreous hemorrhage, or new pupil's irregularity. *Conclusions*. In conclusion, each scleral technique has its own advantages and its inherent postoperative complications. To date, there is no evidence of superiority of any single technique. By improving our scleral sutured lens techniques, we could improve peroperative ocular stability, potentially decrease postoperative complication rate, and offer a rapid recovery with a stable visual acuity within a month.

1. Should the Sutured Scleral Fixation IOL Technique Be Ostracized? A Mini-Invasive Technique

The ideal place for an intraocular lens (IOL) is in the capsular bag, where it can be tolerated by ocular tissues for decades. Problems arise when the in-the-bag implantation is not feasible. The surgeon has multiple options at this point: sulcus placement, anterior chamber IOL, iris-sutured IOL, or iris-claw IOL, but none of the abovementioned techniques are without potential complications.

The IOL placement in a nonphysiologic anatomical position may result in recurrent iritis, UGH syndrome, ocular hypertension and glaucoma, macular edema, corneal endothelial cell loss and decompensation, retinal detachment, or IOL dislocation. Additionally, many of the abovementioned techniques require large incisions and result in high induced corneal astigmatism.

A different approach of scleral-fixated IOL has been gaining popularity since it was first employed by Maggi and Maggi in 1997 [1]. The major advantages of such placement are that it can be employed irrespective of the iris anatomy and capsular support, closely mirrors the physiological lens position in the eye minimizing aniseikonia, and has a reduced risk of recurrent iritis. Scleral fixation has further evolved in the 21st century with two major techniques emerging: suture fixation and sutureless techniques.

Most techniques require large incisions of 3.0 to 7 mm or scleral flaps leading to eye fragility and instability during surgery and in the immediate postoperative period. This is a raising concern, especially in the elderly population prone to falls, increasing the incidence of ruptured globes with the expulsion of the intraocular content, especially in the cases of previous large scleral incisions or flaps [2, 3].

In this paper, the authors describe their minimally invasive technique of scleral-fixated IOL with suture fixation and present the preliminary outcomes of three patients treated with this technique.

2. Materials and Methods

This is a retrospective case series of 3 consecutive cases performed at Geneva University Hospital between November 2020 and March 2021. All patients signed an informed consent for the surgery and for research purposes during follow-up in accordance with the tenets of the Declaration of Helsinki. Data were retrieved from institutional electronic medical records.

Inclusion criteria for scleral-fixated IOL were aphakia with no capsular bag and poor iris support (i.e., iridodonesis or iris defect) and/or poor endothelial cell count (<1000 cells/mm^2). Exclusion criteria were pregnancy or inability to give informed consent.

2.1. Description of the Surgical Technique. The appropriate lens power was selected preoperatively using the IOL master 700 and the SRK/T formula with the target of small myopia (−0.25–0.75D). The patient's cornea was marked at the slit lamp at 90° and 270° preoperatively to account for cyclotorsion (Figure 1).

The procedure was performed under general anesthesia.

First, a 23G vitrectomy trocar is placed through the pars plana in the inferior temporal sclera and the infusion is opened at 20 cmH_2O after confirming its intravitreous placement. Next, an approximately 4 mm conjunctivotomy is performed superiorly and inferiorly with Westcott scissors exposing the bare sclera. Then, the sulcus is located and marked 2 mm from the limbus with gentian violet at 6 and 12 hours (Figure 1(a)). The correct position of the sulcus is confirmed by trans-illumination using an endo-ocular fiber optic illuminator that shows the sulcus as a white line between two darker lines corresponding to the iris root anteriorly and the ciliary body posteriorly.

Next, a clear corneal incision is performed at 120° with a standard angled 2.4 mm phaco knife, which is then slightly enlarged by around 0.5 mm to avoid excessive pressure on the eye during IOL insertion. The IOL is fixated with a double-armed 10-0 polypropylene suture with a STC6 needle. A transcleral passage at one millimeter on each side of the marked limbus on the sclera is necessary. The 10-0 polypropylene threads should stay parallel and go out of the eye through the cornea close to the opposite limbus. To achieve this, the needle should be held as far as possible (Figure 1(b)) and care must be taken in order not to cross the suture. The needles are cut after completion of the transcleral passage. Then, the distant 10-0 polypropylene thread is grasped in the anterior chamber with the McPherson forceps passing over the nearest 10-0 polypropylene thread through the main incision (Figure 1(c)). Once out of the eye, it should be fixed on the left part of the upper eyebrow with a strip. The same procedure should be performed with the another 10-0 polypropylene thread, which should be fixed on the right part of the eyebrow (Figure 1(d)). Again, care must be taken not to cross the threads.

