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# New Approach to Secondary Implantation: Sutureless Scleral Fixation with the Carlevale FIL-SSF Implant (A Prospective Study Regarding 24 Cases)

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**Abstract** | **Original Research Article**

The management of aphakia in the absence of capsular support is becoming increasingly common, largely due to the rising incidence of implant dislocations [1]. This scenario presents a significant surgical challenge, with several options available: anterior chamber implantation (using an angulated support lens or an iris-claw lens on the anterior surface of the iris), posterior fixation to the iris (with either an iris-claw lens or sutures), or scleral fixation (with or without sutures). Each approach has its own set of advantages, disadvantages, and potential complications. Despite the advancements in techniques reported by various authors in recent years [2, 3], there is still no consensus on the optimal approach. The Carlevale FIL-SSF implant, a novel hydrophilic lens specifically designed for sutureless scleral fixation and placement in the ciliary sulcus, has shown promising results in recent publications [4-6]. We conducted a prospective interventional study at the Intercommunal Hospital Center of Villeneuve-Saint-Georges, Île-de-France, Paris, including 24 eyes diagnosed with aphakia, subluxation or dislocation of an intraocular implant. All our patients consulted in the ophthalmology department between March 2023 and December 2023. Our patients underwent secondary implantation surgery by Sutureless scleral fixation technique (SSF) with a Carlevale-type lens (Soleko, Italy). The post-operative follow-up was adjusted to the evolution of each case, with a minimum of 6 months' follow-up. It included at each visit the assessment of the best corrected visual acuity (BCVA), refraction, Intra-ocular pressure, clinical ophthalmic examination, implant centering, endothelial cellularity count and the occurrence of peri- and post-operative complications. Seven women and seventeen men were included in the study. The mean age was 62.55 years. The surgical indications were posterior chamber implant dislocation in 11 cases, secondary implantation due to post-traumatic aphakia in 10 cases (one of which was associated with post-traumatic aniridia, requiring combined surgery involving the placement of an artificial iris sutured to a Carlevale implant), and secondary implantation due to intraoperative posterior capsular rupture in 4 cases. Preoperatively, the mean best corrected visual acuity (BCVA) was 0.2 log MAR (ranging from 0.05 to 1), and the mean intraocular pressure (IOP) was 18.18 mmHg (ranging from 10 to 28 mmHg). The average surgical duration was 50 minutes, with no intraoperative complications in any of the patients. Postoperatively, the mean BCVA improved to 0.7 log MAR (ranging from 0.2 to 1), and the mean IOP was 15.15 mmHg (ranging from 10 to 18 mmHg). All implants were well-centered, and no cases of postoperative ocular hypertension were observed. Notably, one case of cystoid macular edema resolved within three months, and one case of corneal edema is still under follow-up and treatment. The technique is safe, reproductible, promising and provides excellent post operative results.

**Keywords:** Aphakia, Sutureless scleral fixation, Carlevale FIL-SSF implant, Secondary implantation, Intraocular lens dislocation.



## INTRODUCTION

Inadequate capsular support presents one of the most challenging surgical scenarios in aphakia correction. Various techniques have been described in the literature, each offering distinct advantages and drawbacks. However, the search for the optimal approach remains ongoing and complex. While open-loop haptic anterior chamber intraocular lenses (ACIOLs) are widely accepted, they are associated with complications such as glaucoma, endothelial cell loss, inflammation, hyphema, and cystoid macular edema. Alternatively, scleral fixation of posterior chamber intraocular lenses (PCIOLs) offers several advantages, yet the ideal surgical technique and the optimal

intraocular lens design specifically Adapted for scleral fixation are still subjects of investigation [7].

The Carlevale FIL-SSF implant, a novel hydrophilic lens specifically designed for sutureless scleral fixation and placement in the ciliary sulcus, has shown promising results in recent publications [1-6]. The aim of the present study is to report the clinical outcomes of the use of a novel specially designed scleral fixated intraocular lens, the Carlevale intraocular lens (carlevale IOL, Soleko, Italy) for the correction of aphakia with inadequate capsular support due to different etiologies.

