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Results of Secondary Implantation by Sutureless Scleral Fixation Carlevale Intra Ocular Lens: A Prospective Study of 15 Cases

Omar Bengebara[1, 2*], Lina Lahlou[1], Habiba Ouazzani Taybi[1], Ahmed Bennis[1], Fouad Chraibi[1], Meriem Abdellaoui[1], Idriss Benatiya Andaloussi[1], Malek Slim[2]

[1]Ophthalmology Department, Universitary Hospital Hassan II, Fez, Morocco
[2]Ophthalmology Department, Jacques Cœur Hospital, Bourges, France

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***Corresponding author:** Omar Bengebara
Ophthalmology Department, Universitary Hospital Hassan II, Fez, Morocco

Abstract **Original Research Article**

Implantation of an intraocular lens (IOL) in the capsular bag is considered the gold standard in cataract surgery. However, ophthalmologists often face patients with aphakia or insufficient capsular support following complicated cataract surgery, trauma or various zonulopathies. In such cases, the implantation of an IOL in the capsular bag is risky or impossible. Managing this type of patients remains a real challenge for surgeons, despite the considerable progress made in secondary implantation techniques. Lately, the new Carlevale Sutureless scleral fixation implant has enlarged this therapeutic arsenal, establishing itself as an attractive alternative for secondary implantation,offering good functional results with a low complication rate. We conducted a prospective interventional study including 15 eyes diagnosed with aphakia, subluxation or dislocation of an intraocular implant. All our patients consulted in the ophthalmology department of Jacques Coeur hospital in Bourges between November 2020 and November 2021. 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 12 months' follow-up. It included at each visit the assessment of the best corrected visual acuity (BCVA), refraction, Intra-ocular pressure, clinical ophthalmic examination and endothelial cellularity count. The mean age of our patients was 76 ± 13.5 years, with a slight male predominance (53%). The indication for the secondary implantation surgery was the presence of aphakia in 60% of cases. IOL subluxation was noted in33% of cases, while the remaining 6% concerned intraocular implants dislocated in the vitreous cavity. Mean best corrected visual acuity (BCVA) was 0.7 ± 0.25 log MAR preoperatively and 0.15 ± 0.33 log MAR at one year postoperatively, representing a mean gain of 5 lines on the Snellen scale. As for refractive results, the mean preoperative spherical equivalent was +5.34 ± 4.93 diopters (60% aphakia), compared with -0.68 D ± 0.93 Dpt at the one year postoperative control (with extremes ranging from -2.12 Dpt to +1.75 dpt). Surgically induced astigmatism (SIA) was 0.43 Dpt ± 0.66 dpt. The mean preoperative intraocular pressure was 14.50 ± 2.95mmHg and 15.25 ± 3.39mmHg at the one year postoperative control. Mean corneal endothelial cell densities decreased from 1,928 to 1,683 cells/mm2 at one year, nevertheless no cases of endothelial decompensation were reported during our follow-up. Regarding postoperative complications, one case of intravitreal hemorrhage and two cases ofpostoperative cystoid macular edema (Irvine Gass) were recorded, all of which were medically managed with spontaneous resolution at one month postoperatively. One case of haptic exposure was observed; however,given the absence of discomfort reported by the patient and the absence of complications on the ocular surface, we decided to keep the patient under simple surveillance. No cases of reverse pupillary block, ocular hypotony, subluxation or dislocation of the IOL or endophthalmitis were observed (one-year follow-up). Secondary implantation using a Carlevale-type Sutureless intraocular implant fixed to the sclera represents an attractive, reproducible and minimally invasive surgical technique with excellent functional results and minimal induced postoperative astigmatism. By guaranteeing optimal refractive results and a low complication rate, this IOL enlarges the secondary implantation therapeutic arsenal to improve the prognosis of patients with aphakia and insufficient capsular support.

Keywords: intraocular lens (IOL), cataract surgery, zonulopathies, Sutureless scleral fixation technique.

INTRODUCTION

Implantation of an intraocular lens (IOL) in the capsular bag is considered the gold standard in cataract surgery, as the implant is inserted in the physiological position of the natural lens while maintaining a safe distance from the ciliary body, the iris and the corneal endothelium. However, ophthalmologists often face

cases of patients with aphakia or insufficient capsular support following complicated cataract surgery, trauma or various zonulopathies. In these cases, placing an IOL in the capsular bag is either risky or impossible.

