

# New surgical approach for sutureless scleral fixation

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## Abstract

**Purpose:** The aim of this article is to describe a novel surgical technique for sutureless scleral fixation of an intraocular lens using the newly developed FIL SSF Carlevale IOL (Soleko, Italy).

**Methods:** Four eyes of four patients with poor capsular support were recruited to our study, three resulting from intraocular lens subluxation and one case resulting from traumatic cataract. A novel sutureless sclera-fixated intraocular lens was implanted into the posterior chamber of each eye with sclerocorneal plugs fixating the lens to the wall of the eye.

**Results:** Mean age of patients was  $52 \pm 16$  years, ranging from 35 to 70 years. Mean follow-up was  $6.50 \pm 1.29$  months (range: 5–7 months). Mean preoperative best-corrected visual acuity was  $0.50 \pm 0.33$  logMAR (range: 1–0.3 logMAR). Postoperative best-corrected visual acuity improved to  $0.08 \pm 0.08$  logMAR (range: 0.2–0 logMAR). There was no significant change in the mean intraocular pressure and there were no postoperative complications, such as iatrogenic distortion or breakage of the intraocular lens haptic, intraocular lens decentration, endophthalmitis, or retinal detachment.

**Discussion:** To the best of our knowledge, this is the first report of outcomes using the novel sutureless sclera-fixated FIL SSF Carlevale IOL. This new surgical technique offers a simplified and effective approach for sutureless scleral intraocular lens fixation with good refractive outcomes.

## Keywords

Intraocular lens, lens/cataract, surgical instruments/special techniques, secondary intraocular lens implantation, phacoemulsification, lens changes

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## Introduction

Techniques for intraocular lens (IOL) placement in cases where capsular support is lacking have evolved considerably over the years. Sutureless sclera-fixated IOL techniques are the most recently introduced solutions, with Scharioth and Pavlidis first describing a method of sutureless intrascleral IOL fixation in 2007. Sutureless sclera-fixated IOL surgery was developed to reduce or eliminate suture-related complications of scleral sutured IOL, such as suture breakage or degradation, endophthalmitis, and chronic inflammation.<sup>1–5</sup> Despite the large learning curve for surgeons learning sutureless sclera-fixated IOL surgery, studies have shown that these techniques are safe and provide good refractive outcomes for patients.<sup>4,5</sup>

At present, scleral-fixated posterior chamber IOL surgery is widely regarded as a safe and efficacious method of implanting an IOL in eyes with inadequate capsular support. We report a novel surgical technique of sutureless

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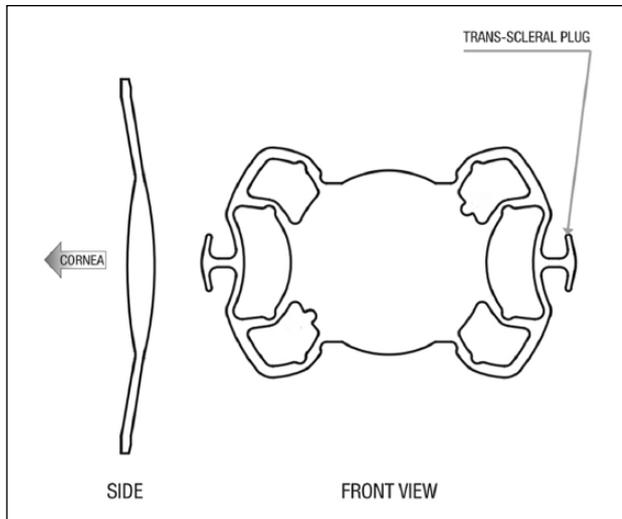
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**Figure 1.** FIL SSF Carlevale intraocular lens with trans-scleral plugs on haptics.

