

Secondary IOL Implantation Without Capsular Support



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INTRODUCTION

NUMEROUS TECHNIQUES AND TECHNOLOGIES HAVE been developed for implantation of intraocular lens (IOL) implants with inadequate or absent zonular or capsular support. These situations may arise following crystalline lens subluxation or dislocation (eg, Marfans), ocular trauma, surgical lensectomy/vitreectomy, cataract surgical complications, or postoperative dislocation of the capsule-IOL complex. Many different strategies for noncapsular IOL fixation have evolved since IOL implantation was first performed following intracapsular cataract extraction. However, no single approach has produced demonstrably superior outcomes in terms of visual acuity or safety.¹ This review summarizes current techniques for IOL implantation without capsular support. These options use either the anterior chamber angle, the iris, or the sclera to fixate the IOL, both with and without sutures.

In a large review of different noncapsular IOL fixation approaches, the weighted mean postoperative BCVA ranged from 20/35 to 20/87.¹ The best visual outcomes were seen with intrascleral haptic fixation (ISHF) techniques and the worst outcomes with CV-8 polytetrafluoroethylene scleral suture haptic fixation. Similarly, a retrospective review of a national registry reported that overall visual acuity improved to a mean of 20/40 by one year following intraocular lens exchange.² Worse visual outcomes were associated with greater age, worse baseline vision, non-White race/ethnicity, Medicaid insurance, smoking, and concurrent anterior or posterior vitrectomy, likely reflecting more complex surgical scenarios.²

Some intraoperative complications, such as suprachoroidal hemorrhage precipitated by iatrogenic hypotony, may be mitigated by using an anterior chamber maintainer

or pars plana infusion. Early postoperative risks include IOL decentration or tilt, pupillary optic capture and pupillary block, hyphema, or vitreous hemorrhage, and wound leak. Long-term complications include IOL dislocation, suture or haptic erosion or exposure, secondary glaucoma, corneal decompensation, chronic uveitis, pigment dispersion from iris chafing, uveitis-glaucoma-hyphema (UGH) syndrome, retinal tears and detachment, and cystoid macular edema. Endophthalmitis can occur during the early postoperative period or later secondary to suture or haptic erosion or exposure. Weighted mean percentages of complications from all methods are summarized in Table. A recent meta-analysis found similar overall complication rates among different IOL fixation techniques in adult eyes without adequate capsular support, with iris fixation showing a nonsignificantly lower rate (4.4%) compared to anterior chamber placement (7.4%) and scleral fixation (7.4%).³ Transient corneal edema was most commonly reported with ACIOL implantation (29.9%) compared to scleral fixation (11.9%) and iris fixation (4.1%) techniques. On the other hand, vitreous hemorrhage was seen more frequently after scleral fixation methods (8.5%) compared to ACIOLs (5.4%) and iris fixation (1.4%), as was IOL decentration/dislocation (8.9% for scleral fixation vs. 1.1% for ACIOLs and 4.0% for iris fixation).³

Because no single technique has demonstrably superior visual outcomes or complication profiles, the approach to IOL fixation should take into account other factors, including ocular anatomy (eg, iris or angle abnormalities), patient age, and comorbid ocular pathologies (eg, glaucoma, uveitis). Additional considerations include surgeon experience and expertise, the commercial availability of IOL models, and specific elements of the surgical plan, such as incision size, the need for concurrent vitrectomy, and the degree of intraocular manipulation required.

ANTERIOR CHAMBER IOL

Open-loop anterior chamber IOLs (ACIOLs) remain the only US Federal Drug Administration (FDA)-approved option for adult aphakic patients without zonular or capsular support. Nonintracapsular fixation of posterior chamber IOLs (PCIOLs) is off-label. Positioned in the anterior chamber with slight forward vaulting of the optic, modern ACIOL designs incorporate flexible, open-loop haptic

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This invited article was submitted as part of the Cataract and Refractive Surgery Joint Virtual Special Issue with the Asia-Pacific Journal of Ophthalmology (APJO).

Accepted for publication August 10, 2025.

