


# Comparison of two different scleral fixation techniques of posterior chamber Carlevale lens

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## Abstract

To investigate the surgical outcomes of 2 different scleral fixation techniques of the new single-piece foldable acrylic Carlevale lens (Soleko) and to compare our results with previous reports of the literature.

A retrospective, non-randomized comparative study involving 2 series of patients who underwent 2 different scleral fixation techniques of Carlevale lens was performed. Minimum follow-up of 3 months was requested for inclusion in the study. All the patients underwent a standard ophthalmologic examination including best correct visual acuity, measurement of intraocular pressure, anterior segment, and fundus examination. In the first technique (group 1), plugs were externalized through a 23 gauge sclerotomy and placed within 2 scleral pockets. In the second technique (group 2), plugs were externalized through a 25-gauge sclerotomy and covered by 2 scleral flaps. For an estimation of the refractive prediction error, the postoperative spherical equivalent of objective refraction was calculated (IOL Master 750, Carl Zeiss Meditec AG, Jena, Germany). Spectral domain optical coherence tomography (Spectralis HRA +OCT2, Heidelberg Engineering, Heidelberg, Germany) of anterior segment was used to check plugs positioning postoperatively.

Twenty-three eyes in group 1 and 9 eyes in group 2 were included. Preoperative diagnosis was aphakia, dislocated posterior chamber intra ocular lens, dislocated lens, anisometropia, Uveitis-Glaucoma-Hyphema syndrome, perforating trauma with dislocated intra ocular lens, and open globe injury with dislocated intra ocular lens. Respectively, in groups 1 and 2, refractive spherical equivalent prediction error was  $-0,31 \pm 0,74$  D and  $-0,27 \pm 0,80$  D, and postoperative best-corrected visual acuity was  $0,42 \pm 0,31$  logMAR and  $0,47 \pm 0,45$  logMAR. In group 1, 1 eye developed cystoid macular edema, 1 eye vitreous haemorrhage, and 3 eyes showed plugs located outside the scleral pockets under the conjunctiva. Rupture of 1 of the 2 tips of the plug was observed in 1 patient of group 1 during the externalization.

Carlevale lens is a scleral fixated intra ocular lens specifically designed for posterior chamber implantation that could be successfully managed without any significant difference between the 2 surgical techniques, and appears approachable for anterior and posterior segment surgeons. A 25-gauge sclerotomy should be preferred with the aim of a sutureless surgery regardless the technique employed.

**Abbreviations:** AC = anterior chamber, CME = cystoid macular edema, IOL = intra ocular lens, PPV = pars plana vitrectomy, SFIOL = scleral fixated intra ocular lens, SO = silicon oil.

**Keywords:** Carlevale lens, secondary IOL implantation, sutureless scleral fixation

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A written consent was obtained from the patient for the purpose of publication of images.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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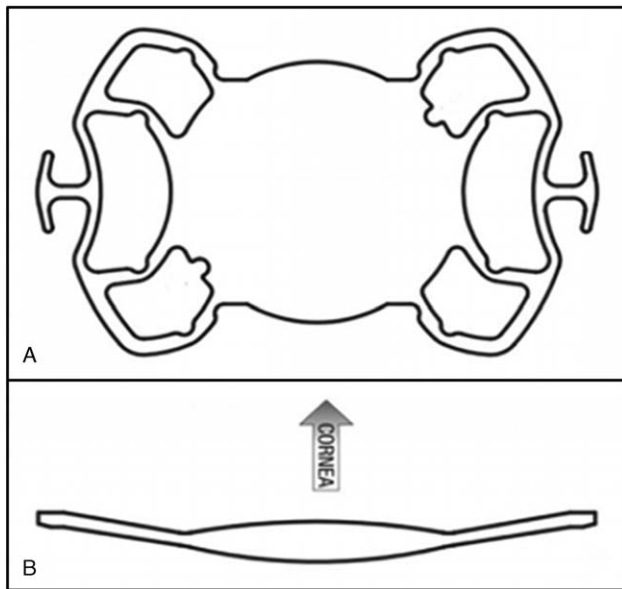
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## 1. Introduction

Over the last years, there is a growing interest on the implantation of an intraocular lens (IOL) in the absence of a capsular support. Several surgical techniques were employed such as placing the IOL in the anterior chamber (AC) using an anterior chamber intra ocular lens, or in the posterior chamber using a posterior chamber intra ocular lens. The latter can be iris fixated intra ocular lenses or scleral fixated intra ocular lenses (SFIOLs).<sup>[1,2]</sup>