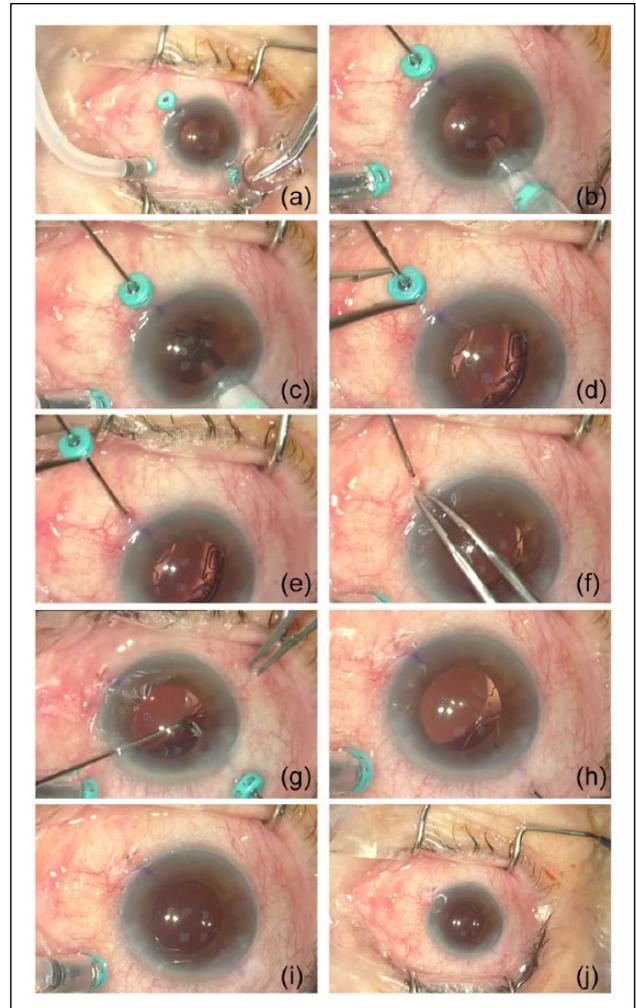
intrascleral posterior chamber IOL fixation using the newly developed FIL SSF Carlevale IOL.

## Methods

Patients were recruited to undergo a novel surgical technique of sutureless intrascleral posterior chamber IOL fixation at the University of Bologna Hospital (Policlinic S. Orsola-Malpighi, Bologna, Italy). Complete ophthalmic examinations were performed preoperatively including measurement of best-corrected visual acuity (BCVA), slit lamp examinations, Goldmann applanation tonometry, as well as anterior segment and dilated fundus examinations. We calculated the IOL power using LenStar LS 900 (Haag Strait) optical biometry and utilizing an A-constant of 118.5 for the IOL, as suggested by the IOL manufacturer. Traditional IOL power calculations are based on endocapsular IOL localization. In general, IOL power should be decreased as the lens is positioned further anteriorly within the eye (typically by a half or full diopter for placement in the ciliary sulcus or iris fixation). Some studies of extracapsular fixation report using the SRK II formula for baseline IOL power calculation.<sup>6,7</sup>

## Surgical technique

**IOL.** The new FIL SSF Carlevale IOL (Soleko, Italy) is a foldable one-piece acrylic IOL with a novel design of flexible sclerocorneal plugs on the end of two haptics meant to be implanted and anchored in the sclera in a sutureless fashion (Figure 1). With an optic diameter of 6.5 mm and a total length of 13.2 mm, the lens is specifically engineered for intrascleral implantation posterior to the iris. The lens is composed of a 25% H<sub>2</sub>O acrylic with an ultraviolet (UV) filter and is available in IOL powers ranging from -5.0 to +35.0 diopters.



**Figure 2.** Scleral fixation without scleral tunnels using FIL SSF Carlevale intraocular lens: (a) visualization of IOL before insertion, (b) the IOL injector is inserted into the anterior chamber, (c) the IOL is pushed forward until the first plug is seen in the anterior chamber and captured by forceps, (d, e) the first plug is externalized by removal of both the trocar and the forceps, (f) extraction of the first plug, (g) the second plug is captured by forceps, (h) the second plug is externalized along with the second trocar and forceps, (i) visualization of both plugs externalized, and (j) removal of the final trocar.