## PATIENTS AND METHODS

### *Study Design*

A prospective, non-comparative, interventional study was performed at the Department of Ophthalmology of the Intercommunal Hospital Center of Villeneuves St Georges, Ile de France, Paris.

All surgeries were performed by a vitreoretinal surgeon. Informed consent was obtained from all patients. No conflict of interest is declared by any of the authors and funding was not obtained for this study.

Inclusion criteria for this study were at least 6 months' follow-up period, patients > 18 years old who underwent vitrectomy and Carlevale IOL placement for aphakia and inadequate capsular support.

24 eyes of 24 patients were included in the study, between March 2023 and December 2023. Pre operative data included the diagnosis, the age, the gender, the medical history, the best-corrected visual acuity (BCVA), intraocular pressure (IOP) measurement, lens status and indication for surgery. Intraoperative data included the operated eye, the surgical technique, the position of scleral flaps and corneal incision size, and the occurrence of any intraoperative complications.

Post-operative data included the length of follow-up period, the BCVA and IOP, the post-operative complications, the position and stability of the IOL and the refraction.

### *Surgical Technique*

### *Lens Description*

The Carlevale IOL (Fig. 1) is a uniquely designed, foldable, acrylic IOL with 25% H20 an UV filter. It has an optical diameter of 6.5 mm and a total diameter of 13.2 mm. The haptic angulation is of 10 degrees. The haptics are angled at 10 degrees to the frontal plane [8]. Each haptic end is fitted with a T-shaped plug/anchor (width 2mm and length 1mm). It should be noted that the haptic part which connects the anchoring T to the optical part of the implant is flexible and stretchable. The refractive index of the lens is 1.461 and the recommended injection system is Medicel Viscojet suitable for 2.2mm or 2.7mm incisions. The IOL is available in a range of refractive powers going from -5.0 diopters to +35.0 diopters in 0.5 diopter increments. The implant is available in a toric version [9].

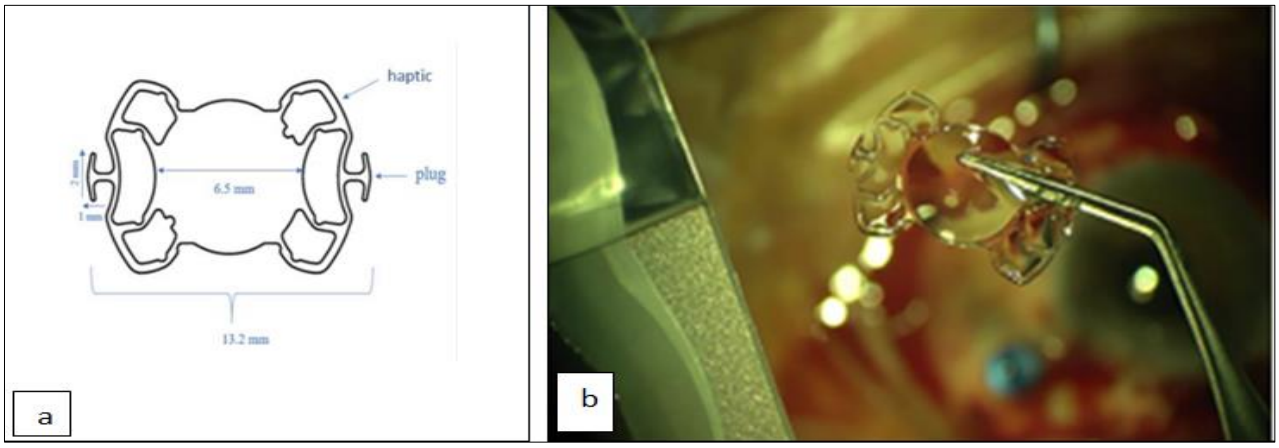



**Figure 1: a/ Design and Diameters of the Sutureless Scleral Fixation Implant Carlevale." b/ The Carlevale Implant before injection during surgery**

