Enhanced surgical technique for sutureless intra-scleral fixation intraocular lenses.

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ABSTRACT

We describe a simplified intra-sclera fixation technique involving implantation of the Carlevale IOL in the posterior chamber that lodges the T-shaped IOL haptics in the scleral wall, not requiring scleral flaps. This surgical modification reduces operative time, limits iatrogenic damage to the sclera and avoids friction between haptics and conjunctiva, which may cause conjunctival erosion and infection in the long term. Thirteen patients with crystalline lens or IOL dislocation/subluxation underwent surgery involving implantation of the Carlevale IOL in the posterior chamber. Mean best-corrected visual acuity (BCVA) before surgery was 0.75 ± 0.5 logMAR (range: 0.2 – 1.5 logMAR) and improved to 0.28 ± 0.3 logMAR (range: 0 - 1.0 logMAR) after surgery. Complications rarely occurred and were not sight threatening. The sutureless scleral fixation of the Carlevale IOL utilizing the modified surgical technique may represent a safe and effective procedure to restore visual function in patients with damaged zonular-capsular support.
INTRODUCTION

Cataract microincisional surgery with phacoemulsification and implant of an in-the-bag foldable intraocular lens (IOL) currently represent the gold standard procedure to restore visual function in patients with cataract related visual impairment or blindness.\(^1\) In-the-bag IOL dislocation and/or subluxation following uncomplicated cataract surgery can occur months or years after surgery, due to zonular weakness and rupture.\(^2,3\) Pseudoexfoliation (PEX) is the most commonly associated condition in patients with zonular weakness, accounting for more than a half of all cases. Other causes of dislocation/subluxation include trauma, connective tissue disorders, high myopia, prior vitrectomy and uveitis.\(^4,5\) This complication can also occur for not evident/unknown reasons. Zonular rupture and capsular instability can also be present preoperatively like in traumatic cataracts.\(^4\)

Scleral fixation of an IOL represents a safe and effective procedure to restore visual function when zonular and capsular support is compromised. Different surgical techniques have been described to execute this type of implant with sutureless procedures becoming popular due to the absence of suture-related complications such as scleral erosion, haemorrhage, chronic inflammation, suture degradation and IOL tilting, damaging or displacement.\(^6,7\) Intrascleral sutureless fixation was firstly described by Gabor and Pavlidis in 2007,\(^8\) and several variants with specific names and features have been introduced since then, such as the glued-IOL,\(^9\) the Yamane double needle\(^10\) and the Y-fixation\(^11\) techniques. In our study, we describe a case series of sutureless intrascleral IOL fixation using a recently introduced IOL (FIL SSF Carlevale, Soleko, Italy) with a modified surgical technique.

METHODS

This study includes patients assessed retrospectively with either traumatic cataract or dislocated in-the-bag IOL with insufficient zonular and capsular support that underwent sutureless intrascleral
fixation of Carlevale IOL with 25-gauge via-pars-plana vitrectomy. All patients were operated in our Ophthalmology Department at the University Hospital of Udine, Italy from December 2018 to October 2020. The study was in compliance with the tenets of the Helsinki’s Declaration, and written informed consent was obtained from all participants prior to testing. The study was in compliance with institutional review boards (IRBs) and HIPAA requirements of the University Hospital of Udine, Italy.

The analysis included presence of PEX, history of trauma or any other possible cause of lens or IOL dislocation, BCVA values (using LogMAR notation) at baseline and at the follow-up visits, ocular comorbidities, surgery duration and complications. All patients underwent a complete anterior segment and dilated posterior segment slit-lamp examination at each preoperative and postoperative visit. B-scan ultrasound and A-scan biometry were executed when fundus examination and optical IOL power calculation were not possible due to media opacities (e.g. vitreous haemorrhage).

**Intraocular lens characteristics and design**

The aim of our study was to assess the surgical and functional results obtained with the sutureless intrascleral implant of a novel foldable IOL (FIL SSF Carlevale, Soleko Inc., Italy) (Figure 1). This lens was specifically designed for intrascleral fixation and equipped with T-shaped plugs designed to anchor the IOL, in which the T-shaped extremities can be easily positioned and buried within the scleral thickness without suturing. The haptics have a 10° anterior inclination with respect to the 6.5 mm optic plate, with an overall IOL length of 13.2 mm. The flexibility and elasticity of this lens help to maintain the IOL in a physiological position, even in significantly myopic or hyperopic eyes. The IOL has a 118.5 A-constant and is available with a broad range of refractive powers, starting from − 5 to + 35 diopters. Customized toric versions of the lens also exist to correct astigmatism up to 10 diopters. The hydrophilic single-piece lens is very soft and easily foldable,
thus permitting intraocular injection through a 2.2 mm corneal incision, by means of a dedicated injector.

