

In vivo evaluation of a 1-piece foldable sutureless intrascleral fixation intraocular lens using ultrasound biomicroscopy and anterior segment OCT



Alessandro Mularoni, MD, Aurelio Imburgia, MD, Matteo Forlini, MD, Laura Rania, MD, Giovanna Linda Possati, MD

Purpose: To evaluate the optic plate and haptics of a specially designed sutureless intrascleral-fixated intraocular lens (IOL) using ultrasound biomicroscopy and anterior segment optical coherence tomography (AS-OCT).

Setting: Department of Ophthalmology, San Marino Hospital, Republic of San Marino.

Design: Retrospective observational case series.

Methods: Eyes that underwent intrascleral fixation with IOL implantation (Carlevale) were included. Preoperative and postoperative refractive outcomes were reported. Optic plate tilt and haptics position were assessed with ultrasound biomicroscopy, whereas intrascleral plug depth and conformation were evaluated with AS-OCT.

Results: The study comprised 10 aphakic eyes. Postoperative visual acuity improved in all patients. At postoperative month 3, 3 eyes (30%) had a vertical tilt of more than 100 μm , whereas no

horizontal tilt was observed in any patient. The mean vertical intraocular tilt was 0.19 ± 0.22 mm. Of 20 haptics, 13 (65%) passed through the ciliary sulcus, 4 (20%) posterior to the ciliary body, and 3 (15%) through the ciliary body. AS-OCT scans showed a mean intrascleral plug depth of 247.20 ± 62.82 μm in the nasal sector and 265.50 ± 30.11 μm in the temporal sector, with adequate integration of the T-shaped plugs in the scleral tissue.

Conclusions: This secondary IOL showed good intraocular stability and safe haptics fixation, making it suitable for the intrascleral fixation technique. The specific foldable design results in a low predisposition to optic plate tilt and haptic torsion. In long eyes, the sulcus-to-sulcus distance should be carefully evaluated preoperatively because the flexible structure of the IOL could be subjected to excessive stretching.

J Cataract Refract Surg 2020; ■:1–7 Copyright © 2020 Published by Wolters Kluwer on behalf of ASCRS and ESCRS

Aphakia is a possible consequence of complicated cataract surgery, especially in the presence of poor capsular support. Trauma, pseudoexfoliation syndrome, zonular dialysis, and lens subluxation are mainly responsible for this situation.^{1–3} The options for managing this condition include a variety of surgical techniques and secondary intraocular lenses (IOLs), such as anterior chamber IOLs, iris-fixated IOLs, or scleral-fixated IOLs.⁴ Each approach has advantages and disadvantages related to surgical technique, duration of surgery, and postoperative complications, and currently, there is no consensus on the best technique for dealing with these situations.^{1,3–5}

The scleral fixation technique has proven to be effective in the absence of capsular support, allowing IOL placement in the correct anatomical location with predictable refractive outcomes.^{1,3,4} IOL implantation in the posterior chamber can

result in less corneal decompensation, glaucoma, and cystoid macular edema compared with the other procedures.^{1,5} However, this technique involves needle penetration through the scleral and uveal tissues, predisposing to vitreous hemorrhage, hyphema, and ocular inflammation.^{1,3–5} Scleral fixation can be performed with or without sutures. The sutureless scleral fixation technique has been proposed to solve problems such as long-term suture erosion, protrusion, and breakage.⁶ Modified surgical techniques, such as fibrin glue-assisted sutureless scleral fixation and flanged intrascleral fixation, have been described and good visual outcomes with minimal complications have been reported.^{7–9} The goal of these techniques is to symmetrically fixate the 2 haptics of a 3-piece IOL to the scleral tissue. However, the use of an IOL that is not specifically designed for sutureless intrascleral fixation could result in haptic torsion and optic

Submitted: May 27, 2020 | Final revision submitted: September 3, 2020 | Accepted: September 3, 2020

From the Department of Ophthalmology, Istituto per la Sicurezza Sociale, San Marino State Hospital, Cailungo, Republic of San Marino.

Corresponding author: Aurelio Imburgia, MD, Via Scialoja 20, 47893, Cailungo, Republic of San Marino. Email: aurelioimburgia@yahoo.it.

plate tilting, causing ocular aberrations, iris chafing, and chronic inflammation.^{10–14}

A specially designed sutureless intrascleral fixation IOL has recently been developed (Carlevalle FIL SSF, Soleko, Inc.). The sutureless intrascleral fixation technique used with a Carlevalle IOL has shown good postoperative outcomes, few intraoperative complications, and reduction in surgical complexity, as reported by several authors.^{15–17} Although the Carlevalle IOL has shown good intraoperative and postoperative results, there is still no study investigating the haptic position and optic plate tilt of this new secondary IOL.