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TABLE 1. Comparison of mean postoperative BCVA and complications among different IOL fixation techniques with a minimum average of 6 months follow-up

	Mean postoperative BCVA	Transient corneal edema	Pupillary capture	IOL tilt	IOL decentration	IOL dislocation or haptic displacement	Erosion of suture or haptic	Wound leak
Overall ¹	20/35-20/87		0-3.5%	0-1.6%	0-3.3%	0-3.5%	0.7-3.3%	0-2.7%
Anterior chamber ³⁻⁸	20/35-20/96	29.9%	1.1-5.5%		0-3%			
Iris fixation (aggregate)		4.1%						
Sutured ^{20,23}	20/50-20/60					0-4.3%		
Iris-claw ¹⁰⁻¹⁸	20/37-20/115		0-1.6%			0.8-6%		0-6%
Scleral fixation (aggregate)		11.9%						
10-0 prolene ^{19,27-35}	20/35-20/117		0-9.6%	0-10.4%	3-6.3%		0-11%	1.6-3.7%
Gore-Tex ^{37,38}	20/50-20/80							
ISHF ^{18,46,48-55}	20/22-20/83		0-8.6%	0-1%	0-4.3%	0-5.7%	0-1%	
^a Carlevale IOL ^{60,61}	20/24-20/89	0-33.3%					0-4%	
	Uveitis	Glaucoma	Cystoid macular edema	Vitreous hemorrhage	Supra-choroidal hemorrhage	Retinal breaks	Retinal detachment	Endophthalmitis
Overall ¹	0-5.6%	0.2-13.2%	2-16.2%	0.3-4.3%	0-0.7%	0.4%	0-3.3%	0-1.7%
Anterior chamber ³⁻⁸	0-20%	0-16.7%	0-15%	0-6.7%			0-2.2%	0-2.2%
Iris fixation (aggregate)								
Sutured ^{20,23}		2.1%	2.8%				2.1-5.5%	
Iris-claw ¹⁰⁻¹⁸	0-11.5%	0-0.8%		1.0-2.6%		0.8%	0-3.2%	
Scleral fixation (aggregate)								
10-0 prolene ^{19,27-35}	0-3.7%	4.9-8.3%	5.7-10.4%	2.9-8.3%	0-4.2%	0-1.6%	0-8.2%	0-1.2%
Gore-Tex ^{37,38}		0-12%	2-9%	7-13%			0-6%	
ISHF ^{18,46,48-55}	0.4-4%	1-3.2%	1-21.3%	0-22.1%			0-3.3%	0-0.8%
^a Carlevale IOL ^{60,61}	0-8.3%		2.8%-43.8%	1.4%-16.7%			1.4%-4%	0-7.7%

BCVA: best corrected visual acuity; IOL: intraocular lens; ISHF: intrascleral haptic fixation.

^aMinimum average of 2 months follow-up.

footplates that offer improved safety and enhanced stability when properly sized and seated within the angle. ACIOLs have equivocal visual acuity outcomes reported compared to PCIOLs.⁴⁻⁸ However, because ACIOLs are often implanted following significant surgical complications, interpreting and comparing outcomes from different retrospective studies is difficult. Properly sized modern ACIOL designs have demonstrated excellent long-term follow-up, and they remain a popular option because of the relative ease with which they can be implanted.

Many complications from ACIOL implantation arise from improper sizing. ACIOLs that are too large may cause iris tuck, pupillary distortion, peripheral anterior synechiae, and elevated intraocular pressure (IOP) due to angle trauma. Those that are too short may result in IOL mobility, rotation, or dislocation, with resulting endothelial cell loss, iridocyclitis, or hyphema. ACIOLs are made of polymethylmethacrylate (PMMA) and are not foldable. Therefore, a larger incision with suture closure is required to insert the full 6.0 mm diameter lens. A scleral tunnel approach is preferred by some to minimize induced astigmatism.

Constricting the pupil with miotics and the use of a Sheet's glide reduces the risk of peripheral iris tuck by the ACIOL haptics or incarceration of iris tissue in the incision. Either may cause ovalization of the pupil. Peripheral iridotomy is recommended to reduce the risk of postoperative pseudophakic pupillary block and angle closure glaucoma due to iris bombe.