Posterior chamber intra ocular lenses have the advantage of minimizing the risk of glaucoma and bullous keratopathy as the lens is located away from the anterior segment structures.<sup>[3–5]</sup> SFIOLs can be sutured to the sclera or be sutureless IOLs.<sup>[6]</sup> The latter have some advantages over the scleral sutured IOLs that can cause suture-induced infection and inflammation, suture degradation, and delayed IOL dislocation owing to broken sutures.<sup>[7]</sup>

Recently, a new promising intraocular one-piece foldable acrylic SFIOL called FIL SSF Carlevale lens (Soleko IOL Division, Italy) has been developed (Fig. 1). This IOL is characterized by a novel design of flexible sclero-corneal plugs at the end of 2 haptics to be implanted and anchored to the sclera. A sutureless technique with plugs left under the conjunctiva<sup>[8]</sup> or anchored



**Figure 1.** The shape and profile of one-piece foldable acrylic Carlevalens lens are shown of the lens and the images were obtained from the manufacturer website. This IOL is characterized by a novel design of flexible sclero-corneal plugs at the end of 2 haptics meant to be implanted and anchored to the sclera. (A) Haptics are wider than the optic. (B) The optic is placed slightly posterior to the haptics. Images were obtained from the manufacturer website (<https://www.soleko-iol.it/prodotti/carlevalens-lens>). We hereby confirm the permission to use the images in both main document and submission screen. IOL = intra ocular lens.

intrasclerally with different methods of sutureless technique<sup>[9,10]</sup> were already reported with promising results.

The purpose of this study is to investigate the surgical outcomes of 2 different intrascleral fixation technique of the new FIL SSF foldable Carlevalens lens and to compare our results with previous reports of the literature.

## 2. Methods

This is a cross-sectional, non-randomized retrospective comparative study that involves 2 series of consecutive patients who underwent 2 different intrascleral fixation technique with the same single-piece acrylic foldable IOL Carlevalens lens at the S. Maria della Misericordia Hospital, Perugia, Italy. Minimum follow-up of 3 months was requested for inclusion in the study. Patients enrolment started in July 2018. From July 2018 to June 2020 patients were operated with the first technique, whereas from July 2020 with the second technique. The study was performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from each patient. The study was approved by the Institutional Review Board of the University of Perugia. All surgeries were performed by 2 experienced surgeons (T.F. and G.T.).

All the patients underwent a standard ophthalmologic examination including best-corrected visual acuity, measurement of intraocular pressure, anterior segment, and dilated fundus examination. Demographic information, preoperative diagnosis, comorbidities, intraoperative and postoperative complications were also recorded.

For an estimation of the refractive prediction error, the postoperative spherical equivalent of objective refraction was

calculated. This was calculated as the difference between postoperative refractive outcome expressed as the spherical equivalent and refraction predicted by the preoperative biometry (IOL Master 750, Carl Zeiss Meditec AG, Jena, Germany).<sup>[11]</sup>

Spectral domain optical coherence tomography (Spectralis HRA + OCT2, Heidelberg Engineering, Heidelberg, Germany) of anterior segment was used to check plugs positioning postoperatively.

Statistical comparison of refractive prediction error between the 2 groups was performed by means of the paired samples two-tailed Student *t* test. A *P* value <.05 was considered statistically significant.