### *Lens Fixation*

A 6.0 mm conjunctival incision is made at the 3 o'clock and 9 o'clock positions. After scleral marking at 3 and 9 o'clock, two partial-thickness, limbal-based scleral flaps measuring approximately 4.0 mm × 4.0 mm, positioned 180° apart, are fashioned. A 25-gauge vitrectomy is performed, with the infusion cannula placed in the inferonasal quadrant to avoid interference with the scleral flaps. An anterior vitrectomy is also carried out to remove any residual vitreous traction. Two straight sclerotomies are created using a 25-gauge needle approximately 2.0 mm from the limbus, positioned within the beds of the scleral flaps. A 2.5 mm clear corneal incision (CCI) is made at the 11 o'clock position. Viscoelastic is injected into the anterior chamber to maintain space. A foldable Carlevale intraocular lens (IOL) is inserted into the anterior chamber using an injector (Medicel Viscojet 2.2) through the 2.5 mm CCI

and gradually unfolded. The leading haptic is grasped with 25-gauge end-gripping vitrectomy forceps and passed through the corresponding sclerotomy using the other hand. The leading haptic is carefully adjusted through the sclerotomy. Once outside the sclerotomy, the plug reopens and, like a harpoon, automatically locks itself in place beneath the scleral flap, preventing the intraocular lens (IOL) from falling into the vitreous cavity. Once the IOL is fully deployed in the anterior chamber, a second corneal incision of 1.5 mm is made at the 2 o'clock position. Through this new opening, a 25-gauge vitrectomy forceps is introduced to grasp the second haptic of the IOL and gently guide it beneath the iris. The second plug is then secured using another 25-gauge vitrectomy forceps and passed through the opposite sclerotomy at the 3 o'clock position. The IOL is automatically centered, requiring no further adjustment. After verifying the condition of the retina, the 25-gauge trocars are removed, and the scleral flaps along with the conjunctiva are sutured with 8-0 Vicryl. Finally, the corneal incisions are closed using hydro-suturing.