The purpose of this study was to evaluate the intraocular position of the Carlevalle IOL in a group of patients who underwent sutureless intrascleral fixation. The optic plate and position of the haptics were assessed with ultrasound biomicroscopy (UBM), which represents the gold standard for determining IOL position and its relation to the surrounding tissues.^{10,11} Anterior segment optical coherence tomography (AS-OCT) was used to assess intrascleral haptic depth and plug conformation. To the authors' knowledge, this is the first study evaluating *in vivo* placement of the optic plate and harpoon haptics of a Carlevalle IOL with UBM and AS-OCT.

METHODS

This is a retrospective observational case series in which 10 aphakic patients (3 men and 7 women) undergoing Carlevalle IOL implantation between December 2017 and March 2020 in San Marino State Hospital, Department of Ophthalmology, were assessed. All patients were informed about the risks and benefits of surgery and gave their informed consent. The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Istituto per la Sicurezza Sociale, San Marino State Hospital, Republic of San Marino.

All patients underwent a complete ocular examination, including measurements of uncorrected (UDVA) and corrected distance visual acuity (CDVA), spherical equivalent, and intraocular pressure, and slitlamp examination, fundus examination, and measurements of endothelial cell density (ECD) and central macular thickness (CMT), both preoperatively and during the follow-up. IOL power calculation was performed with optical biometry (IOLMaster 700, Carl Zeiss Meditec AG) using the Barrett formula with the IOL constants provided by the manufacturer. Minimum follow-up was 3 months (range 3 to 15 months).

Inclusion criteria were aphakia with insufficient capsular support, IOL subluxation, or IOL opacification. Exclusion criteria were postoperative follow-up shorter than 3 months, previous ocular surgery except cataract surgery, and ocular morbidity (glaucoma, amblyopia, ocular inflammation, etc.). Surgery was performed by the same surgeon (A.M.). UBM examination with a 50 MHz probe (Aviso S, Quantel Medical) and AS-OCT scans (MS-39, CSO) were performed by the same physician (A.I.). Statistical analysis was performed using Microsoft Excel for Mac (version 14.0.0).

IOL Design

The Carlevalle FIL-SSF IOL is a 1-piece foldable acrylic IOL designed for sutureless intrascleral fixation, where IOL stabilization is ensured by means of special plugs on the end of haptics that harpoon into the scleral tissue. The overall length is 13.2 mm with an optic diameter of 6.5 mm, and the IOL can be injected through a 2.2 mm corneal incision. Each haptic consists of a T-shaped anchor plug linked to the optical plate by flexible connection mesh (Figure 1, A).

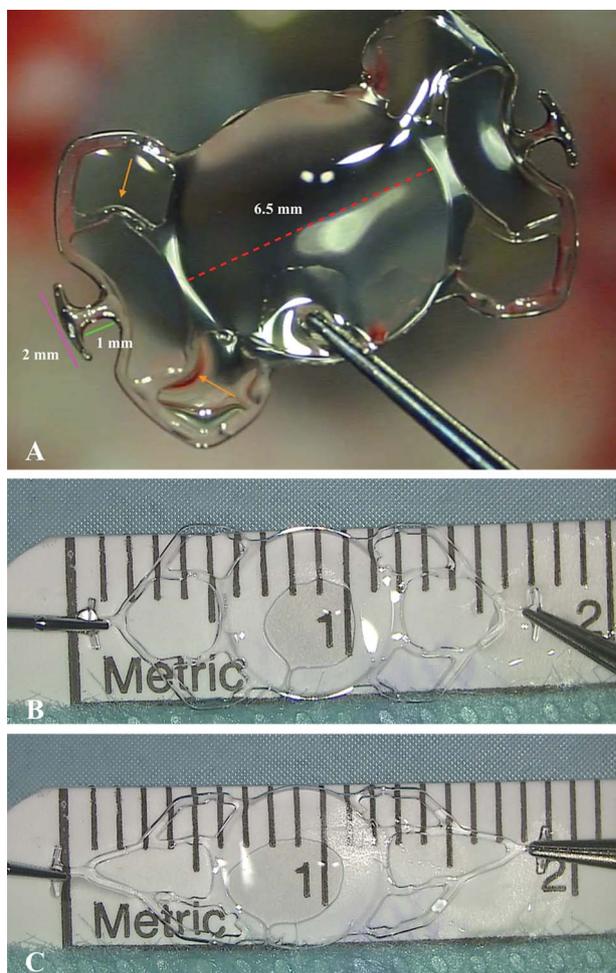


Figure 1. The Carlevalle IOL is characterized by 2 haptics with T-shaped anchor plugs linked to the optical plate by a flexible connection mesh (arrow). (A). The plugs are soft and not very extendable; by contrast, the connection mesh is extendable and can be stretched under traction (B). When the IOL is subjected to excessive stretching, an alteration of the lens design can be provoked (C).