### 2.1. Surgical technique

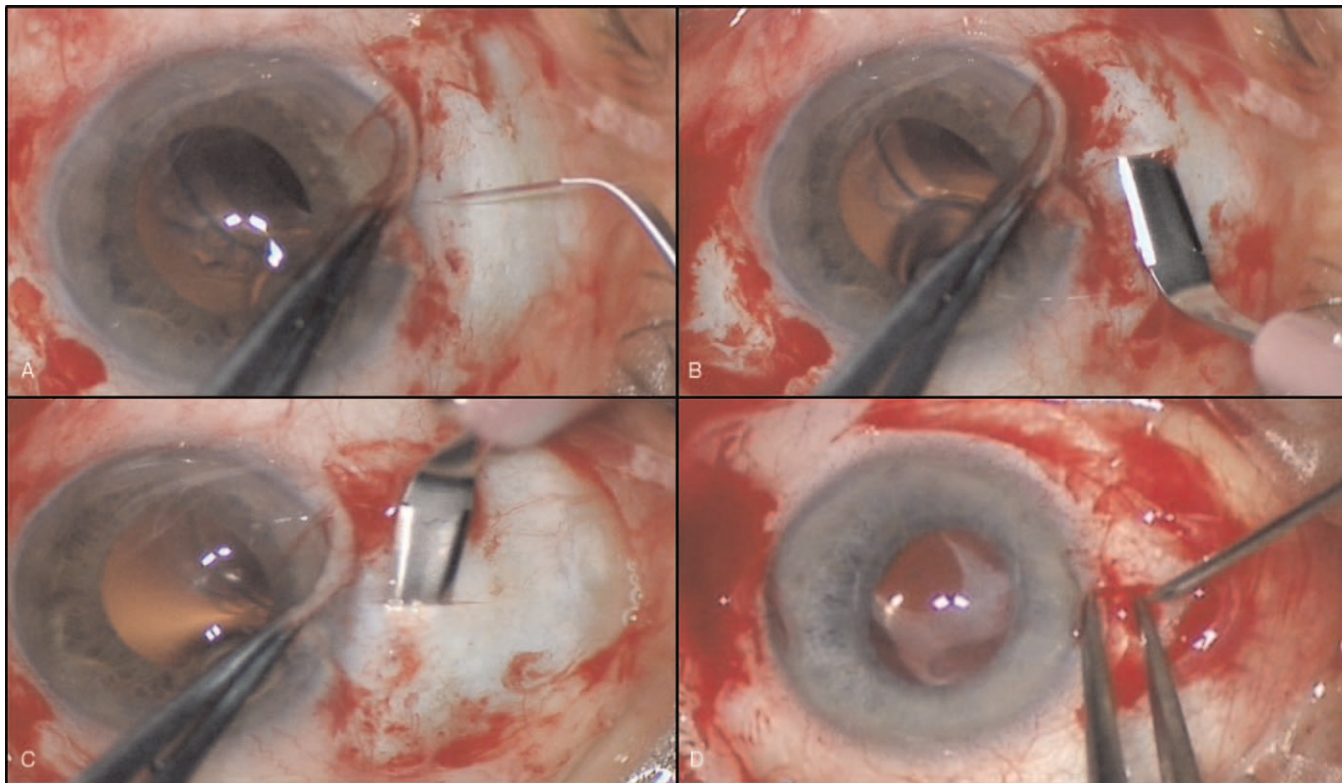
The first technique (group 1) has been previously described.<sup>[10]</sup> A conjunctival peritomy was performed nasally and temporally and a crescent blade was used to perform 2 opposite straight incisions running posteriorly to the limbus for 2.5 mm at 0° and 180° axis (Fig. 2A). The sclera was dissected to create 2 opposite pockets at each side of the incisions (Fig. 2B, C) and a sclerotomy was performed at 1.75 mm from the limbus within each incision with a 23-gauge needle (Fig. 2D). In the second technique (group 2), the conjunctival peritomy was performed nasally and temporally, 2 partial thickness scleral flaps 4 × 4 mm were performed (Fig. 3A–C) and 2 opposite sclerotomy were created at 1.75 mm from the limbus with a 25-gauge needle within the scleral bed (Fig. 3D). Afterwards, in both groups, a clear corneal tunnel of 2.2 mm and a side port were created and the IOL was slowly injected in the AC while a 23-gauge crocodile-tip forceps (group 1) and 25-gauge crocodile-tip forceps (group 2) were inserted through the sclerotomy to grab and externalize the haptic using the handshake technique as previously described (Fig. 4 A–D).<sup>[10]</sup> In group 1, scleral incisions were sutured with a butterfly or cross-stitch<sup>[10,12]</sup> to theoretically immobilize the plug within the pockets, the knot was then placed inside the scleral incision and conjunctiva was finally sutured with a 7.0 or 8.0 vicryl. In group 2, the scleral flap was simply overlapped to the underlying sclera without any suture, and the conjunctiva finally sutured above the scleral flap.

In all surgeries, soft dislocated IOL were cut into 2 pieces and removed through a sclero-corneal tunnel enlarged up to 3.0-mm. When a rigid IOL had to be removed, a wider peritomy was performed and IOL itself was extracted through a curvilinear partial-thickness scleral incision as previously reported.<sup>[10,13,14]</sup>