A significant complication historically associated with ACIOLs is corneal decompensation, and transient corneal edema remains the most common complication following implantation of ACIOLs (29.9%).³ However, it is difficult to know how much endothelial cell loss occurred during the original complicated surgery compared to the secondary procedure to implant the ACIOL. Whether progressive, long-term endothelial cell loss continues following implantation of a properly sized ACIOL is unknown. Comparative studies have reported other ACIOL complication rates of 1.1% to 5.5% for pupillary block, 0% to 3% for IOL decentration, 0% to 16.7% for glaucoma, 0% to 20% for chronic uveitis, 0% to 15% for CME, 0% to 6.7% for vitreous hemorrhage, 0% to 2.2% for retinal detachment, and 0% to

2.2% for endophthalmitis (Table).³⁻⁸ Many surgeons avoid ACIOLs in younger patients and those with significant iris abnormalities or defects. Older, rigid, single-piece ACIOL designs and those with closed-loop haptics have been discontinued because of much higher complication rates.

IRIS-FIXATED IOL

Iris fixation provides an excellent means of IOL stabilization if intracapsular placement is precluded by the loss of zonular or capsular support. This can be achieved with anterior or retropupillary fixation of iris-claw IOLs or by suturing 3-piece IOL haptics to the mid-peripheral iris with 10-0 polypropylene sutures. First introduced by J G Worst in 1972,⁹ the iris claw IOL is currently available as the Artisan IOL, a single-piece PMMA lens with two iris-claw haptics. Although not FDA-approved in the United States, iris-claw IOLs are widely used globally where available. Compared to ACIOLs, iris-claw IOLs avoid contact with anterior chamber angle structures and therefore avoid the problem of excessive or inadequate IOL length. However, corneal endothelial contact and damage can still potentially occur with prepupillary placement. Many favor retropupillary fixation of iris-claw IOLs to reduce the risk of progressive endothelial cell loss for this reason. Proper centering and enclavation techniques are essential to prevent IOL dislocation. Ovalization of the pupil may occur with asymmetric enclavation or if the haptics are placed too close to the pupil margin rather than the mid-peripheral iris.

Reported visual outcomes for iris-claw IOLs range from 20/37 to 20/115 with an average follow-up of at least one year.¹⁰⁻¹⁹ By avoiding the need for sutures, iris-claw IOLs may be easier to insert and avoid late suture-related complications. In addition, the effective lens position of iris claw IOLs tends to be more predictable than with scleral-fixation techniques. However, iris-claw PMMA IOLs require larger incisions for implantation and may induce greater postoperative astigmatism. The approach also requires normal iris anatomy. Although localized iris atrophy or defects may still allow secure fixation to the iris, diffuse areas of traumatic scarring and atrophy, large iris defects, significant iridodonesis, congenital iris anomalies (eg, iris coloboma), or active uveitis may compromise fixation stability. Other reported complications for iris-claw IOLs (Table) include pupillary capture (0%-1.6%), IOL dislocation (0.8%-6%), wound leak (0%-6%), glaucoma (0%-0.8%), uveitis (0%-11.5%), vitreous hemorrhage (1.0%-2.6%), retinal break (0.8%), and retinal detachment (0%-3.2%).¹⁰⁻¹⁸

Iris suture fixation of 3-piece IOL haptics was first described by Malcom McCannel in 1976 with later modifications reported by Walter Stark, Garry Condon, and one of the authors (DFC).²⁰⁻²² The technique typically involves first constricting the pupil pharmacologically, followed by

anteriorly prolapsing a 3-piece PCIOL optic through the pupil. This optic capture temporarily fixates the mobile IOL and compresses the two haptics against the posterior iris. A curved needle is used to snare each underlying haptic with 10-0 polypropylene sutures that are then tied with a Siesper slipknot technique. This is an excellent option to re-fixate a subluxated or dislocated 3-piece monofocal PCIOL in the ciliary sulcus. If adequate posterior capsular support remains, suture fixation of a single haptic may be sufficient to prevent rotation or recurrent subluxation.²² Ovalization of the pupil can be avoided by taking small suture passes through the mid-peripheral iris. Postoperative mean BCVA for iris-sutured IOLs with an average follow-up of over one year ranges from 20/50 to 20/60 (Table). Reported complications include IOL dislocation (0%-4.3%), glaucoma (2.1%), CME (2.8%), and retinal detachment (2.1%-5.5%).^{20,23}

A recent study comparing iris suture-fixation of an existing dislocated IOL versus IOL exchange for a retropupillary iris-claw IOL reported similar postoperative visual outcomes and complication rates at six months.²⁴ Although greater postoperative astigmatism was seen due to the large corneoscleral incision required for IOL exchange with an iris-claw IOL, the surgical time was, on average, approximately 20 minutes faster than for iris suture-fixation.