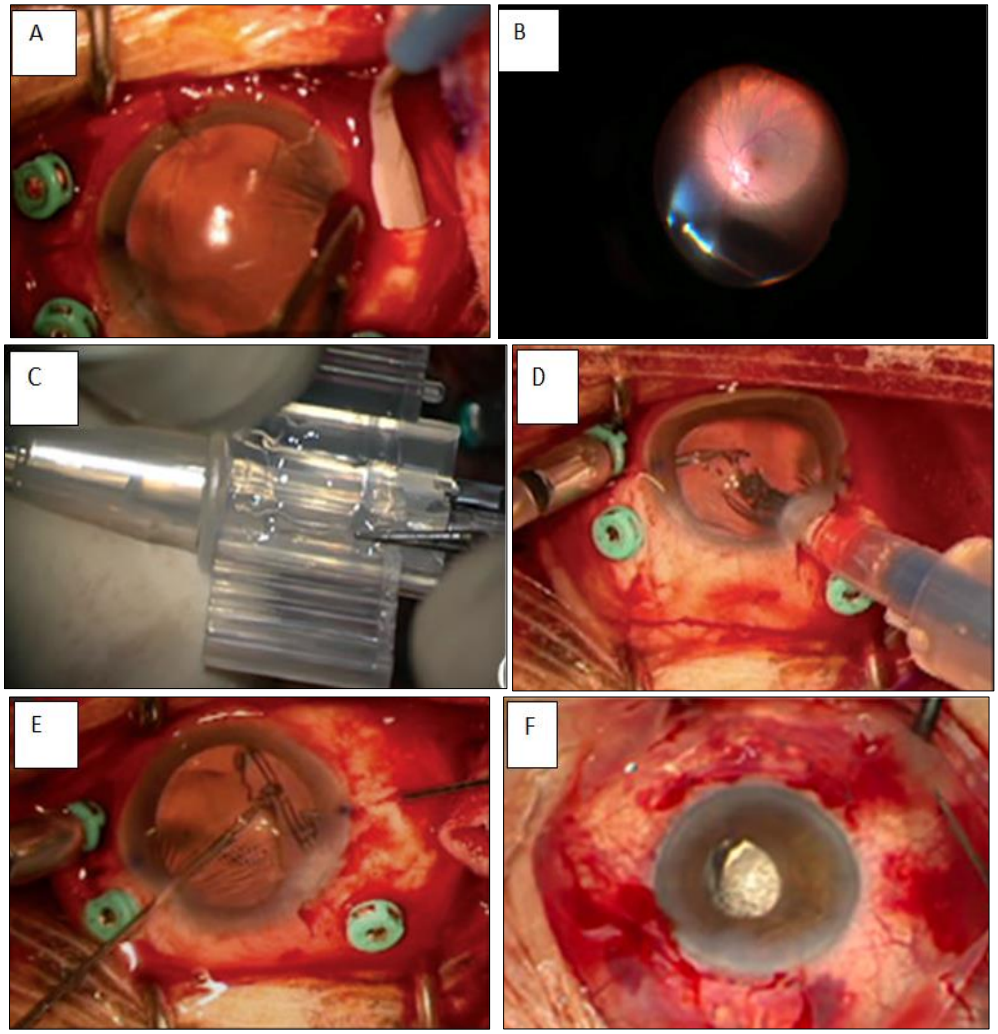



**Figure 2**: ***Summery of important steps in the surgical procedure with images:***
A) Realization of two 4/4mm quadrangular scleral flaps on the 3 and 9 o'clock meridians.
B) Performing a 25- gauge vitrectomy.
C) Loading of the IOL to the injector.
D) The foldable Carlevale IOL is inserted into the anterior chamber with the injector through the 2.5 mm corneal incision and slowly opened; the plug of the leading haptic is gripped by an end-gripping 25-gauge forceps.
E) A 25-gauge forceps is passed through the side anterior chamber incision to keep the second haptic of the IOL and to gently move it under the iris, so that the second plug is gripped by another 25-gauge forceps and passed through the opposite sclerotomy.
F) Closure of the scleral flaps, conjunctiva, cornea, injection of pilocarpine and sub conjunctival antibiotics.

## RESULTS

In the present study, 24 eyes of 24 patients who underwent three port pars plana vitrectomy with insertion of Carlevale scleral fixated IOL were included in the analysis. The average age was 62.55 years. The Sex ratio was 2.42 with a male predominance (65% of patients were male compared to 35% female). Pre-operative diagnosis included dropped IOL in 11 eyes (45.8 %), post traumatic aphakia in 10 eyes (41.6%), with a case associated with post-traumatic aniridia that underwent combined surgery; placement of an artificial

iris (AI) (CUSTOMFLEX, Germany) sutured to a Carlevale implant (Figure 4), intraoperative lens nucleus dislocation in 2 eyes (8.33%) and one eye had a Post-traumatic cataract with a large capsular bag disinsertion (4.16%) (Figure 5).

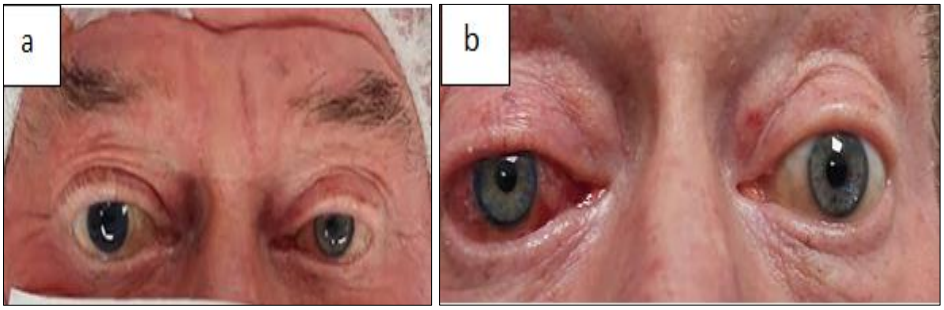



**Figure 3: Clinical image before (a) and after (b) placement of an AI and Carlevale Implant in a post traumatic aniridia associated to aphakia.**