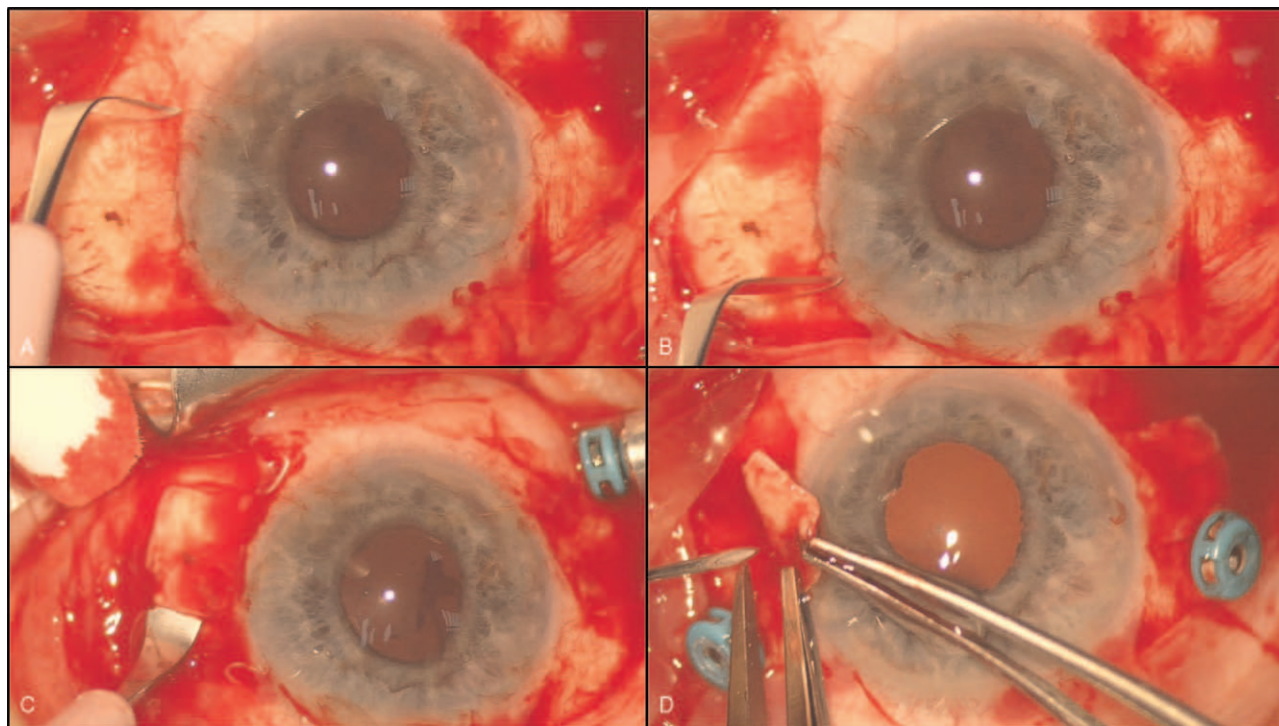
In case of coexisting retinal pathologies or intraoperative complications, a 25-gauge pars plana vitrectomy (PPV) was also performed and trocars were inserted avoiding 0° and 180° axes (Fig. 4B), whereas in cases of surgery limited to the AC, an infusion line was always placed in AC at 6 o'clock position and was used to avoid intraoperative ocular hypotony. Furthermore, an anterior vitrectomy was always performed to clean the capsular bag in case of IOL explantation and to manage vitreous prolapse in AC.

## 3. Results

Twenty-three patients (23 eyes), 13 females and 10 males in group 1, 9 patients (9 eyes), 3 females and 6 males were included in group 2. Preoperative diagnosis is summarized in Table 1. In group 1, mean patients age was 71 ± 17 years (range from 26–89 years), mean follow-up was ±4.1 months (range: 5–18 months),