SCLERAL-FIXATED IOL

Scleral-fixated IOLs (SFIOLs) have gained popularity due to their ability to position the IOL in the posterior chamber without the need for iris or capsular support. This theoretically reduces the risk of corneal endothelial damage, iris chafing, and secondary glaucoma. Variations include scleral fixation using Gore-Tex or polypropylene sutures, and sutureless intrascleral haptic fixation (ISHF) methods that involve tunneling the haptics through or into scleral tracks. Symmetric haptic positioning is critical for optic centration and to avoid lens tilt. Malpositioning of the haptics, especially if they not aligned precisely 180 degrees apart and equidistant from the limbus, can result in IOL tilt or decentration. Mild IOL tilt may induce astigmatism and affect uncorrected visual acuity, while significant optic tilt can result in iris chafing, inflammation, IOP elevation, and partial optic capture by the pupil. Transconjunctival suture or haptic erosion poses a risk for endophthalmitis and chronic irritation. This can generally be prevented by burying knots within sclerotomies or scleral grooves and ensuring adequate overlying conjunctival and Tenon's coverage. The use of scleral flaps and tunnels further reduces the risk of suture and haptic erosion and exposure. Richard Hoffman devised a method to create paired, partial-thickness scleral pockets for scleral suture fixation of haptics without the need for conjunctival dissection.²⁵

When comparing ISHF-IOL outcomes with either full pars plana vitrectomy (PPV) or partial anterior vitrectomy (AV), a 2014 study found similar postoperative BCVA ranging from 20/30 to 20/40. PPV was associated with a lower risk of IOP elevation and IOL dislocation, but a greater myopic shift and a higher incidence of pupillary optic capture.²⁶

- **SCLERAL SUTURE IOL FIXATION:** Scleral suture fixation of IOLs is typically performed with polypropylene (10-0 or 9-0, Ethicon, Somerville, New Jersey) or CV-8 polytetrafluoroethylene (PTFE or Gore-Tex, W.L. Gore & Associates), equivalent in size to 7-0 gauge. IOLs with eyelet designs (ie, Alcon CZ70BD, B&L Envista MX60) or closed-loop haptics (ie, Akreos AO60) are ideally suited for scleral suture fixation, providing a natural opening through which to thread and anchor the sutures. Alternatively, sutures may be used to loop around the haptics of single or 3-piece IOLs, or to fixate an implanted intracapsular tension ring. The surgical approach requires additional steps of conjunctival peritomies and dissection down to bare sclera to adequately bury suture knots and prevent later exposure and conjunctival erosion. Furthermore, precise and proper suture placement is important to avoid IOL torque and tilt.

Reported mean BCVA for 10-0 polypropylene scleral-sutured PCIOLs ranges from 20/35 to 20/117, with follow-up from an average of six months to nearly seven years.^{19,27-35} Suture degradation and breakage with subsequent IOL dislocation is a long-term concern. One study found that 28% of eyes required reoperation for scleral suture breakage presenting an average of 4 years after initial surgery.²⁷ Another with at least 10 years of follow-up reported approximately 80% IOL survival at 10 years, with 39% exhibiting decentration or dislocation by a mean of nine years, likely due to suture degradation.³⁶ Larger-gauge polypropylene suture theoretically reduces the risk of late IOL dislocation due to suture breakage; however, long-term data remain limited. Less common complications reported with 10-0 polypropylene scleral suture fixation (Table) include pupillary capture (0%-9.6%), IOL tilt (0%-10.4%), IOL decentration (3%-6.3%), erosion of suture (0%-11%), wound leak (1.6%-3.7%), glaucoma (4.9%-8.3%), uveitis (0%-3.7%), CME (5.7%-10.4%), vitreous hemorrhage (2.9%-8.3%), suprachoroidal hemorrhage (0%-4.2%), retina breaks (0%-1.6%), retinal detachment (0%-8.2%), and endophthalmitis (0%-1.2%).²⁷⁻³⁵