Problems with adequate surgical eye exposure arise when the upper limbus is covered by the upper eyelid when the eye is pushed up. It is then not possible to insert the 10-0 polypropylene holding the STC6 needle at its basis as for the 12 o'clock approach. A useful tip is to use two needle holders: the first one holds the needle in the middle when doing the transcleral insertion, and once it arrives at the sclera, the other needle holder grabs the needle at its base and pushes it down into the conjunctival cul-de-sac (Figure 1(e)). With this maneuver, the needle passes in front of the pupil with a straight eye. A gentle push with some upper counteraction allows the needle to pass easily through the upper part of the cornea.

Next, a nasal paracentesis is performed at 4 o'clock with a 20G curved knife. Usually for more comfort, it is advisable to enlarge it slightly. Then, the lower distal 10-0 polypropylene thread is grasped by using a Synskey hook passing through the side incision over the nearest 10-0 polypropylene thread. It is fixed with a strip on the lower right eyelid. The same maneuver is performed for the other 10-0 polypropylene thread, which is fixed on the lower left eyelid with a strip.

A viscoelastic is then injected into the anterior chamber, and the AR40e lens is injected in front of the iris plane while maintaining the upper haptic outside the main incision.

Several knots (at least 2-1-1-1 knots) are necessary to ensure a good IOL fixation at the level of the haptic, taking care not to cross them. The first knot should always be the closest to the lens optic, i.e., the left superior thread of 10-0 polypropylene for the upper haptic and lower right for the lower haptic. The 10-0 polypropylene thread is passed under the haptic in the direction of the lens (Figure 1(f)). The first knot should be very tight and the other tight enough to block the first knot.

Grasping of the lower haptic might sometimes be difficult. It should be positioned under the side incision (Figure 1(h)). A crocodile 20G curved forceps or a tiny McPherson forceps might be necessary to grasp the lower haptic in front of the pre-iris plane and preiris plane and exteriorize it through paracentesis (Figure 1(i)).

Once the surgical knots are completed, the lower haptic is reintroduced into the anterior chamber with Troutman forceps and the lens is pushed back behind the iris plane with the help of a vitreous spatula (Figure 1(k)). This will help the lower haptic to pass behind the iris plane. Simultaneously, the lower 10-0 polypropylene should be pulled, which allows the lower haptic to be positioned without difficulty at the level of the sulcus (Figure 1(k)).

Then, the upper haptic is then reintroduced into the anterior chamber by using a Troutman or McPherson forceps at its extremity and pushed under the iris plane through the main incision (Figure 1(l)). Sometimes the upper haptic tends to go into the angle. In such a case, a Sinskey hook can be used to pass the haptic under the iris plane. Again, the upper 10-0 polypropylene should be pulled.