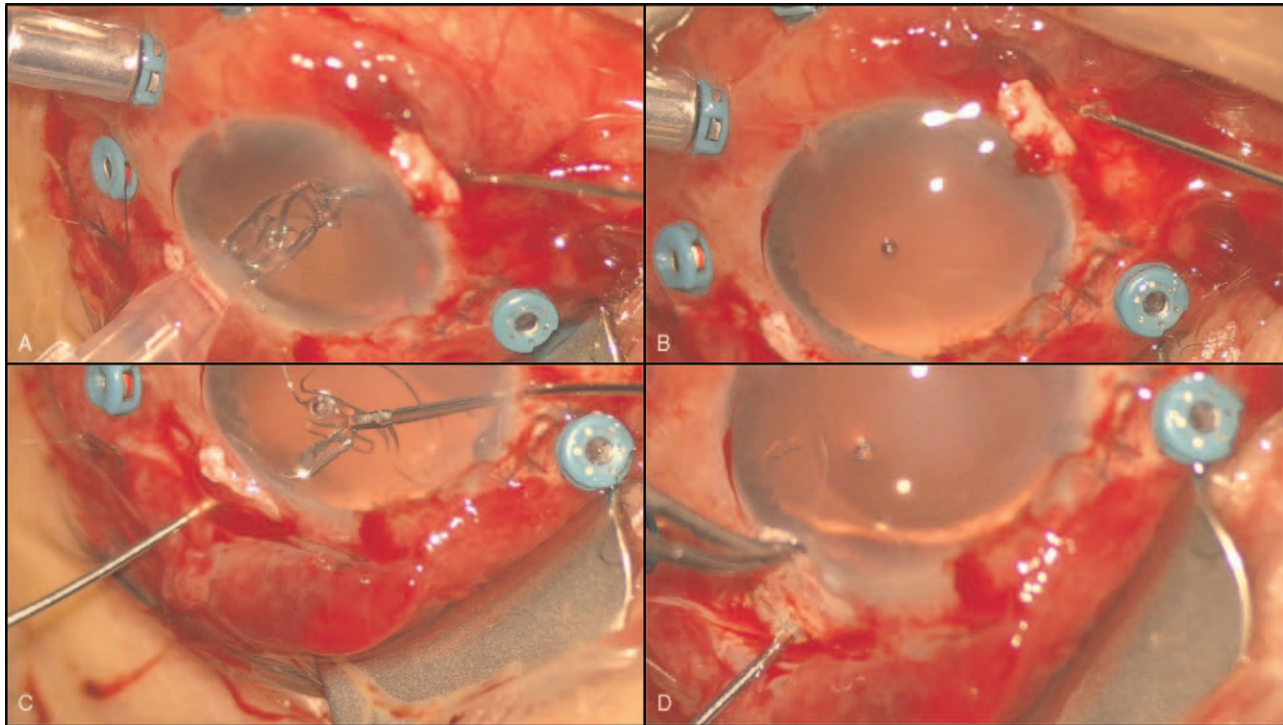


**Figure 2.** Technique with scleral pockets (group 1). (A) Two opposite straight incisions running posteriorly to the limbus for 2.5 mm at 0° and 180° axes are performed; (B, C) scleral dissection to create 2 opposite pockets at each side of the incisions are made; (D) sclerotomy is placed at 1.75 mm from the limbus within each incision with a 23-gauge needle.



**Figure 3.** Technique with scleral flap creation (group 2). (A, B, C) Two partial thickness scleral flaps 4 × 4 mm were performed; sclerotomy is placed at 1.75 mm from the limbus within each incision with 25-gauge needle.





**Figure 4.** Injection of Carlevalde lens (groups 1 and 2). (A) Then lens is injected in the AC while the leading plug is grasped with a crocodile-tip forceps, and (B) externalized. (F) The trailing plug is grasped by the second forceps and is transferred to the first forceps entering the opposite sclerotomy (C) to be externalized (D). AC = anterior chamber.

mean axial length was  $23.4 \pm 1.64$  mm (range 21.21–27.72 mm), the refractive spherical equivalent prediction error was  $-0,31 \pm 0,74$  D, and postoperative best-corrected visual acuity was  $0,42 \pm 0,31$  logMAR. In group 2, mean patients age was  $70 \pm 15$  years, (range from 40–86 years), mean follow-up was  $4 \pm 1$  months (range: 3–7 months), mean axial length was  $23.9 \pm 1.57$  mm (range 21.21–26.14 mm), the refractive spherical equivalent prediction error was  $-0,27 \pm 0,80$  D, and postoperative best-corrected visual acuity was  $0,47 \pm 0,45$  logMAR. One patient in each group was excluded from the analysis of refractive outcomes because the other eye was used for IOL power calculation. No statistically significant difference was found between the 2 groups for the refractive prediction error ( $P < .05$ ).

No complications such as iatrogenic dislocation of the IOL, IOL decentration, lens calcification, pseudophacodonesis, hypotony, endophthalmitis, or retinal detachment were observed. No sign of densiron (Fluoron GmbH, Ulm, Germany) or silicon oil

(SO) (Fluoron GmbH, Ulm, Germany) migration in AC was seen during follow-up in any of the 2 patients of group 1 receiving multiple surgeries for a concomitant retinal detachment. No patients of group 2 received SO or densiron injection. Two patients in group 1 had postoperative cystoid macular edema (CME): one was a transient CME in a patient on topical therapy with beta-blockers and prostaglandin, whereas the other one was a chronic CME already present before Carlevalde implantation. One case of vitreous haemorrhage was observed in group 1. Rupture of 1 of the 2 tips of the plug was observed in 1 patient of group 1 during the externalization, the plug was sutured to the sclera and no slippage or decentration of the IOL was observed during follow-up. Data on plug positioning were available in 16 eyes of group 1 and 7 eyes of group 2. In all the examined eyes plugs were placed within the sclera and completely covered by scleral tissue (Fig. 5A–B) except for 3 eyes of group 1 in which anterior segment optical coherence tomography showed that plugs were located outside the scleral pockets under the conjunctiva (Fig. 5C) and rotated in 2 of these eyes (Fig. 5D).