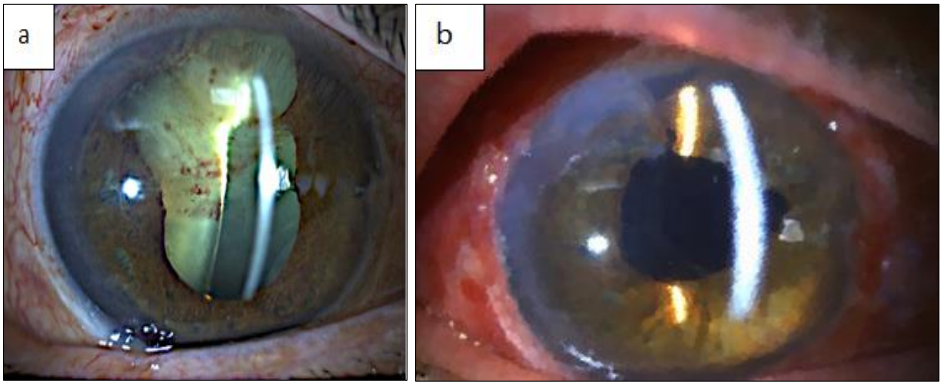



**Figure 4: a) Post traumatic cataract with a large capsular bag desinsertion. b) Post operative image after placement of a Carlevale Implant.**

The mean duration of the surgery was 50 minutes, no incidents occurred during surgery. All patients had at least 6 months follow up.

The mean pre operative best corrected visual acuity (BCVA) was *0,6 log MAR +/-0,15 ((0,2 à+2,3* Log Mar) pre operatively, and increased to *0,18 Log MAR+/-0,25* at one month follow up and *0,15 log MAR +/-0,15* at six months.

As for the refractive results, the mean preoperative spherical equivalent was *+6,24 D+/- 4 dpt, after one month of surgery it was -0,5 dpt +/-0,8 dpt* and after six months *-0,24 dpt +/-0,45 dpt.*

The mean preoperative intraocular pressure was *18,18 mm Hg;* with extremes ranging from *9mm Hg to 28 mm Hg* (one case of hypotony in a post traumatic case), *15,16 mm* Hg in one month follow up *(11 à 18 mm Hg) and 14,9 mm Hg (10 à 21 mm hg*) in the last follow up of six months. The mean density of corneal endothelial cells decreased from *2000 cellules / mm² to 1700 cells/mm2* at six months, one case of endothelial decompensation was reported during the follow up.

**Table 1: Results of follow up during 1, 3 and 6 months after surgery**

| | **The mean best corrected visual acuity (BCVA)** | **The mean spherical equivalent** | **The mean intraocular pressure** | **The mean density of corneal endothelial cells** |
|---|---|---|---|---|
| Pré opérative period | *0,6 log MAR +/-0,15* (0,2 à+2,3 Log Mar) | *+6,24 D+/- 4 dpt* | *18,18 mm Hg (9 à 28 mm Hg)* | *2000 cellules / mm²* |
| 1 month follow up | *0,18 Log MAR+/-0,25* | *-0,5 dpt +/-0,8 dpt* | *15,16 mm Hg (11 to 18 mm Hg)* | *1800 cellules / mm²* |
| 3 months follow up | *0,16 log MAR +/-0,14* | *-0, 38 dpt +/- 0,85 dpt* | *14,8 (10 à 19 mm hg)* | *1765 cellules / mm²* |
| 6 months follow up | *0,15 log MAR +/-0,15* | *-0,24 dpt +/-0,45 dpt* | *14,9 mm hg (10 à 21 mm hg)* | *1700 cellules / mm²* |

All the implants were well centered without tilt in the immediate post-operative period and during follow up, IOL T-shaped haptics were in position without any signs of erosion, exposure or local inflammation at the last of the follow-up visit.