**Scleral fixation.** Following a standard 25-gauge three-port pars plana vitrectomy (Constellation 25-Gauge System; Alcon, Inc., Hunenber, Switzerland), two trocar sites are marked with surgical ink 180° away from one another at the 5 o'clock and 11 o'clock positions 1.5 mm posterior to the limbus, with care taken to ensure that the trocar sites are 180° away from one another. A third trocar site for an infusion canula is marked at the 1 o'clock position 3.5 mm posterior to the limbus (Figure 2(a)). All trocars are then placed in a standard trans-conjunctival fashion.

A clear corneal incision of 2.75 mm is created at the 12 o'clock position to insert the IOL into the eye using the

injector. The IOL is inserted into the anterior chamber (Figure 2(b)) while 25-gauge intraocular forceps are inserted through the trocar 180° away, with care taken to grab the sclerocorneal plug on the haptic as the IOL enters the eye (Figure 2(c)). With the assistance of the forceps, the leading sclerocorneal plug and haptic is placed carefully behind the iris. The IOL is then drawn completely into the posterior chamber of the eye using the leading sclerocorneal plug (Figure 2(d)). The forceps holding the sclerocorneal plug are withdrawn from the eye along with the inferior trocar, which positions the sclerocorneal plug outside of the eye (Figure 2(e)). The surgeon then confirms the correct positioning of the acrylic plug extending completely through the sclera (Figure 2(f)). The same procedure is then performed for the second sclerocorneal plug superiorly (Figure 2(g)–(i)). Care is taken to ensure that the optic vaults posteriorly so as to avoid pupillary block.

At the end of the surgery, the infusion canula and final trocar is removed. All sclerocorneal plugs are covered by intact conjunctiva (Figure 2(j)). Finally, intact sclerotomy sites without leakage are confirmed (Supplemental Video 1).

## Results

A total of four patients (four eyes), one female and three males, were included in our study. Three eyes had IOL subluxation and one eye had a traumatic cataract. Mean patient age was  $52 \pm 16$  years, ranging from 35 to 70 years. Mean follow-up was  $6.50 \pm 1.29$  months (range: 5–7 months). Mean preoperative BCVA was  $0.50 \pm 0.33$  logMAR (range: 1–0.3 logMAR). Postoperative BCVA improved to  $0.08 \pm 0.08$  logMAR (range: 0.2–0 logMAR). There was no significant change in the mean intraocular pressure (IOP) (preoperative IOP:  $16.50 \pm 2.65$  mmHg; postoperative IOP:  $17.25 \pm 3.59$  mmHg). There were no postoperative complications, such as iatrogenic distortion of the IOL, breakage of IOL haptic, IOL decentration, endophthalmitis, or retinal detachment. Macular optical coherence tomography (OCT) did not reveal cystoid macular edema (CME) in any eyes. IOL haptics remained well seated within the sclera without erosion through the conjunctiva and without any local inflammatory reaction.

## Discussion

IOL placement in patients with poor zonular support can be a challenge, though many options now exist for surgical implantation of an IOL in these eyes. Zonular weakness can be the result of ocular trauma, zonular or capsular trauma after complex cataract surgery, or medical conditions resulting in poor zonular support such as Marfan syndrome, pseudoexfoliation syndrome, or homocystinuria. Placement of an IOL in the capsular bag is often not possible or prudent in these cases due to the risk of dislocation or subluxation and the need for potential subsequent

surgical intervention. When capsular support is lacking, many surgeons choose to implant either an anterior chamber intraocular lens (ACIOL), an iris-fixated intraocular lens (IFIOL), or a scleral-fixated intraocular lens (SFIOL).