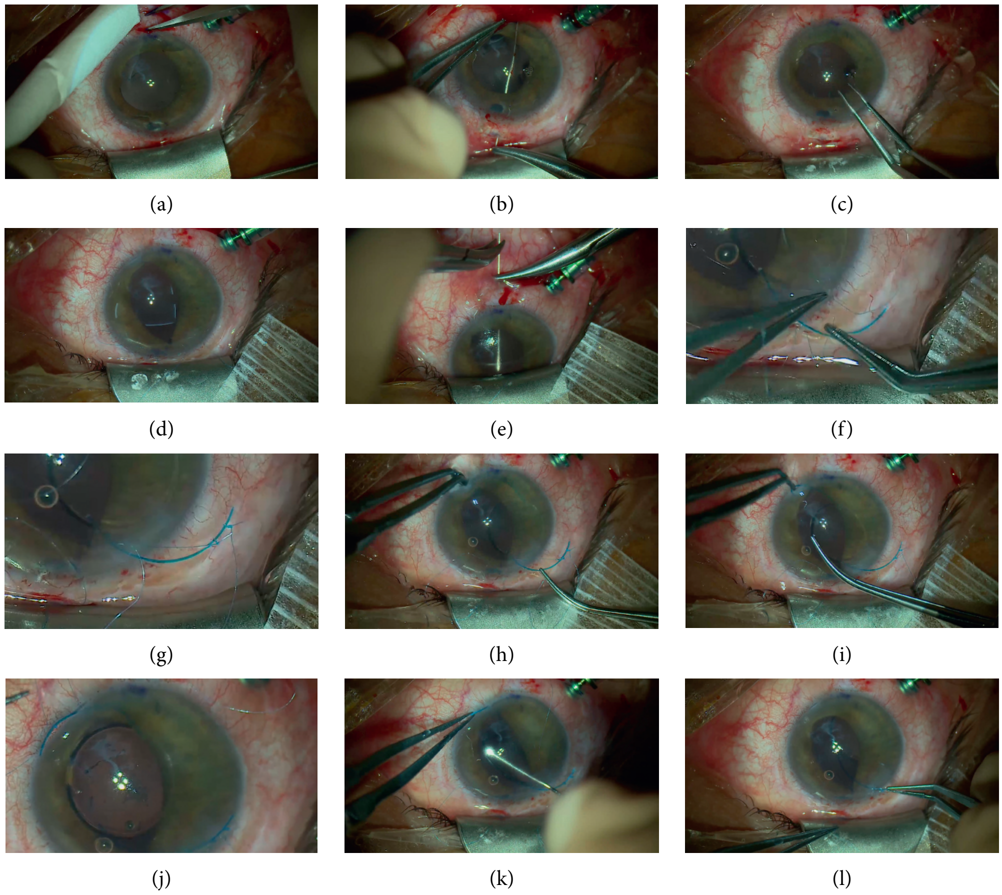


Figure 1: Most important steps of the surgical technique. Intraoperative photographs showing the most important surgical steps (patient 2) (a). Marked sulcus position confirmed with endo-trans-illumination, usually at about 2 mm from the limbus (b). Insertion of the needle passing through the upper sulcus to the contralateral cornea by holding the needle at it basis (c); grasping the 10-0 polypropylene thread with the McPherson forceps, starting with the opposite threads (d), both 10-0 polypropylene threads are passed through the main incision and fixed with stripes superiorly. (e) Needle passing through the lower sulcus to the contralateral cornea by holding the needle with the right hand in the middle and then grasping the needle with the second hand at its basis (f); the right hand is grasping the upper left 10-0 polypropylene thread passed under the haptic, whereas the left hand is pushing the upper right thread of 10-0 polypropylene away (g). Both 10-0 polypropylene threads are well tied on the upper haptic (h). Right hand is maintaining the upper haptic to position the lower haptic in the paracentesis, while the left hand grabs the lower haptic with a small McPherson forceps as close as possible to its extremity (i). Externalization of the lower haptic with McPherson forceps (j). First knot is tied over the lower haptic, starting proximal to the optic (i.e., lower right 10-0 polypropylene) (k). Internalization of the lower haptic: the left hand is holding the extremity of the haptic with a McPherson forceps and pushing it inside in a clockwise movement while the other hand is pushing back the IOL's optic with a vitreous spatula. Same manoeuver with the upper haptic; note the left hand which is pulling on the 10-0 polypropylene to guide the haptic under the iris plane (l).

Closure of the main incision with 10-0 nylon might be necessary if it is not properly watertight. The eye is then pressurized to 60 cmH_2O. The exteriorized 10-0 polypropylenes are tied 2 by 2 without exerting too much pressure on the knot. Next, the globe pressure is decreased to more physiological values (20 to 30 cmH2O) and the 10-0 polypropylene threads tend to relax; its ends are then heated with a cautery to make them round.

The 10-0 polypropylene threads are then flattened on the sclera, and the conjunctiva along with the Tenon capsule is closed with 6.0 Vicryl absorbable suture. Next, the viscoelastic is washed from the anterior chamber, the main incision and paracentesis are hydrosutured, and the vitrectomy trocar is removed. Finally, the surgery is finished by an injection of intracameral cefuroxime, as in a standard phacoemulsification.