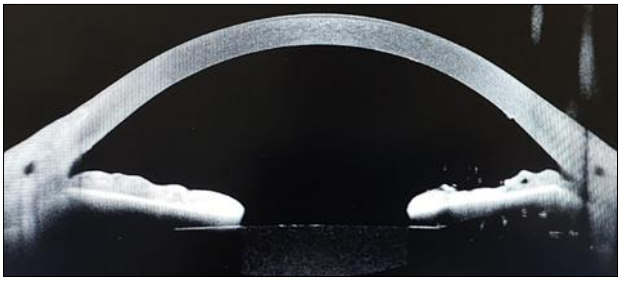
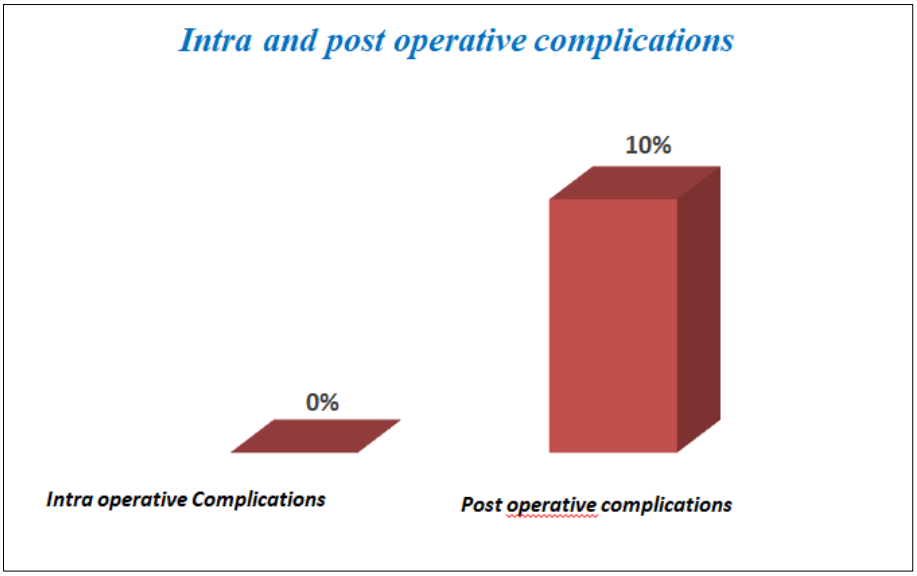
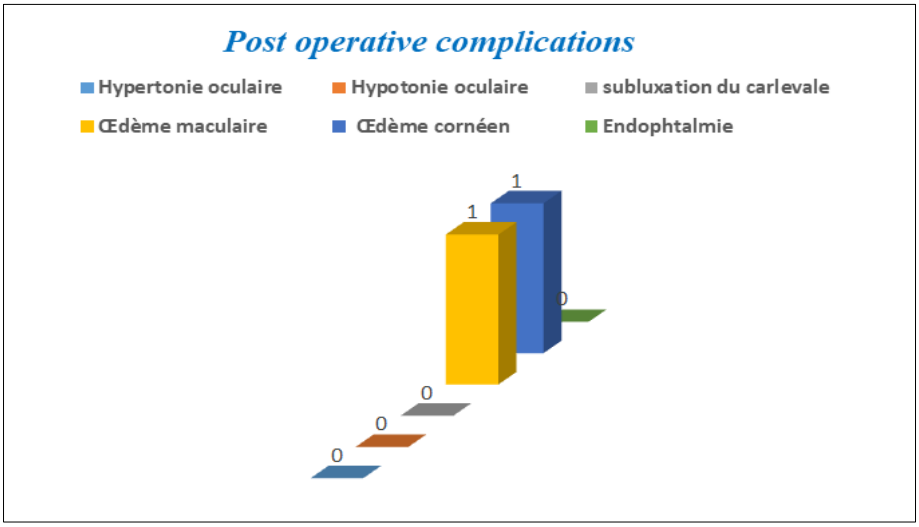


**Figure 5: An OCT image of the anterior segment of the eye, using an ANTERION device, showing a well-centered Carlevale lens implant. The implant is positioned with its haptics embedded symmetrically in the sclera on both sides.**

Iris capture or pupillary block was not observed in any of our patients and none of our patients required re-operation. In the immediate post operative period, no cases of ocular hypertension were observed. One case of cystoid macular edema was noted, which resolved after 3 months, and one case of corneal edema remains under follow-up and treatment.



# DISCUSSION

The Carlevale intraocular lens (IOL), designed for sutureless scleral fixation, has emerged as a novel and effective option for patients with aphakia and insufficient capsular support.