Managing this type of patient is still a real challenge for surgeons despite the considerable progress made in secondary implantation techniques. Conventional treatment options for this type of cases include the use of anterior chamber implants, iridium-fixed implants or scleral-fixed implants with or without sutures. Lately, the new Carlevale Sutureless scleral fixation (SSF) IOL has been added to this therapeutic arsenal, and has established itself as an attractive alternative for secondary implantation, offering good functional results coupled with a low complication's rate.

METHODS

- ***Purpose and characteristics of the study:***

In this context, we felt it was important to evaluate the results and safety profile of the SSF Carlevale latest- generation foldable acrylic monoblock IOL (Soleko, Italy).

To fulfill this purpose, we conducted a prospective interventional study including 15 eyes diagnosed with aphakia, subluxation or dislocation of IOL. Our patients consulted in Jacques Coeur hospital in Bourges, France between November 2020 and November 2021. They underwent secondary implantation by scleral fixation without sutures (SSF) using a Carlevale type lens (Soleko, Italy).

All our patients have had a meticulous preoperative ophthalmological examination with measurement of best corrected visual acuity (BCVA), preoperative refraction and intra-ocular pressure. Surgery was performed by a single experienced surgeon (TP).

We performed in all our patients a three-port 25 gauge trans pars-plana central vitrectomy, explantation of the IOL (in case of implant dislocation or subluxation) and secondary implantation of the Carlevale lens with insertion of anchor-shaped (T-shaped) haptics into 2 intra scleral pockets dissected in the 0° axis. The evolution of endothelial cell count and complications were also documented (per- and post-operative). All the patients included in our study had a close and adapted follow-up, with a minimum of 12 months' follow-up period.

- ***Carlevale IOL description:***

The Carlevale lens is a one-piece hydrophilic foldable acrylic implant with a special design; it is composed of 25% H2O and equipped with an ultraviolet filter. It has an optical diameter of 6.5mm and a total diameter of 13.5mm.

The haptics are angled at 10 degrees to the frontal plane. 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.