Surgical Technique

The surgical procedure is performed under local anaesthesia, which is obtained with a retrobulbar injection of lidocaine and bupivacaine. After sterile eye prepping and draping, a circumscribed conjunctival peritomy is performed to expose the sclera at 3 o’clock and 9 o’clock (Figure 2A), then a gentle scleral diathermocoagulation is delivered on the sclera to prevent excessive bleeding. The procedure continues with 2 radial partial thickness 2 to 3 mm long sclerotomies at 3 e 9 o’clock using a 30º knife (Alcon Ophthalmic Knife 30º, Alcon, Inc., Hunenberg, Switzerland) (Figure 2B).

Four scleral pockets are then created, one on each margin of the two radial sclerotomies, using a crescent knife (Sharpoint Sharptome 1.25 mm Mini-Crescent Knife Angled, Surgical Specialties Corporation, Westwood, MA, USA; Figure 2C and 2D). The pockets must be at the appropriate depth and of the right size to stably host the IOL T-shaped plugs at the end of the surgery, therefore the dissection is made with the upper face of the crescent blade barely visible while tangentially proceeding in the scleral depth up to approximately half of the blade length (Figure 2D). Three 25-gauge cannulas are placed at 3.5 mm from the limbus, with an inferotemporal endoilluminated high-flow infusion (Synergetics USA Inc., O’Fallon, MO, USA). A 2.7 - 3 mm main corneal incision and secondary corneal incisions are performed and viscoelastic is injected to safely extract the dislocated lens and capsular bag.

Adequate mydriasis can be obtained mechanically using disposable iris retractors (Alcon Grieshaber Flexible Iris Retractors, Alcon, Inc., Hunenberg, Switzerland) requiring additional small corneal accesses or a specific preloaded silicone ring shaped pupil dilator (I-Ring Pupil Expander, Beaver-Visitec, Heidelberg, Germany) introduced thorough the main incision (Figure 2E). The anterior vitreous and possible capsular remnants are then removed via pars plana vitrectomy (Constellation 25-Gauge System; Alcon, Inc., Hunenberg, Switzerland or Stellaris PC 25-Gauge...
System; Rochester, NY, USA). Vitrectomy can be extended to posterior and peripheral vitreous depending on specific circumstances (e.g. combined macular surgery, penetrating trauma involving vitreous, vitreous haemorrhage). Full thickness scleral holes are obtained along the radial sclerotomies at 1.5 mm distance from the limbus, using a 25-gauge needle.

The Carlevale IOL is then partially injected into the anterior chamber, its distal haptics is then grasped using a 25-gauge forceps (either crocodile or Eckardt forceps) introduced through the homolateral scleral hole (Figure 2F). The IOL is then completely released in the anterior chamber and the distal haptic gently pulled out, exposing the T-shaped plug on the sclera and avoiding the IOL to fall into the vitreous chamber (Figure 2G). At this point the proximal haptic is similarly pulled out through the other scleral hole. The extremities of the 2 T-shaped of the haptics are then placed in the scleral pockets in order to obtain the IOL sutureless intrascleral fixation (Figure 2J and 2H). The manipulation of the IOL must be particularly delicate and decisive in order to avoid haptics damage. Corneal accesses are sealed by hydrosuture, then vitrectomy cannulas are removed and their corresponding sclerotomies are sealed using diathermocoagulation. Finally the conjunctiva is sealed with absorbable sutures (Vicryl 8-0, Ethicon, Inc., Bridgewater NJ, USA) to complete surgery (Figure 2K).

RESULTS

Our case series was composed of 13 patients: 3 females and 10 males, with a mean age of 75.2 ± 8.8 years (range: 58 to 91), of which 11 showed unilateral in-the-bag IOL dislocation and 2 had traumatic cataract with zonular damage. Crystalline lens or IOL and capsular bag were displaced behind the iris/in the anterior vitreous in all 13 eyes. In the 11 pseudophakic patients, the dislocation occurred 19.8 ± 26.6 months (range: 2 to 46) after the primary cataract surgery and was spontaneous in 8 patients, 4 of which had PEX and 4 without evident causes. Closed-globe ocular trauma caused the IOL displacement in 2 pseudophakic patient, one of them had PEX. The mean
BCVA at baseline was 0.75 ± 0.5 LogMAR and improved to 0.28 ± 0.3 LogMAR (p < 0.001, paired t test) at the last follow-up visit. The average follow-up was 7.5 ± 7 months.