The improvement in best-corrected visual acuity (BCVA) in our cohort is particularly notable. All patients demonstrated significant gains in visual function, with none requiring reoperation or experiencing major complications such as retinal detachment, endophthalmitis that have been reported with other fixation techniques. One patient did develop corneal edema, and one a macular cystoid edema which resolved with medical treatment, supporting the overall safety profile of this technique.

A significant advantage of the Carlevale IOL is its minimally invasive nature. The average surgical time in our series was approximately 50 minutes, with no intraoperative complications, suggesting that the procedure is both efficient and reproducible. This shorter operative time, combined with the elimination of suture-related risks, positions the Carlevale IOL as an ideal solution for aphakic patients with poor capsular support.

Our findings align with recent studies suggesting that the Carlevale IOL offers stable fixation and excellent refractive outcomes with minimal complications [1-9]. In our study, the IOL was consistently well-centered without significant tilt, indicating that the design of the haptic plugs—acting as "harpoons"—effectively anchors the lens in place under the scleral flap. This mechanism reduces the risk of IOL displacement and obviates the need for long-term suture integrity, which can be compromised over time [1-9].

**Table 2**

| | **Our Series (2024)** | **Barca and al (2020) 32 cases [5]** | **Rossi and al (2020) 78 cases [4]** | **H. Rouette and al (2021) 72 cases [1]** | **Georgalas and al (2021) 169 cases [7].** | **Omar.B and al (2023) 15 cases [9].** |
|---|---|---|---|---|---|---|
| *Surgical indication :* Dropped IOL | *48%* | *62,5%* | *54%* | *70,8%* | *8.9% (major indication was dislocated posterior chamber intraocular lens (70.4%)* | *6%* |
| *Surgery Duration* | *50 min +/- 10 min* | *Not Defined* | *69,4+/-26,1 min* | *53,4+/-11,2 min* | *Not Defined* | *Not defined* |
| *The Mean Spherical equivalent* | *-0,5 dpt* | *-0,24 dpt* | *Not defined* | *-0,3 dpt* | *Not defined* | *-0.68 ± 0.93 dpt* |
| *Post operative complications* | ***Macular Edema*** : 1 patient (2%) ***Corneal Edema*** : 1 patient (2%) | ***Macular Edema*** 1 patient (3,1%) ***Inverse pupillary block:*** 2 patients (6,2%) ***Vitreous hemorrhage***:1 case (3,1%) | ***Macular Edema*** : 4 patients (5,1%) ***Corneal Edema***: 2 patients (2,5%) ***Retinal tears :*** 2 patients (2,5%) ***Vitreous Hemorrhage*** : 2 patients (2,5%) ***Ocular Hypertony*** : 2 patients (2,5%) | ***Macular Edema :*** 2 patients (2,8%) ***Corneal Edema :*** 1 patient (1,4%) ***Retinal detachement :*** 1 patient (1,4%) | ***Ocular Hypertony :*** *28 patients (16.5%)* ***Vitreous hemorrhage***:8 cases *(4.7%)* | ***Macular Edema : 2 cases (13%) Vitreous Hemorrhage : 1 case (6%) Epimacular membrane : 1 case (6%) Haptic exposition : 1 case ( 6%)*** |

When comparing sutured scleral-fixated IOLs to sutureless techniques, the former can lead to complications such as inflammation, suture knot exposure, suture breakage, subluxation, intraocular hemorrhage, and even suture-related endophthalmitis [3].

As a result, sutureless methods have gained popularity among surgeons in recent years.

This chart summarizes the advantages and disadvantages of each technique used for secondary implantation.

**Table 3: Summery of the advantages and disadvantages of various techniques used for secondary implantation (Iris fixation, sutured scleral fixation, the Yamane technique and the new sutureless scleral technique with Carlevale Implant**