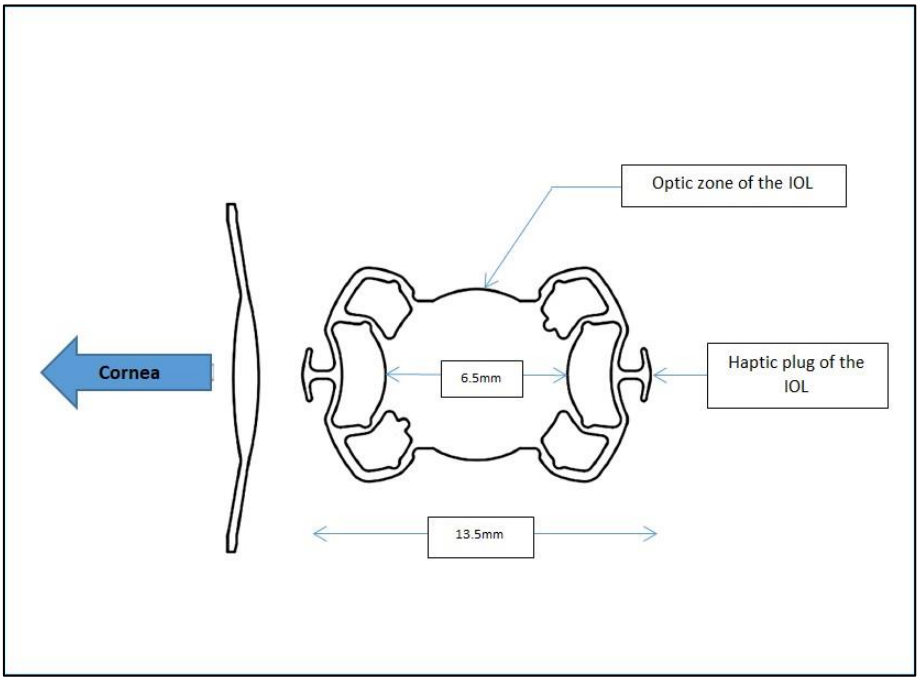


Figure 1: Front (on the right) and side (on the left) view of the Carlevale IOL

- ***Surgical Technique***

All surgical procedures in our study were performed under retro bulbar anesthesia. After anesthesia, corneal markings on the 0-180° axis were made to ensure correct positioning of the IOL. A careful nasal and temporal conjunctival peritotomy is then performed, followed by cauterization of the sclera under irrigation with Balanced Saline Solution (BSS). Two points were marked 1.5 mm from the limbus behind the 2 previous markings on the 0°- 180° axis. A nasal and temporal sclerotomies are initiated at this point using a Micro vitreo retinal blade curved at 45 degrees (DORC, Nederland, Sterile Disposable) in an orientation perpendicular to the limbus followed by dissection of two opposite 1mm intra scleral pockets parallel to the limbus using a Crescent 2.2mm blade (DORC, Nederland, Sterile Disposable).

In cases of subluxated or dislocated IOLs, these were explanted through a 2.75mm tunneled corneal incision. Anterior and central vitrectomy was performed (Three-port Trans-parsplana Vitrectomy) using 25-gauge sclerotomies (Stellaris Elite™ Bausch and Lomb, USA) in all our patients.

The Carlevale IOL is then inserted into the anterior chamber using the Medicel Viscojet 2.7 IOL injector. After checking the orientation of the implant using the two notches on the lens body (one on the inferior left side and one on the superior right side), a 25 gauge distal control intraocular micro forceps is used through the sclerotomy to grasp the IOL anchoring T. The forceps is then slowly withdrawn pulling the first haptic plug through the sclerotomy.

The micro-forceps is then inserted through the 2nd sclerotomy, which is diametrically opposed, and the same technique is used to externalize the 2nd haptic plug of the implant through the second sclerotomy.

The crucial phase of this surgery is the exteriorization of the main haptic using the dedicated micro forceps, as well as the injection of the implant into the anterior chamber; however, the manipulation of the haptic plug is quite forgiving as it can be manipulated to a certain extent without deforming. It should also be noted that the length of the haptic part that should be externalized through the sclera is minimal.

Finally, the two haptic plugs are positioned in the previously dissected scleral pockets. The centering of the lens is checked, then the sclerotomies are tested for leaks and the conjunctiva is sutured with 7/0 absorbable polyglactin (Vicryl). If there is a leak, the sclerotomies are sutured with 8/0 Vicryl. An intracameral injection of cefuroxime is given at the end of the surgery.

RESULTS

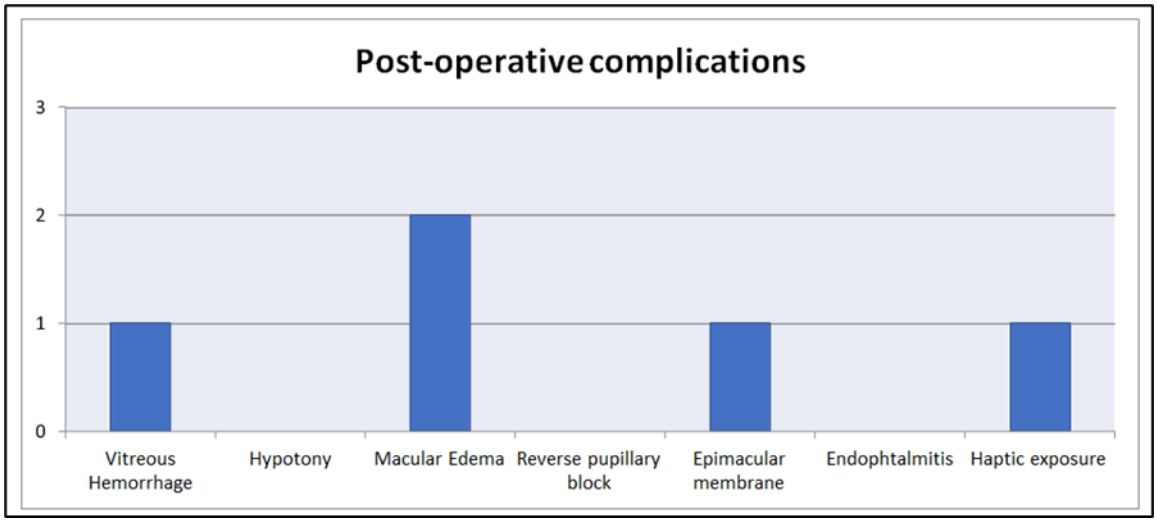
The mean age of our patients was 76 ± 13.5 years with a slight male predominance (53%). The indication for secondary implantation surgery was the presence of aphakia in 60% of cases. IOL subluxation was noted in 33% of cases, and the remaining 6% were cases of intraocular implants dislocated in the vitreous cavity. Pseudo- exfoliative syndrome was noted in 66% of cases and Marfan's syndrome was found in 13% of our patients (2 cases).