The patient is discharged on a topical postoperative regimen of ofloxacine drops 4 times a day for one week and tobramycine and dexamethasone drops 4 times a day for one week, which is then decreased by one drop per day every week. At week 4, topical bromfenac 2 times a day is introduced for 2 weeks.

2.2. Data Assessment. The following data were assessed: pre- and postoperative visual acuity (Snellen best corrected visual acuity: BCVA), slit lamp examination, intraocular pressure and fundus examination, and Scheimpflug imaging (Pentacam, Oculus, Wetzlar, Germany) at one month. Eyes were observed for modifications in astigmatism magnitude and axis, IOL centration, tilting, and any postoperative complications. Our operations are routinely recorded, and surgery time and technique of all three cases were reviewed after the cases were finished.

Due to the low number of patients in the preliminary study, no statistical analysis was performed.

3. Results

Three patients were recruited in this retrospective study, two males (45 and 51 y.o.) and one female (77 y.o.—patient 1). Aphakia resulted from ocular injury in the 2 male subjects and from a complicated cataract surgery for the female patient.

Clinical data such as visual acuity (logMAR), refraction, intraocular pressure with Goldman applanation tonometry, and astigmatism are summarized in Table 1.

Surgical data such as IOL centration, IOL tilting, and surgery time are summarized in Table 2.

Lenses tilting assessed with the Scheimpflug tomography could retrieve only minor tilting as shown in Figure 2.

They were no peroperative complications such as hypotony, hemorrhage, or eye instability. One patient presented a conjunctival disinsertion of the limbus at week one and required a conjunctival suture in the OR to protect the 10-0 polypropylene threads. No postoperative hypotony, hypertony, corneal edema, IOL dislocation, vitreous hemorrhage, retinal detachment, or new pupil irregularities were noted.

Figure 3 shows the pre- and postoperative aspects of all patients.

4. Discussion

In our preliminary study, all three consecutive cases recovered visual acuity at one month without the classic complications associated with other scleral fixation techniques. Aphakia correction without a proper capsular bag support remains a challenge, and many different approaches exist. Malbran et al. reported 3 techniques with scleral sutures [4], but they had disadvantages such as suture breaks and cheese wiring. Later, a sutureless approach was developed, albeit with its own set of complications [5, 6]. We have developed a technique of scleral fixation with 2 10-0 polypropylene sutures with a trans-scleral approach and a 6 mm scleral self-sealed incision [7], which could help overcome the 2 main complications of scleral sutured IOLs: suture breaks [8] and cheese wiring effect on the sclera, observed in up to 16% of cases at 7 and 5 years [9]. We have published a case series with more than 20 years follow-up confirming the efficacy of our scleral suture technique [10].

In this paper, we have improved this technique to allow for minimally invasive surgery, small corneal incisions, and fast postoperative recovery.

Visual acuity reached 20/20 at one week in patient 2, whereas the other patients reached their preoperative BCVA at one month. This is an encouraging result when compared to other studies, were BCVA was achieved only after three months [11]. Rapid recovery is mainly due to less eye manipulation and no scleral flap and, in turn, low postoperative inflammation. Visual acuities were limited in patients 1 and 3 due to preoperative optic nerve damage (pituitary adenoma) and posttraumatic macular lesions, respectively.

No complications occurred during surgery, including the absence of ocular hypotony. In comparison, techniques such as sclerotomy and handshake technique require intraoperative haptic extrusion during intrascleral IOL fixation and are usually associated with hypotony or eye instability [12].

Moreover, we did not experience any ocular hypotony in the postoperative period, which is known to occur in intrascleral haptic fixation [13]. This is due to the small corneal incision when compared to our previous technique making it as small as for a standard cataract surgery and to limited transecting of the sclera with one-way passage of the 10.0 polypropylene needle. Yamane et al. had to develop a thin-wall needle to overcome the latter complication with their approach [14]. We had no ocular postoperative bleeding in our series, which might be related to the appropriate localization of the sulcus with trans-illumination, small needle diameter, and finally, the apposition of haptics which plug the holes made in the sclera. Regarding the long-term outcomes and the rising concern about lens opacification, especially with the hydrophilic IOLs, our technique uses the hydrophobic AMO AR40e [15].