| | Iris-fixated implant | Sutured scleral-fixated implant | Scleral fixation implant "without suture" using the YAMANE technique | Scleral fixation implant "without suture" by CARLEVALE |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Advantages** | -Quick and reproducible<br>-No conjunctival manipulation or scleral flap required<br>-Short learning curve [10] | - Positioned close to the anatomical and physiological location of the natural lens<br>-Protects the corneal endothelium from damage during explantation<br>-Effective in cases with highly fibrosed capsular bags or rigid PMMA implants, where extraction requires large corneal incisions [3] | - Respect as much as possible the shape of the haptics by cauterizing them instead of suturing, preserving the sclera and conjunctiva, and reducing postoperative hypotony.<br>-Simple and quick.<br>-Stable refractive results over time, without induced astigmatism.<br>-Optical results are superior to those of scleral fixation with sutures.<br>-Best indication: dislocation of a 3-piece implant that is difficult to explant; bring it directly into the pupillary space and secure it by its haptics to the sclera using the YAMANE technique [12] | -Haptics are more stable due to their T-shape, which embeds into the sclera without the need for sutures, cauterization, or glue.<br>-Reduced risk of dislocation or decentration of the implant due to its great stability.<br>-Very good refractive outcome (less astigmatism due to the small corneal incision).<br>-Shorter operative time compared to other scleral fixation techniques, with or without sutures.<br>-Fewer optical aberrations (distance from the cornea to the fixed implant).<br>-Best indication: insufficient iris support, post-traumatic mydriasis, combined procedures (corneal or vitreoretinal), as there is good sealing of the anterior segment. [4,5,6] |
| | Iris-fixated implant | Sutured scleral-fixated implant | Scleral fixation implant "without suture" using the YAMANE technique | Scleral fixation implant "without suture" by CARLEVALE |
| **Disadvantages** | -Large incision >> induced astigmatism.<br>-Risk of intraoperative hypotony / iris herniation.<br>-Not suitable for traumatic, atrophic irises / dystrophic corneas with low endothelial reserve / pathological pupils.<br>-Postoperative complications: elevated intraocular pressure (IOP), postoperative astigmatism, early dislodgment, macular edema. [13] | -Requires a good learning curve.<br>-Suture loosening and dislodgment.<br>-Exposure of haptics.<br>-Tilting and decentration, even subluxation of the implant if not secured properly during the procedure.<br>-Risk of postoperative endophthalmitis (due to suture points). [3] | -Requires a learning curve and gentle handling of the haptics.<br>-Tilt or decentration if there is any deformation of the haptics.<br>-Early dislocation, inverse pupillary block, exposure of the haptic, endophthalmitis. *[14]* | -Early hypotony ++<br>-Implant opacifications (hydrophilic).<br>-Cystoid macular edema / corneal decompensation, less frequently. *[15-16]* |

Gabor and Pavlidis [17], described a sutureless technique using a standard flexible three-piece IOL, where the haptics were inserted into an intrascleral tunnel parallel to the limbus, created with a 24-gauge needle. However, creating the intrascleral tunnel and inserting the haptic were often technically challenging.

Agarwal [18], later modified this procedure by introducing scleral flaps. Two partial-thickness, limbus-based scleral flaps were created 180 degrees apart, with the haptics externalized and placed under the flaps. Fibrin glue was then used to secure the haptics to the scleral bed beneath the flap [19]. Unfortunately, fibrin glue was not always available in all ophthalmic centers.

To summarize, the Carlevale IOL is a new revolutionary therapeutic weapon in the treatment of aphakia in the absence of capsular support, it has the advantage of being placed through a small incision, having refractive reliability, anatomical positioning, great stability (thanks to T-shaped anchors), good centration, no contact with the iris and can be successfully used in a variety of indications, including difficult trauma cases.

However, while short- and medium-term outcomes are promising, long-term follow-up is needed to fully assess the durability of this technique. Future studies should explore whether this IOL remains stable and free from complications, such as late dislocation, over several years. Additionally, comparisons with other techniques, such as glued IOLs and conventional sutured scleral fixation, will further clarify the role of the Carlevale IOL in the therapeutic arsenal for complex aphakia.

## CONCLUSION

In conclusion, the Carlevale IOL appears to provide an excellent balance of safety, efficacy, and ease of use for managing aphakia in cases with inadequate capsular support. With its novel sutureless design and demonstrated clinical outcomes, it represents a significant advancement in the field of scleral-fixated IOLs. Further research is warranted to confirm these benefits in a larger population and over a longer follow-up period.

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