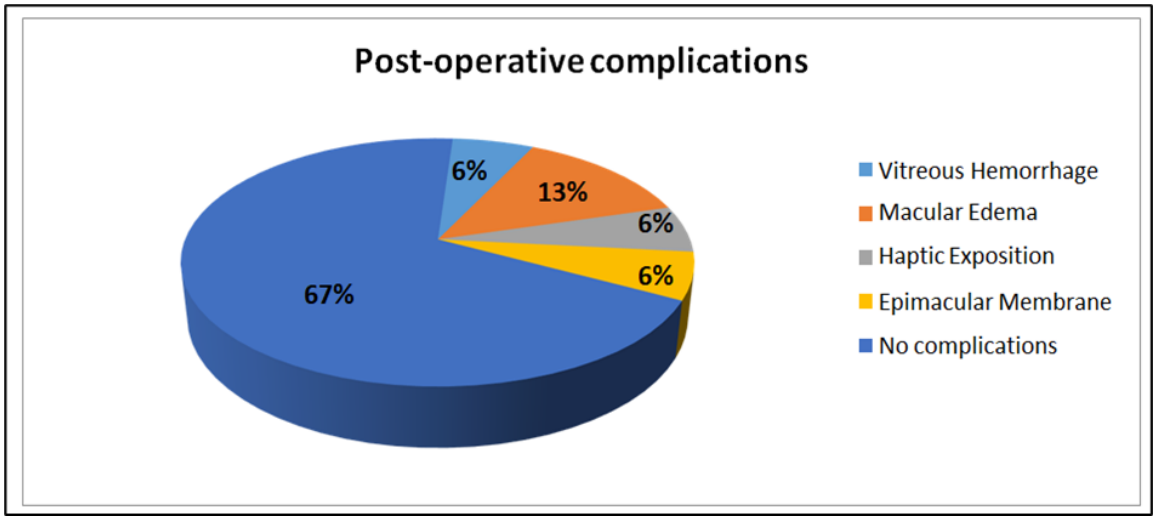
The mean best corrected visual acuity (BCVA) was 0.7 ± 0.25 log MAR preoperatively and 0.15 ± 0.33 log MAR one year postoperatively, representing a mean gain of 5 lines on the Snellen scale. As for the refractive results, the mean preoperative spherical equivalent was +5.34 D ± 4.93 (60% of cases of aphakia), compared with -0.68 ± 0.93 dpt at the one-year postoperative control (with extremes ranging from -2.12 dpt to +1.75 dpt). Surgically induced astigmatism (SIA) was 0.43 ± 0.66 dpt. The mean preoperative intraocular pressure was 14.50 ± 2.95mmHg, with a mean of 15.25 ± 3.39mmHg at the last follow-up. The mean density of corneal endothelial cells decreased from 1,928 to 1,683 cells/mm2 at one year, although no cases of endothelial decompensation were reported during our follow-up.