**4. Discussion**

Different strategies have been so far described in the management of aphakic eyes with capsular insufficiency.

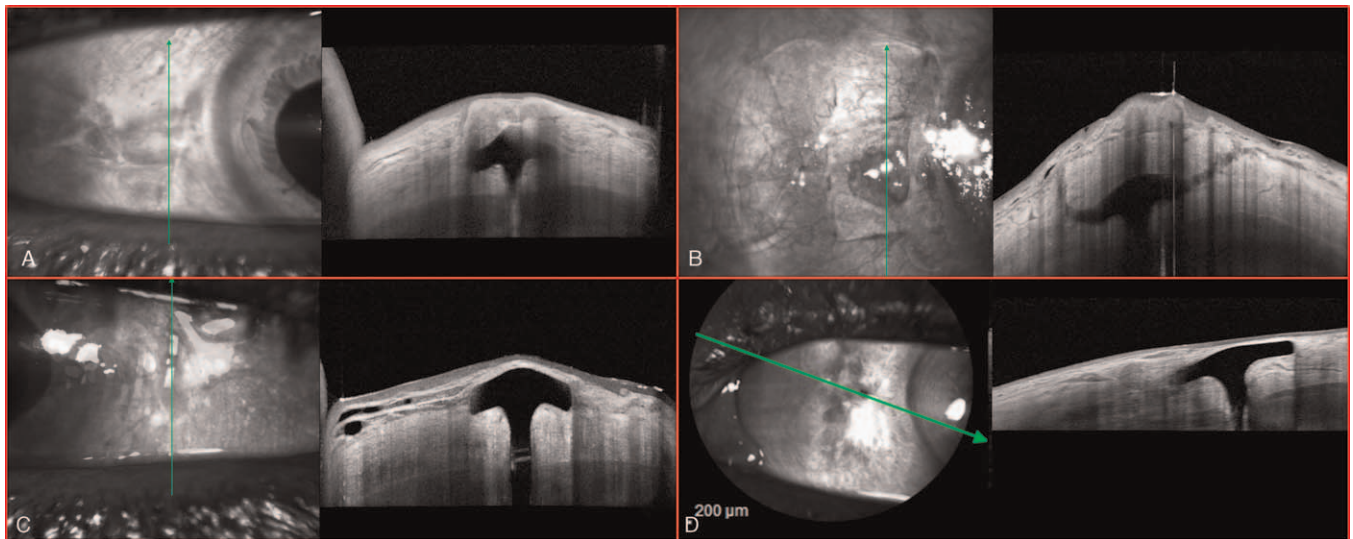
The intrascleral IOL fixation technique has become a popular procedure for its advantages over conventional trans-scleral suturing IOLs and the iris claw IOLs. In fact, in cases of iris claw IOLs, an intact iris diaphragm is needed for implantation, and possible problems related to the AC placement include postoperative iris shafting, unstable refraction, and secondary glaucoma.<sup>[15]</sup> In order to avoid these complications posterior

**Table 1**

**Preoperative diagnosis.**

Preoperative diagnosis	Group 1 n (%)	Group 2 n (%)
Aphakia	8 (35)	1 (11)
Dislocated PC IOL	9 (39)	6 (67)
Dislocated lens	3 (13)	1 (11)
Anisometropia	1 (4)	–
UGH syndrome	1 (4)	–
Perforating trauma + dislocated lens	1 (4)	–
Open globe injury + dislocated lens	–	1 (11)

IOL = intra ocular lens, PC = posterior chamber, UGH = uveitis glaucoma hypHEMA.



**Figure 5.** OCT of anterior segment (AS-OC) shows the correct placement of the plug (A) within the scleral pockets and (B) under a scleral flap. Infrared (IR) image shows the border of the scleral flap (white arrows). AS-OCT shows the plug (C) dislocated under the conjunctiva and (D) dislocated under the conjunctiva and rotated. AS-OCT = anterior segment optical coherence tomography.

positioning of the iris-claw was also proposed, but possible disenclevation remains a concern mainly in cases of progressive iris atrophy at the site of enclavation or trauma. Moreover, a wider sclero-corneal tunnel is needed to introduce and fix the lens inside the eye and pupillary distortion are more frequent, and residual astigmatism is less predictable.<sup>[16,17]</sup>

On the other hand, in cases of trans-scleral suturing IOLs, there is a risk of suture erosion and associated endophthalmitis, lens tilt, and dislocation caused by degradation of suture material.<sup>[18,19]</sup> These risks can be prevented using different sutureless techniques,<sup>[20,21]</sup> but complications such as haptic slippage with intraocular lens dislocation and iris capture from the IOL's optic have been previously described with sutureless technique.<sup>[21–23]</sup>