The surgery duration was 60 ± 16 minutes (range: 37 to 90). Additional surgical procedures in selected cases included: the use of a pupillary dilatation ring (I-Ring® Pupil Expander, Beaver Visitec, USA) for insufficient mydriasis in one case; and a complete vitrectomy in the 2 eyes, which was needed to peel a macular epiretinal membrane following a penetrating injury, and for traumatic vitreous haemorrhage, respectively. One IOL haptic broke in one case during manipulation, when the plug was pulled through the sclerotomy, thus surgery was prolonged for the removal of the damaged IOL and substitution with the new IOL, which was easily performed thanks to the IOL softness.

Postoperative complications included early transient and self-limiting vitreous hemorrhage in one case, with bleeding from a sclerotomy, and mild endophthalmitis in one patient. In the latter case, which was a spontaneous IOL dislocation in a patient with PEX, the surgical time was the shortest of our series (37 min), the IOL exchange with intrascleral fixation intervention proceeded without any relevant issue, anterior vitrectomy was performed via pars plana, with no external vitreous loss and 1mg of cefuroxime was injected in the anterior chamber at the end of the surgery and sclerotomies were sutured. Nevertheless, a mild endophthalmitis occurred and was successfully treated with intravitreal injections of vancomycin 1mg/0.1 ml and ceftazidime 2.25mg/0.1ml on the 9th and 11th day after surgery. Transient intraocular pressure (IOP) elevation was observed in 2 cases in the first postoperative days and controlled with hypotensive eye drops (dorzolamide 2% + timolol 0.5%).

**DISCUSSION**

IOL implant in eyes with zonular and capsular support insufficiency has been broadly discussed in the last decades, when pseudophakia has become common in the elderly population. Several surgical techniques have been described to safely restore visual function. Studies describing anterior
chamber IOLs, iris-fixation IOLs and scleral fixation IOL were described in 2003 in a report by the American Academy of Ophthalmology that found no evidence to recommend any of these techniques over the others.\textsuperscript{12} Advantages and disadvantages exist for each of these solutions: iris-fixation and anterior chamber implants can be more easily performed by anterior-segment surgeons but require adequate anterior chamber amplitude and may compromise the anterior segment integrity leading to complication such as endothelial cells loss (that may lead to severe corneal decompensation), pupillary block, iris traumatism, irido-corneal angle narrowing and structural damage impairing aqueous drainage.\textsuperscript{13}

Scleral-fixation allows for a more posterior and physiologic IOL placement and is preferable in cases of shallow anterior chamber or augmented risk for corneal decompensation, such as Fuch’s dystrophy, or in patients that have undergone corneal transplant. There are, however, risks of complications, which include suprachoroidal and vitreous hemorrhages, retinal detachment and suture-related complications such as scleral erosion, hemorrhages and IOL tilting and dislocation.\textsuperscript{13} Potential vitreoretinal and choroidal complications may represent a disincentive to choose sclera fixation for surgeons with limited experience in posterior segment surgery or in surgical settings where there is no possibilities of promptly managing these complications.

Scleral fixation surgery has evolved over time to reduce such risks. Sutured scleral fixation involved the use of non-absorbable sutures (either polypropylene o Gore-Tex) tied to the 2 IOL haptics and to the sclera. Lewis reported an important contribution in this matter by proposing the ab-externo suturing technique to anchor the IOL to the sclera wall avoiding the large corneal cuts required in previous ab-interno techniques.\textsuperscript{14} Further advances to reduce the ocular tissues manipulation and suture-related issues were then proposed, which include Hoffmann pockets that spares conjunctival dissection and sutureless intrascleral fixation of three-piece IOLs, introduced by Gabor and later by other authors describing alternative strategies such as glued IOLs, Y-fixation technique, Yamane technique and its variants to reduce the haptic exposure.\textsuperscript{8-11,15-18} Intrascleral fixation studies have shown that these techniques proved to be effective, however, several problems
were reported due to the off-label use of 3-piece IOLs, and relevant IOL stability and centration issues.\textsuperscript{16,17}