CV-8 PTFE is a nonabsorbable monofilament suture with greater tensile strength than polypropylene. Although not FDA-approved for ophthalmic use, it is frequently used off-label for scleral suture fixation of PCIOLs due to its presumed greater suture longevity. With an average of 10 months of follow-up, mean reported BCVA ranges from 20/50 to 20/80 (Table), with complications including glaucoma (0%-12%), CME (2-9%), vitreous hemorrhage (7%-13%), and retinal detachment (0%-6%).^{37,38} Although

CV-8 PTFE suture breakage has not been reported, published studies document follow-up of only 1 to 5 years.

The choice of IOL for scleral suture fixation influences incision size, ease of implantation, and long-term suture stability and durability. The Akreos, a foldable, hydrophilic acrylic single-piece IOL with 4 eyelets, enables four-point fixation but is prone to opacification if gas or oil is used in subsequent endothelial keratoplasty or vitreoretinal surgery. The CZ70BD and MX60 are both single-piece IOLs with two eyelets. While the CZ70BD IOL is made of nonfoldable PMMA and necessitates a larger incision, late postoperative eyelet fractures have been reported with the foldable hydrophobic acrylic MX60 model, potentially due to fragility of the acrylic material when subjected to long-standing suture tension.³⁹

In 2018, Sergio Canabrava described a method for “knotless” scleral IOL fixation utilizing flanged polypropylene suture tips rather than tied suture knots to secure haptics to the sclera. Canabrava initially devised this technique to suture fixate capsular bag stabilization devices, such as the Ahmed capsule segment, in eyes with zonular instability.⁴⁰ He subsequently applied this technique for scleral fixation of IOLs.⁴¹ The double-flanged technique features one flange of 5-0 or 6-0 polypropylene secured against an eyelet of a capsular tension segment, modified capsular tension ring, or IOL haptic, while the other flange is secured subconjunctivally ab externa through the sclera. Long-term stability has been reported with 5-year results, but includes complications such as exposed haptic flanges (2.9%) and scleral internalization of haptic flanges (2.2%).⁴²

The principle of the Canabrava technique has led to new variations, including a “belt loop” haptic suturing technique described in 2019 by Cathleen McCabe to rescue an existing IOL that has decentered or dislocated, as long as adequate capsular support remains.⁴³ Flanged sutured belt loop scleral fixation of haptics can be used for any type of posterior chamber IOL, including single-piece models. Re-fixating an existing IOL with this technique can be done through small paracentesis incisions, avoiding a lengthier and more complex IOL exchange or conjunctival dissection with traditional sutured haptic fixation. This strategy may be preferred for patients who wish to keep their existing IOL (e.g. refractive IOL model). The Canabrava technique has also been used with the IOL punch, recently developed by J Morgan Micheletti in 2021, to salvage an existing subluxated single-piece IOL. A small opening at each optic-haptic junction is created with the punch device through which a flanged 5-0 polypropylene suture can be threaded and secured to the sclera.⁴⁴

- **SUTURELESS ISHF:** Sutureless intrascleral haptic fixation techniques were developed to avoid long-term suture complications, such as breakage, erosion, and exposure. Use of scleral tunnels for ISHF of 3-piece PCIOL haptics was first described in 2007 by Gabor Scharioth and demonstrated good centration and stability.^{45,46} Subsequent mod-