More recently, a new promising intraocular one-piece foldable acrylic SFIOL called FIL SSF Carlevalle lens (Soleko IOL Division, Italy) has been introduced. No iatrogenic IOL distortion, IOL dislocation, IOL haptic rupture, IOL decentration, hypotony, and endophthalmitis were described, whereas complications such as intraocular pressure elevation, iris capture, and CME have been reported.<sup>[10,24]</sup> Purpose of this study was to confirm previous results from the literature and to investigate the feasibility and possible differences between 2 different intrascleral fixation technique of the new FIL SSF foldable Carlevalle lens comparing our results with previous reports of the literature.

In our study, the new one-piece foldable acrylic SFIOL called FIL SSF Carlevalle lens specifically designed for an intrascleral placement was used. This IOL was stable and, regardless the type and number of surgeries, the material injected in the AC (air, water) or in the posterior chamber (water, air, gas, SO, and heavy SO), none of our patients of both groups showed IOL dislocation. Furthermore, no signs of densiron, SO, or gas migration from vitreous cavity in the AC were found throughout the follow-up in more complex cases, showing that Carlevalle lens provided a good stability regardless the employed technique and was able to compartmentalize the front from the back of the eye. No clinical evidence of inflammation such as inflammatory cells in the AC was seen throughout the follow-up. This was likely related to the

hydrophilic properties of the lens (25% H<sub>2</sub>O) that theoretically provides a good uveal compatibility.<sup>[24]</sup>

A critical step of the surgery is the externalization and correct positioning of the plugs. When intrascleral fixation is performed using a 3-piece-foldable IOL, it is necessary a proper alignment of the 2 opposite scleral tunnels to the limbus, and manipulation of the haptics is usually required to centre the IOL. In our patients the only critical step was to place 2 symmetrical sclerotomy within 2 opposite symmetrical scleral incisions (group 1) or within the scleral bed (group 2) to have the Carlevalle lens centered in the eye without any further manipulation of the haptics. Furthermore, compared to a 3-piece-foldable IOL, the stretching and elastic properties of the connection mesh between the plugs and the optic promote lens centring in eyes with different dimensions,<sup>[10,24]</sup> and provide a minimal risk of haptic rupture. Finally, regarding the plugs, they are more flexible and thicker than those ones of a 3-piece-foldable IOL, can be grasped more safely, and, once externalized, reopen immediately thus preventing any slippage of the IOL regardless any use of sutures. In only 1 case (group 1) we observed a rupture of 1 the 2 tips of the plug, the plug was sutured to the sclera and no slippage or decentration of the IOL was observed during follow-up. This complication was not related to the technique employed nor to the dimension of the sclerotomy used to externalize the plug that was in fact a 23-gauge sclerotomy. It is important to keep in mind that the first technical difficult aspect of this surgery is the procedure of grasping and externalize the plug, avoiding rupture of the haptic or plug. For this reason, although this lens appears forgiving, the key point is to manage the lens gently and to grasp the lens at the site of connection between the haptic and the plug, avoiding the plug itself (Fig. 4C). The second technical difficult aspect is the injection of the lens. In fact, when a 3-piece-foldable IOL is injected in the eye, the chance of the IOL to slip into the vitreous cavity can be minimized by the possibility to grasp the trailing haptic, operation that is not possible with the one-piece foldable Carlevalle lens. Therefore, when there is no iris support, such as in cases of pupillary stupor or aniridia, the lens can unfold

quicker and more posteriorly before the leading plug is grasped as it happened in 1 case of pupillary stupor in group 1. According to these observations the second key point is to place the corneal tunnel opposite to the sclerotomy to ease the grasping manoeuvres and the externalization of the lens. Furthermore, to ease the manoeuvres through the sclerotomies particularly in the nasal side, we routinely use bent forceps inside the eye (Fig. 4A).