These limitations have been addressed by the recent development of a single piece foldable IOL specifically conceived for sutureless intrascleral fixation (FIL SSF Carlevale, Soleko, Italy) with 2 T-shaped haptic that can be exposed under the conjunctiva or placed into properly created scleral pockets.\textsuperscript{13,18-20} Several recent reports have been published on this IOL intrascleral implant, describing its favourable surgical and functional outcomes.\textsuperscript{13,19-21} Veronese et. al reported positive functional results on 4 patients with traumatic cataracts and in-the-bag IOL dislocations and a mean follow-up of approximately 6 months.\textsuperscript{13} The technique reported in this study reported that the T-shape haptic extremities were left exposed under the conjunctiva and gave no significant complications such as endophthalmitis, retinal detachment, IOL damage or decentration.\textsuperscript{13} A study by Barca et al. described the intrascleral fixation of Carlevale IOL in a larger group composed of 32 eyes with aphakia or dislocated/subluxated IOLs having a mean follow-up of 8 months.\textsuperscript{19} The authors reported favourable surgical and refractive outcomes. The authors reported that IOL-related complications such as dislocation, conjunctival erosion or haptic externalization were avoided by hiding the T-shaped haptic under a sutured 4 x 4 mm scleral flap.\textsuperscript{19}

A study by Rossi et al. on 78 patients undergoing intrascleral implant of Carlevale IOL for a variety of surgical indications (i.e. dropped nucleus and/or lens fragments, dropped IOL, traumas, aphakia, intraocular lens exchange and Marfan syndrome) has recently been published. The study reported good functional results at 6 months with possible intra and postoperative complications in a small percentage of patients.\textsuperscript{20} Good refractive outcomes were recently described by D’Agostino et al. who compared the outcome of intrascleral fixation of Carlevale IOL, with or without scleral flaps and of three-piece IOLs with haptics inserted into scleral tunnels. The authors also observed that Carlevale IOL implant appeared easier, more comfortable and less time consuming in comparison to the three-piece IOL implants.\textsuperscript{21}
In our study, we describe a simplified intra-sclera fixation technique that lodges the T-shaped IOL haptics in the scleral wall, which does not require scleral flaps, sutures or fibrin glue. Diego Ruiz-Casas showed a case of the same technique in a recent surgical video, http://links.lww.com/JRS/A384, in which the radial sclerotomies were secured with suturing. To the best of our knowledge, this is the first case series based on the suture-less version of this technique. This surgical modification and IOL design allow for a simpler execution, shorter operative time without suturing and the associated inflammation still allowing a stable intrascleral lodging for the IOL plugs that also protects the conjunctiva from direct friction and potential erosion, sub conjunctival aqueous leakage and infection. The retrospective design, small number of cases and the short follow-up clearly represent significant limitations of our study, however, our results with this modified surgical technique can be of potential clinical interest in enhancing surgical outcomes and reducing complications when using this new IOL. Further studies on larger group of patients with longer follow-up are required to better understand the potentials and the drawbacks of this type of implant.
VALUE STATEMENT

What was known

- Scleral fixation of IOLs is a safe and effective surgical method in patients with compromised zonular and capsular support. Postoperative complications are seldom, however, may occur even after long follow-ups.

What this paper adds

- Carlevale IOLs represent a valid and advantageous option in sutureless scleral fixation surgery in the treatment of lens subluxation and IOL bag dislocation.

- Our simplified intra-scleral fixation technique, which does not require scleral flaps, is advantageous in reducing operative time, providing proper IOL stability, and reducing postoperative complications and conjunctival erosions even after long follow-ups.
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FIGURE LEGENDS

FIGURE 1: The sutureless intrascleral foldable Carlevale IOL.

FIGURE 2A-2K: Surgical steps when implanting the Carlevale IOL. Circumscribed conjunctival peritomy is performed to expose the sclera at 3 o’clock and 9 o’clock (Figure 2A). Radial partial thickness sclerotomies at 3 e 9 o’clock (Figure 2B). Scleral pockets are then created, one on each margin of the two radial sclerotomies, using a crescent knife (Figure 2C and 2D). Mydriasis, that allows for dislocated IOL extraction, can be obtained mechanically using disposable iris retractors (Figure 2E). The Carlevale IOL is then partially injected into the anterior chamber (Figure 2F). The IOL is then completely released in the anterior chamber and the distal haptic gently pulled out, exposing the T-shaped plug on the sclera and avoiding the IOL to fall into the vitreous chamber (Figure 2G). The extremities of the 2 T-shaped of the haptics are then placed in the scleral pockets in order to obtain the IOL sutureless intrascleral fixation (Figure 2H and 2I). Corneal accesses are sealed, vitrectomy cannulas are removed, and sclerotomies and conjunctiva are sealed to complete surgery (Figure 2J).