ifications by Amar Agarwal led to the so-called “glued IOL” technique, in which the haptics were embedded in scleral tunnels underneath partial-thickness scleral flaps that were secured with fibrin glue.⁴⁷ In 2017, Shin Yamane introduced the flanged transconjunctival ISHF technique that commonly bears his name. This method of noncapsular fixation of 3-piece IOLs rapidly gained popularity because it avoids conjunctival and scleral dissection.⁴⁸ The 2 haptics of a 3-piece IOL are each threaded into 30-gauge thin-wall guide needles placed transconjunctivally and angled transsclerally through the ciliary sulcus, where they are then positioned and visualized through the pupil. Once each haptic is guided externally, low-temperature cautery is used to create a terminal flange that keeps the haptic tip from sliding back into the eye. This transconjunctival approach obviates the need for conjunctival dissection and can significantly reduce surgical time. Due to minimal conjunctival manipulation, it is ideal for patients who may need future glaucoma surgery or have cicatrizing conjunctival disease. The Zeiss CT Lucia 3-piece IOL has been commonly used for the Yamane ISHF technique because its flexible polyvinylidene fluoride (PVDF) monofilament haptics are more flexible and resist permanent deformation following surgical manipulation. However, subsequent reports of postoperative intraocular optic “roisserie” – rotation around the optic-haptic junction – have led some surgeons to prefer alternative 3-piece IOLs, such as the J&J AR40 Sensar, B&L SofPort LI61AO, and more recently, the RxSight light adjustable lens, despite the added difficulty of haptic-needle docking with stiffer PMMA haptics.

Reported visual outcomes with glued or Yamane ISHF are favorable, with mean BCVA reported an average of 6 months postoperatively ranging from 20/22 to 20/83 (Table).^{18,46,48-55} Reported complications include pupillary optic capture (0%-8.6%), IOL tilt (0%-1%), IOL decentration (0%-4.3%), IOL dislocation (0%-5.7%), haptic erosion and tip exposure (0%-1%), glaucoma (1%-3.2%), uveitis (0.4%-4%), CME (1%-21.3%), vitreous hemorrhage (0%-22.1%), retinal detachment (0%-3.3%), and endophthalmitis (0%-0.8%).^{18,46,48-55}

Unlike ACIOLs and iris-claw IOLs, iris-sutured and scleral fixation techniques allow surgeons to implant foldable 3-piece IOLs designed for intracapsular placement in the setting of insufficient capsular support. However, each methodology has its own technical limitations. The Carlevale single-piece IOL was specifically designed by Carlo Carlevale for noncapsular posterior chamber IOL implantation with the goals of greater stability and decreased risk of IOL tilt. While commercially approved in the European Union, the Carlevale IOL is not currently available in the United States.⁵⁶

The original Carlevale model (I71 FIL SSF. Soleko IOL Division, Pontecorvo, Italy) featured a foldable single-piece hydrophilic acrylic IOL with closed haptics and T-shaped anchors that can be secured in the sclera without sutures (Figure 1). The newer model (Carlevale IOL High-Tech.

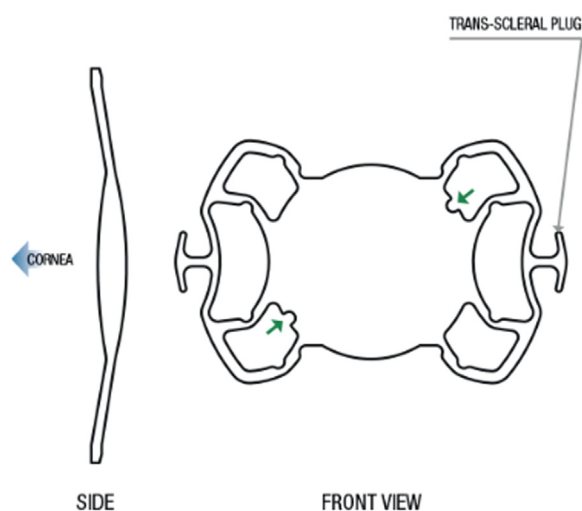


FIGURE 1. Schematic of the Carlevale IOL.