Comparing the 2 techniques, making the 2 scleral incisions was simpler and took less time than making the scleral flap. However, at the time of the first technique, sclerotomy was planned by using a 23-gauge needle. Therefore, at the end of surgery, after placing the plugs within the scleral pockets, a suture with a cross-stitch was put with the aim of avoiding the hypotony and stabilizing the plug, the knot was then placed inside the scleral incision and conjunctiva sutured with a 7.0 or 8.0 vicryl. These steps were more difficult and certainly more time consuming than the simple externalization of the plug, the juxtaposition of the scleral flap to the underlying plug and sclera followed by the suture of the conjunctiva above the scleral flap (group 2). The fact that no case of hypotony was recorded in group 2 is likely related to the fact that a 25-gauge sclerotomy (group 2) better fit with the dimensions of the plug and furthermore the scleral flap could mechanically close the sclerotomy itself. In that instance, suturing seems unnecessary. We also found that the presence of a scleral suture (group 1) was not able to prevent the displacement of the plugs that were found located outside the scleral pockets in 3 cases, and rotated degrees in 2 of them (Fig. 5C, D). This was not recorded as a serious complication because the plugs were found located under a continuous layer of conjunctiva as it was previously reported by Veronese et al.<sup>[25]</sup> describing a technique in which plugs were intentionally left under the conjunctiva. Nevertheless, the acrylic plugs can theoretically erode under the subconjunctival tissue and there should be some concern in terms of endophthalmitis and potential infection during the long-term follow-up.

More importantly, in agreement with previous reports,<sup>[24,25]</sup> none of these cases was associated with a lens tilting. Two observations can be done. The first is that the haptics are soft and elastic and therefore no torsional effect would be transmitted to the lens. The second is that, taking into account the shape of the lens, the stability of the lens could be increased by the contact of the edge of the connection mesh and the eye. Conversely, in all cases of group 2, plugs were properly located intrasclerally and completely covered by a uniform layer of sclera as confirmed by anterior segment optical coherence tomography (Fig. 5 A–B). Finally, in disagreement with our previous report,<sup>[10]</sup> the wider 23-gauge sclerotomy did not ease the externalization of the plugs and the introduction of forceps. For this reason, in agreement with Barca et al,<sup>[24]</sup> a 25-gauge sclerotomy should be preferred with the aim of a sutureless surgery regardless the technique employed.

In a recent study by Barca et al,<sup>[9]</sup> all the patients in which a Carlevalle lens was implanted, were treated only with PPV to avoid the risk of retinal complications. Conversely, our patients were operated with PPV only when needed and in all cases of surgery limited to the AC, intraoperative ocular hypotony was prevented by placing an infusion line in AC at 6 o'clock positioning, and an anterior vitrectomy was always made to clean the capsular bag of the IOL to be explanted and to manage AC vitreous prolapse. The possibility to limit the surgery to the AC

makes the surgical technique feasible also for anterior segment surgeons.

Additional postoperative complications such as vitreous haemorrhage, iris capture, transient hypotony, and CME have been previously reported.<sup>[24,26–28]</sup> Concerning the iris capture, as we previously reported,<sup>[10]</sup> this complication should be prevented by the particular shape and profile of the Carlevalle lens, characterized by haptics wider than the optic and, by an optic placed slightly posterior to the haptics on a transverse section (Fig. 1). For this reason, unlike Barca et al,<sup>[24]</sup> prophylactic iridectomy was never performed.

The spherical equivalent refractive prediction error was similar in both groups and was similar to data previously reported for different technique of secondary intraocular lens implantation,<sup>[29,30]</sup> including Carlevalle lens itself.<sup>[9,24]</sup>

In summary, the Carlevalle lens is a one-piece foldable acrylic SFIOL specifically designed for posterior chamber implantation. This lens is hydrophilic thus theoretically providing a good ueval compatibility, and is soft and elastic providing minimal risk of haptic rupture and/or dislocation. In our study, we could successfully anchor this lens intrasclerally without any significant difference between the surgical technique using the scleral pockets and that 1 using the scleral flaps. According to our results, a 25-gauge sclerotomy to externalize the plugs should be preferred with the aim of a sutureless surgery regardless the technique employed. Furthermore, no difference was found between surgeries limited to AC and those ones combining PPV, thus making Carlevalle lens implantation approachable for both anterior and posterior segment surgeons. Limitations of our study are related to the small sample size, lack of randomization, short term follow up, lower number of patients included in group 2, and to the strong heterogeneity of the sample theoretically affecting the results of visual acuity. A long term study and future studies are required to evaluate the safeness, efficiency, and cost-effectiveness of this platform compared to other platforms, including the IOL repositioning technique.

## Author contributions

**Conceptualization:** Lupidi Marco, Giamberto Casini.

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**Formal analysis:** Alessio Muzi.

**Investigation:** Alessio Muzi, Gianluigi Tosi, Lupidi Marco, Marruso Virginia.

**Methodology:** Gianluigi Tosi, Cagini Carlo.

**Resources:** Lupidi Marco.

**Software:** Alessio Muzi.

**Supervision:** Cagini Carlo.

**Validation:** Cagini Carlo.

**Visualization:** Cagini Carlo.

**Writing – original draft:** Tito Fiore, Cagini Carlo.

**Writing – review & editing:** Marco Messina, Cagini Carlo.

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