In 2003, the American Academy of Ophthalmology undertook a comprehensive review of the literature surrounding IOL implantation in the absence of capsular support.<sup>8</sup> Secondary IOLs, such as ACIOLs, IFIOLs, and SFIOLs were compared in terms of efficacy, safety, and complication rates. Based on the available studies at that time, the conclusion was that insufficient evidence existed to recommend any one type of IOL over any other for patients in whom all three options were available. ACIOLs, IFIOLs, and SFIOLs all had the potential for good refractive outcomes with favorable risk–benefit profiles.<sup>9–13</sup> Since the publication of the Academy's report, conflicting literature has been published on the relative efficacy and safety of ACIOLs compared to SFIOLs. Chan et al.<sup>14</sup> compared primary ACIOL implantation to SFIOL surgery following complicated cataract surgery. This study suggested that primary ACIOL implantation was associated with better visual outcomes and fewer complications. More recent studies fail to bear this out and are more in line with the conclusion of the 2003 report.<sup>14–17</sup> While prior studies assessing sclera-fixated IOL methods report excellent visual acuity outcomes, the small number of patients and short follow-up period of our study make it difficult to compare patient populations or draw conclusions on relative visual outcomes.

Each surgical approach to IOL implantation has its own unique set of advantages and disadvantages, which should all be considered carefully during preoperative evaluation and planning. ACIOLs are accessible for anterior segment surgeons without the need for vitrectomy but require solid anterior segment support and have a theoretical risk of corneal decompensation, erosion into angle structures, pupillary block, and CME. IFIOLs are also accessible for anterior segment surgeons but may cause iris chafing and require intact iris and anterior segment support. SFIOLs are placed in a more physiologic lens location, and dislocated posterior chamber IOLs may be able to be salvaged and utilized, thus preventing lens exchange. However, SFIOLs have a risk of suprachoroidal or vitreous hemorrhage, retinal detachment, lens tilt, or lens dislocation. Scleral sutured IOLs in particular run the risk of suture erosion and associated risk of endophthalmitis, lens tilt, or lens dislocation caused by broken suture material which is more common with 10-0 polypropylene suture than suture materials such as gore-tex. These risks can be prevented using sutureless techniques. Yamane<sup>18</sup> detailed a novel sutureless sclera-fixated IOL technique in 2017 whereby the haptics of a three-piece IOL are externalized and cauterized to create small flanges, effectively fixating the IOL haptics in the wall of the eye. Agarwal<sup>19</sup> detailed an alternative method whereby the externalized IOL haptics were glued in partial thickness limbal scleral flaps using fibrin. Scharioth developed a third method of externalizing the haptics of an IOL

through straight sclerotomies and embedding the haptics in 2- to 3-mm scleral tunnels adjacent to the sclerotomies.<sup>20</sup> We report another novel technique of fixating an IOL to the sclera in a sutureless fashion.

The sutureless scleral fixation (SSF) technique using the Carlevalle IOL with the specially designed sclerocorneal plugs prevents the haptic back into the eye after fixation to the sclera, preserves conjunctiva, and reduces suture-related complications, surgery time, and complexity due to the lack of scleral pockets. In addition, based on our experience, the Carlevalle IOL can minimize IOL torsion and decentration due to secure placement of the haptics through the sclera using the sclerocorneal plugs. It is worth noting that the lens comes in a range of lens powers from  $-5.0$  diopters to  $+35.0$  diopters at 0.5 diopter steps.

Our study has limitations, including the small size of our case series and short follow-up period. However, we offer a new approach for SFIOL implantation using a novel IOL.

In conclusion, this novel surgical technique is safe and effective in providing good refractive outcomes in cases of poor capsular support and where aphakia is not desired. While we have implanted this novel IOL in nine patients, longer follow-up periods are required to verify the safety, advantages, and disadvantages of this new surgical technique.

### Authors' note

This study was performed in the Ophthalmology Unit, Sant'Orsola-Malpighi Hospital, University of Bologna, Bologna, Italy.

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### Supplemental material

Supplemental material for this article is available online.