	Evolution de la MAVC en log MAR	**Evolution de l'équivalent sphérique**	**Pression intraoculaire**	**Cellularité endothéliale**
Préopératoire	0,7 ± 0,25 log MAR	5.34 D ± 4,93 dpt	14.50 ± 2.95 mmHg	1 928 cellules/mm2
Au contrôle du 3ème mois post opératoire	0,13 ± 0,33 log MAR	-0,87 D ± 0,67 dpt	15.37 ± 3.14 mmHg	1 773 cellules/mm2
Au contrôle à un an post opératoire	0,15 ± 0,41 log MAR	-0,68 D ± 0,93 dpt	15.25 ± 3.39 mmHg	1 683 cellules/mm2

Regarding postoperative complications, one case of intravitreal hemorrhage and two cases of postoperative cystoid macular edema (Irvine Gass) were reported, all of which were managed medically with spontaneous resolution at one month postoperatively. However, given the absence of discomfort reported by the patient and the absence of complications on the ocular surface, we kept the patient under simple surveillance. We also noted the development of an epimacular membrane with functional repercussions in a single case; the patient is currently scheduled for surgery (membrane and ILM peeling). No cases of reverse pupillary block, ocular hypotony, subluxation or

dislocation of the implant or endophthalmitis were observed (one year follow-up).





DISCUSSION

Secondary IOL implantation in patients with insufficient capsular support represents a real challenge for ophthalmologists, although there are currently various surgical options available for the management of such cases [1]. Poor capsular support can be seen in many conditions such as ocular trauma, complicated cataract surgery or pseudo-exfoliation syndrome. It can also be seen in other systemic conditions such as homocysteinuria, Marfan and Weill-Marchesani syndromes [2].

The placement of an IOL in the capsular bag in these patients is often a risky or impossible procedure, due to the increased risk of dislocation or subluxation and the eventual need for subsequent surgery [1]. When capsular support is insufficient, the surgeon must make a reasoned choice to implant either an anterior chamber IOL, an iris-fixed lens or a scleral-fixed IOL [3]. Although the percentage of complications varies from a study to another, a report by the American Academy of Ophthalmology (AAO) in 2003 compared the efficacy of different secondary implantation techniques and concluded that the scientific data available in 2003 was insufficient to prove the superiority of any one type of lens or fixation site, and that each of these methods had advantages and disadvantages that should be taken into consideration when tailoring surgical management to each patient [4].

Anterior chamber and iris-fixed implants have long been the most widely used because their operative techniques are relatively simpler and, above all, accessible to anterior segment surgeons. However, an increasing number of recent studies published since the 2003 AAO report have focused on the advantages of secondary implantation techniques using scleral fixation [5].

The use of a posterior chamber intraocular lens for secondary implantation offers a number of advantages: the IOL is close to the physiological position of the natural lens and therefore far from the corneal endothelium and angular structures. This technique

provides a good mechanical barrier between the vitreous cavity and the anterior chamber and its stability is independent of the conditions of the iris diaphragm, which can often be damaged after a first complicated cataract surgery or ocular trauma [3].

However, scleral fixation techniques also have their drawbacks. Those using suture fixation to the sclera are technically demanding, with a long and slow learning curve, and above all can lead to complications such as post-operative inflammation, alteration of the ocular surface, exposure, erosion or loosening of the suture knot, tilting and decentering of the implant, or even its subluxation or dislocation, as well as intra-vitreal hemorrhage and even increased risk of endophthalmitis. Sutureless techniques have therefore gained in popularity among ophthalmologists in recent years [6-9].

Recently, Yamane *et al*., [10] proposed another attractive Sutureless scleral fixation technique that has become very popular: 30 gauge needles are used to create scleral tunnels and to engage a three piece IOL haptics, which are cauterized at their edges.

Agarwal also described another alternative method whereby the haptics of a three-piece intraocular implant are externalized and glued into partial-thickness limbal scleral flaps using fibrin glue [11]. Scharioth then developed a third method of externalizing the IOL haptics using direct sclerotomies and integrating the haptics into 2 to 3 mm scleral flaps adjacent to the sclerotomies [12].

However - in our experience - it is a delicate and difficult procedure to insert the haptic into a needle without bending it and possibly damaging it. Furthermore, the creation of tunnels, pockets or intra-scleral flaps with perfectly symmetrical engagement of the haptic parts of the three-piece IOL is a challenge that often compromises the final position of the implant and therefore results in tilting and decentering of the IOL.

Deformation of the haptic of the IOL during its externalization is also a factor to be taken into account, as it can affect the final refractive and functional prognosis of the surgery [10].