In our study, the IOLs were well centered postoperatively without any clinically significant tilt. When considering the haptics of sulcus IOLs, their designed position is within the sulcus with their extremities being curved toward the back and the center of the eye. If they are placed outside of this position, they will exert a counterpressure and, as a result, tilting/decentration of the IOL's optic or haptic extrusion might happen [16, 17]. Placing the haptics in their "physiological" position with 2 threads of 10-0 polypropylene guarantees a central position of the IOL with no tilting or instability. However, those results might not be reproduced if the suture is performed on haptics with an eyelet or with only one suture per haptic [18, 19].

Another advantage of this small incision technique is low induced astigmatism with less than 1 diopter depending on the incision placement on the steep or flat meridian. In a clear corneal approach for angular support IOL or for iris clipped IOL, the induced astigmatism might reach up to 3 diopters [20]. In the example of a Carlevale IOL (Soleko SPA, Pontecorvo, Italy), implanted through a clear corneal incision of 2.75–3.00 mm [21], vision too might be significantly decreased, depending on the preoperative amount of astigmatism and the localization of the steep axis [22].

Finally, one major advantage of this technique is its accessibility in any operating room and its low cost as no special instruments nor any assistant are required.

On the downside, our technique has a learning curve and surgery time substantially decreased from patient 1 to patient 3. Still, an 80 minute surgery is longer than the 54-minute time needed to implant the Carlevale IOL [23]. These time figures are consistent with reports comparing the time necessary for flanged vs. sutured IOLs (20 vs. 50 minutes) [16]. Surgery time could be decreased by fixating the lower haptic with the lens

Table 1: Evolution of visual acuity, spherical equivalent, astigmatism, and intraocular pressure in the patient population.

Patient: $n = 3$	Preoperative	Postoperative	Change
Visual acuity (logMAR)	0.22	0.22	0
	0	−0.1	−0.1
	0.9	0.7	−0.2
Refraction in spherical equivalent	+10.25	−2.25	−12.5
	+11	−0.75	−11.75
	+13	−1.25	−14.25
Astigmatism (in diopters/axis in degrees)	−1.5/87°	−2.25/79°	−0.75
	−1.25/116°	−1.5/128	−0.25
	−2.75/180°	−2.75/1°	0
Intraocular pressure (mmHg)	14	16	
	20	14	
	16	14	

Table 2: Details of preoperative iris status and postoperative IOL centration and tilt in the patient population.

Patient number	1	2	3
Preoperative iris status	Iridodonesis	Damaged sphincter	Damaged sphincter and anterior synechia
IOL centration	Centered	Centered	Centered
IOL tilt	Minor	Minor	Minor
Surgery time (minutes)	140	90	80

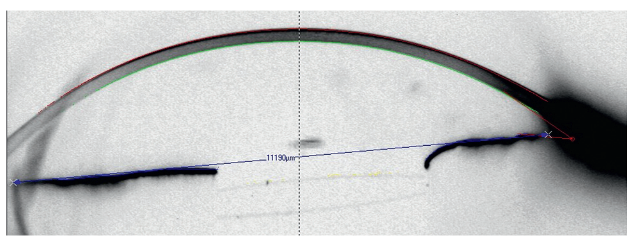
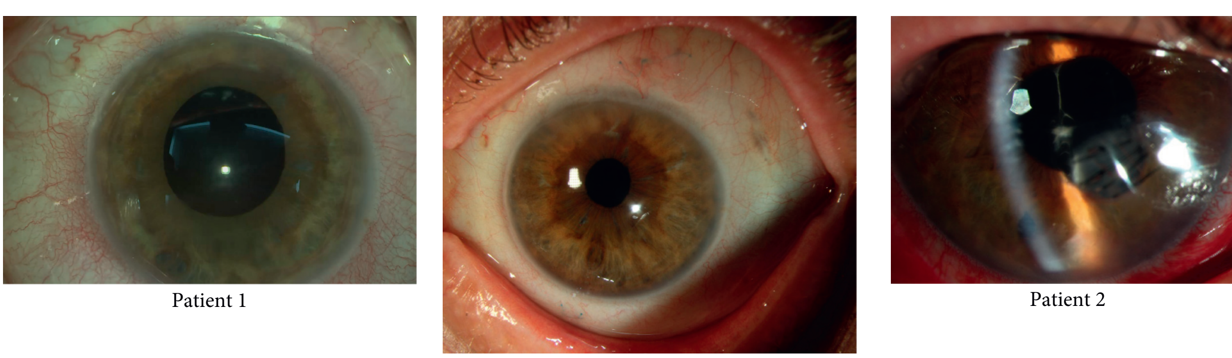
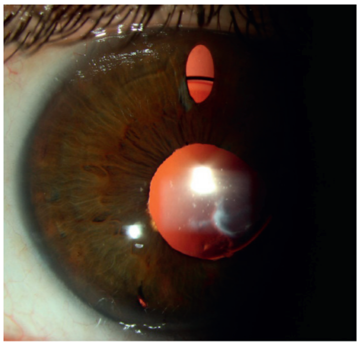