Md-tech, Casoria, Italy) has both hydrophobic and hydrophilic properties with stiffer scleral anchors. Anterior angulation of the haptics from the optic plane minimizes the potential for iris chaffing and pupillary block. The Carlevale IOL can be inserted through a small 2.2 mm incision using a specific plunger injector and cartridge (Medicel).⁵⁷ Techniques for Carlevale fixation were first described in 2020, with the anchors externalized through transscleral vitrectomy ports to rest beneath conjunctiva⁵⁸ or alternatively, secured beneath scleral flaps.⁵⁹ After insertion of an infusion line (pars plana infusion or anterior chamber maintainer), 2 limited conjunctival peritomies are performed 180 degrees apart, and scleral flaps or pockets are created.⁵⁷ A sclerotomy is performed within each scleral flap or pocket. As the IOL is injected through the corneal incision, the leading IOL anchor is grasped with 23G micro-forceps through one of the sclerotomies and externalized. The trailing anchor is then grasped by intraocular micro-forceps via the second sclerotomy using a handshake maneuver. Care must be taken to avoid fracturing the delicate haptic anchors as they are grasped and manipulated with forceps. Sutures are used to secure the scleral flaps or pockets and close the conjunctiva. Alternatively, transscleral 27G vitrectomy trocars can be used to properly position the anchors.⁵⁶

From initial studies reported in a 2023 meta-analysis, mean postoperative BCVA with the Carlevale IOL ranges from 20/24 to 20/89.⁶⁰ In a study comparing secondary IOL implantation with the Carlevale scleral-fixated IOL or the Artisan iris-claw IOL, the improvement in vision was comparable between the two methods; however, surgical time was significantly longer with the Carlevale IOL.⁶¹ Postoperative complications include hyphema or vitreous hemorrhage, CME, hypotony, and retinal tears and detachment. Exposure of the anchors may occur if they are not properly embedded in the sclera and covered with conjunctiva.

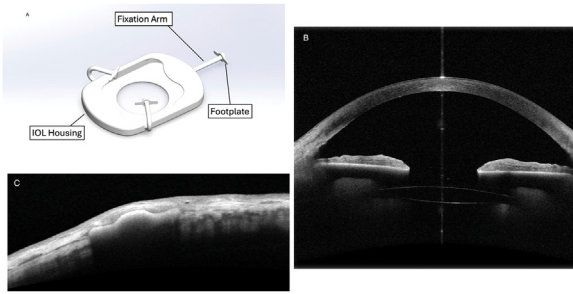


FIGURE 2. Prosthetic capsular bag schematic (A) and anterior-segment OCT images depicting the device with an intraocular lens implant (B) and a footplate covered beneath conjunctiva and Tenon's (C).

FUTURE INNOVATION

The Carlevalle IOL is currently the only IOL specifically designed for posterior chamber implantation in eyes lacking capsular support; most other options for scleral fixation are limited to 3-piece monofocal IOLs. When in-the-bag placement is no longer possible, single-piece IOLs – including most refractive IOLs – are generally excluded. Frank Brodie recently reported results from the first in-human clinical trial of a sutureless, scleral-fixated prosthetic capsular bag (PCB) using single-piece IOLs.⁶² The PCB consists of an IOL housing with three fixation arms and footplates that

rest on the external scleral surface beneath conjunctiva and Tenon's capsule (Figure 2). With three points of fixation, the PCB aims to reduce IOL tilt, a common risk with two-point fixation techniques for secondary IOLs. The device can be implanted with a preloaded IOL or secured prior to intraocular IOL insertion. Made of a flexible, biocompatible material, it can be delivered using a standard IOL injector through a 2.4 mm clear corneal incision.

The unique design of the PCB offers several potential advantages. Surgeons are able to use readily available IOLs rather than require specialty consignments, including single-piece refractive IOL designs to match or complement the fellow eye. The PCB also reduces intraocular maneuvers, eliminates conjunctival or scleral flap dissection, and does not require off-label IOL modifications such as haptic suturing and cauterization. Although not yet commercially approved or available, the safety and efficacy of this novel device at one-year follow-up appear quite promising, with no device-related adverse events reported and excellent refractive outcomes.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Stephanie P. Chen: Conceptualization, Data curation, Writing – original draft, Writing – review & editing.
David F. Chang: Conceptualization, Data curation, Writing – original draft, Writing – review & editing.

Declaration of competing interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding/Support: This review did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Financial Disclosures: DFC is a consultant to Alcon, J&J Vision, Long Bridge Medical, RxSight, and Zeiss. SPC reports no financial disclosures.

Other Acknowledgments: None.

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