In addition to these disadvantages of the Sutureless scleral fixation techniques mentioned above, there is a another major problem, particularly in large eyes with a corneal diameter greater than 11.5 mm, where the haptics of standard three-piece implants are often of insufficient length for intra-scleral manipulation and insertion. Modifications to the technique were therefore used, with more anterior sclerotomies exposing the patient to the risk of iatrogenic uveal lesions and intraoperative bleeding, therefore compromising the final surgical outcome [3, 11].

The Carlevale Sutureless IOL implantation technique, on the other hand, offers the great advantage of not requiring extensive externalization of the haptics or the creation of a scleral tunnel for fixation, the latter being ensured by a system of two self-locking T-shaped haptic anchors that prevent the implant from falling into the vitreous cavity. Because of the ease with which the lens can be fixed to the sclera, and given the large overall diameter of the IOL (13.5 mm), successful implantation is possible even in patients with a large cornea (high myopic patients or patients diagnosed with Marfan Syndrome) [13].

The design of the Carlevale IOL also offers a major advantage: the risk of damage to the haptics is greatly reduced as only the T-anchor is grasped and pulled through the sclerotomy, minimizing the manipulations and preserving the integrity of the haptics, which remain almost completely within the vitreous cavity [14].

In addition, optimal stability and centering of the Carlevale lens is achieved naturally on the sole condition that the sclerotomies are diametrically opposed (located on the 0-180° axis). The distance between the cornea and the lens is therefore fixed, thus minimizing optical aberrations, whereas in other techniques such as Yamane's, the inclination is strongly influenced by the symmetry and orientation of the scleral fixation tunnels [15]. The duration of the operation is also shorter because it is less technically demanding and requires fewer manipulations than other Sutureless procedures. Good centering is further enhanced in the case of the Carlevale lens thanks to its large optic (6.5mm) [16].

To date, and given the relatively recent nature of this technique, few studies evaluating the results of the use of the Carlevale IOL in the secondary implantation of aphakic patients or patients with insufficient capsular support are available.

However, since 2020, few of studies have emerged, all showing very satisfactory surgical and refractive results. Veronese *et al*., (study carried out in 2020 on a series of 4 patients) found an improvement in the BCVA of 0.5 to 0.08 log MAR at 6 months (improvement equivalent to 4 lines on the Snellen scale), and Vaiano *et al*., (study of 54 eyes carried out in 2021) found an improvement of 0.93 to 0.42 log MAR at 6 months (improvement equivalent to 5 lines on the Snellen scale) [17, 18]. The refractive prediction error is minimal in most studies, for example Barca *et al*., (study carried out in 2020 on a series of 32 patients) found a postoperative spherical equivalent at 3 months of 0.24 ± 0.81 diopters [19].

Barca et al. and Veronese *et al*., point out that the most frequently described complications are vitreous hemorrhage and transient hypotony [17, 19]. Although no cases of hypotony were found in our series, we

assume that this is related to the caliber of the sclerotomies used (25 gauge), which are smaller and therefore naturally tighter post-operatively than 23 gauge sclerotomies.

Most studies looking at the stability of the Carlevale implant have also found no cases of IOL subluxation or dislocation [16, 19]. The corneal endothelium was also spared in most studies, including our own. For example, the study by Vaiano et al found a mean reduction in cellularity of 112 at one year [18].

As the Carlevale lens is hydrophilic (25% H2O), its good uveal biocompatibility surely have contributed to the absence of any major post-operative inflammatory reaction in our study, as well as the absence of deposits formation on the IOL during the follow-up period.

As our study is not without its limitations, it is worth emphasizing that we regret the small number of our patient and the short follow-up period, which we would have hoped to be longer to better assess the long-term results of this technique.

CONCLUSION

Secondary implantation using a Carlevale Sutureless scleral fixation IOL represents an attractive, reproducible and minimally invasive surgical technique with very good functional results and very minimal induced post-operative astigmatism.

By guaranteeing optimal refractive results and a low complication rate, this implant has been added to the therapeutic arsenal for improving the prognosis of patients with insufficient capsular support. However, larger-scale studies, comparing it with other techniques and with longer follow-up periods are needed to verify the functional results and the safety profile of this technique over the long term.

Conflict of Interest: No

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