Figure 2: Scheimpflug image of patient 2 in the horizontal meridian with a well-centered IOL and only minor tilt (the blue line connects each angle and is more reliable due to the damaged iris to assess the IOL tilt).



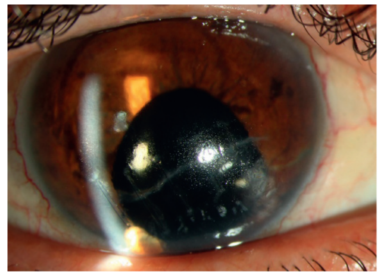
(a) (b) (c)

Figure 3: Continued.



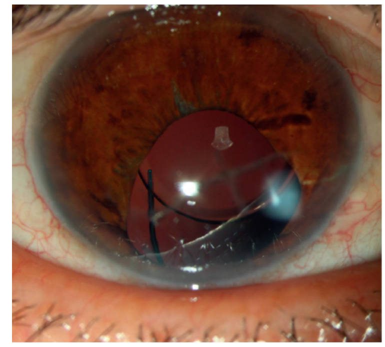
Patient 2

(d)



Patient 3

(e)



Patient 3

(f)

Figure 3: Patient 1: (a) preoperative aphakia with some degree of correctopia and iridodonesis and (b) postoperative slit lamp image; note the 10-0 polypropylene suture visible under the conjunctiva with round ends at 1 and 7 o'clock. Patient 2: (c) preoperative aphakia with remnants of capsular bag and iris sphincter damage and sutured corneal wound and (d) postoperative image with a well-centered IOL as seen through the upper iridotomy. Patient 3: (e) preoperative aphakia, corneal scar, and lower iris sphincter damage with peripheral anterior synechia and (f) well-centered IOL postoperatively. Note the vertical orientation of the lower haptic confirming centration.

still in the cartridge or even by attaching the suture to both haptics before inserting into the cartridge. Unfortunately, the AR40e manufacturer recommends injecting the implant as soon as possible when loaded into the cartridge or at least within 5 minutes to avoid any risk of IOL damage. Fixing the 10-0 polypropylene on the haptic might also be confusing in this position, and an easy error of crossing of the 10-0 polypropylene might waste all time potentially gained. IOL damage was also described when passing through the injector in the presence of the suture with higher risk of disinsertion [24].

A major limitation of our study is the low number of cases and short follow-up; studies have shown that late IOL dislocation occurs after 3-4 years [8, 25]. However, our technique is a less invasive adaptation of our previous one, published in 2003 with a case series of 50 cases and a mean follow-up of 30 months, proving its safety [7].

Another challenge is the refraction target, which must be improved as we experienced a myopic shift in all cases. This could be partially explained by the irregular shape of the traumatized cornea of patients 2 and 3 [26].

Lastly, the difficulty of our technique is that it requires the utmost surgeon concentration when manipulating the 10-0 polypropylene threads and caution is needed to avoid any suture crossing.

In conclusion, many surgical techniques of IOL implantation exist, with each having its own set of advantages and inherent postoperative complications. To date, there is no evidence of superiority of any single technique [27]. We have improved our scleral sutured lens technique in order to allow for the implantation of an IOL through a 2.45 mm corneal incision and suturing with 4 scleral needle passes. This improves peroperative ocular stability, decreases postoperative complication rate, and offers a rapid recovery with a stable visual acuity within a month.

Data Availability

Raw data are available in the supplementary file.

Conflicts of Interest

The authors have no conflicts of interest.

Supplementary Materials

The raw dataset is available in the supplementary file. (*Supplementary Materials*)

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