### References

- Karadag R, Celik HU, Bayramlar H, et al. Sutureless intrascleral fixated intraocular lens implantation. *J Refract Surg* 2016; 32(9): 586–597.
- Gabor SGB and Pavlidis MM. Sutureless intrascleral posterior chamber intraocular lens fixation. *J Cataract Refract Surg* 2007; 33: 1851–1854.
- Nudleman E, Yonekawa Y and Prenner JL. Sutureless transscleral fixation of secondary intraocular lenses. *Curr Opin Ophthalmol* 2018; 29: 210–216.
- Yoshida N, Kojima T, Yokoyama S, et al. New surgical approach for intrascleral fixation using an intraocular lens with hook-shaped haptics. *J Cataract Refract Surg* 2018; 44(2): 129–133.
- Wagoner MD, Cox TA, Ariyasu RG, et al. Intraocular lens implantation in the absence of capsular support: a report by the American academy of ophthalmology. *Ophthalmology* 2003; 110: 840–859.
- Jin GJC and Jones JJ. Intraocular lens power calculation in special occasions. In: Olson RJ and Jin GJC (eds) *Cataract surgery from routine to complex: a practical guide* (1st ed.). Thorofare, NJ: SLACK Incorporated, 2011, pp. 59–65.
- Al-Qahtani FA. Scleral fixation of intraocular lenses combined with penetrating keratoplasty. *J Cataract Refract Surg* 2010; 36(3): 373–376.
- Lyle WA and Jin JC. Secondary intraocular lens implantation: anterior chamber vs posterior chamber lenses. *Ophthalmic Surg* 1993; 24(6): 375–381.
- Bellucci R, Pucci V, Morselli S, et al. Secondary implantation of angle-supported anterior chamber and scleral-fixated posterior chamber intraocular lenses. *J Cataract Refract Surg* 1996; 22(2): 247–252.
- Schein OD, Kenyon KR, Steinert RF, et al. A randomized trial of intraocular lens fixation techniques with penetrating keratoplasty. *Ophthalmology* 1993; 100(10): 1437–1443.
- Sugar A. An analysis of corneal endothelial and graft survival in pseudophakic bullous keratopathy. *Trans Am Ophthalmol Soc* 1989; 87: 762–801.
- Davis RM, Best D and Gilbert GE. Comparison of intraocular lens fixation techniques performed during penetrating keratoplasty. *Am J Ophthalmol* 1991; 111(6): 743–749.
- Kwong YY, Yuen HK, Lam RF, et al. Comparison of outcomes of primary scleral-fixated versus primary anterior chamber intraocular lens implantation in complicated cataract surgeries. *Ophthalmology* 2007; 114: 80–85.
- Chan TC, Lam JK, Jhanji V, et al. Comparison of outcomes of primary anterior chamber versus secondary scleral-fixated intraocular lens implantation in complicated cataract surgeries. *Am J Ophthalmol* 2015; 159: 221–226.
- Hazar L, Kara N, Bozkurt E, et al. Intraocular lens implantation procedures in aphakic eyes with insufficient capsular support associated with previous cataract surgery. *J Refract Surg* 2013; 29(10): 685–691.
- Melamud A, Topilow JS, Cai L, et al. Pars plana vitrectomy combined with either secondary scleral fixated or anterior chamber intraocular lens implantation. *Am J Ophthalmol* 2016; 168: 177–182.
- Kim KH and Kim WS. Comparison of clinical outcomes of iris fixation and scleral fixation as treatment for intraocular lens dislocation. *Am J Ophthalmol* 2015; 160: 463–469.
- Yamane S, Sato S, Maruyama-Inoue M, et al. Flanged intrascleral intraocular lens fixation with double-needle technique. *Ophthalmology* 2017; 124(8): 1136–1142.
- Agarwal A, Kumar DA, Jacob S, et al. Fibrin glue-assisted sutureless posterior chamber intraocular lens implantation in eyes with deficient posterior capsules. *J Cataract Refract Surg* 2008; 34(9): 1433–1438.
- Pavlidis M, de Ortueta D and Scharioth GB. Bioptics in sutureless intrascleral multifocal posterior chamber intraocular lens fixation. *J Refract Surg* 2011; 27(5): 386–388.