The IOL shape is curved, and when it is not stretched, the haptics form an angle of 5 degrees with the optical plate. Two notches on the optic plate indicate the correct direction for inserting the IOL to position it with the concavity facing the posterior surface of the cornea. After implantation, the T-shaped plugs are firmly attached to the sclera, preventing IOL rotation, whereas the connection mesh is elastic and soft and can stretch when subjected to traction (Figure 1, B and C). The spherical power is between -5.00 and $+35.00$ diopters (D). Toric IOLs are available and are built to be positioned at 0 to 180 degrees along the horizontal meridian; the cylinder power and axis are customized for each patient.

Surgical Technique

After application of topical and peribulbar anesthesia, the horizontal corneal meridian was marked, and the conjunctiva was cut using Vannas scissors. In view of the plug size, two 4×4 mm scleral flaps were created with a $250 \mu\text{m}$ precalibrated diamond blade to completely cover the intrascleral plugs, with the sclera even in the event that the scleral flap was accidentally irregular. A 25-gauge straight needle was used to perform the sclerotomies at 1.5 mm from the posterior surgical limbus on both sides, in alignment with the 0- to 180-degree marked meridian. The needle was directed

perpendicular to the sclera in all cases and then redirected parallel to the iris plane until the tip was visible through the pupil.

The Carlevalle IOL was injected through a 2.4 mm corneal incision on the temporal side. During IOL injection, 25-gauge crocodile forceps was inserted through the nasal sclerotomy to grasp the T-shaped plug of the distal haptic and externalize it through the sclerotomy. The IOL was then completely released from the injector and both the optic plate and proximal haptic lay in the anterior chamber above the iris. Two crocodile forceps were used to grasp and externalize the proximal T-shaped plug according to the handshake technique.⁹

In patients with IOL subluxation or opacification, a corneal incision with a size of from 3.0 to 6.0 mm, depending on the material of the subluxated IOL, was made to perform IOL explanation, and the IOL was implanted through the same corneal incision. Anterior vitrectomy through the anterior chamber was performed in all patients, whereas no eyes underwent pars plana vitrectomy. An anterior chamber maintainer was used in 3 patients to manage intraoperative hypotonia. Finally, the scleral flaps were repositioned without sutures to cover the T-shaped harpoon, and the conjunctiva was sutured with an 8-0 Vicryl suture.

Ultrasound Biomicroscopy

UBM is a widely used method that provides in vivo high-resolution images of the anterior segment tissues, with a greater depth of penetration compared with AS-OCT. UBM was performed at postoperative month 3 to assess the optic plate and haptic position of the Carlevalle IOL, including its relationship with the ciliary body and the ciliary sulcus. The examination was performed under standard conditions with no pharmacological mydriasis and with the patient in a sitting position. The IOL position was observed along the vertical (6 o'clock and 12 o'clock) and horizontal (3 o'clock and 9 o'clock) meridians. The IOL optic tilt was evaluated according to the method of previous authors^{10,11,18} (Figure 2). When the difference between the 2 edges of the IOL from the iris plane was more than 0.10 mm, the optic was considered tilted (Figure 3). Using axial UBM scans, the haptic location was classified as passing through the ciliary sulcus, through the ciliary body, or posterior to the ciliary body (Figure 4).

Anterior Segment Optical Coherence Tomography

AS-OCT is a noncontact imaging technology that produces in vivo high-resolution cross-sectional images of the cornea, sclera, and anterior chamber.¹⁹ Although AS-OCT does not have the penetration ability of UBM, it is appropriate for assessing the T-shaped intrascleral plugs. AS-OCT was performed at postoperative month 3 in all patients. The MS-39 provides 25 radial scans on a 16 mm transversal field (1024 A-scan) with an axial resolution of 3.6 μm and a transversal resolution of 35 μm . Temporal and nasal scleral sectors were evaluated with AS-OCT scans to document intrascleral depth and conformation of the haptic plugs.

RESULTS

Table 1 summarizes the data and causes of postoperative aphakia and IOL explantation of the 10 patients included. The mean age at the time of the secondary implantation was 78.8 ± 6.84 years (range 67 to 90 years). The mean follow-up was 8.70 ± 4.16 months (range 3 to 15 months). Three patients were aphakic due to the presence of a complicated cataract (pseudoexfoliation syndrome, phacodonesis, and subluxated ambroid cataract) and underwent intracapsular cataract extraction, 2 patients due to intraoperative capsular rupture, and 3 patients due to IOL subluxation; 1 patient

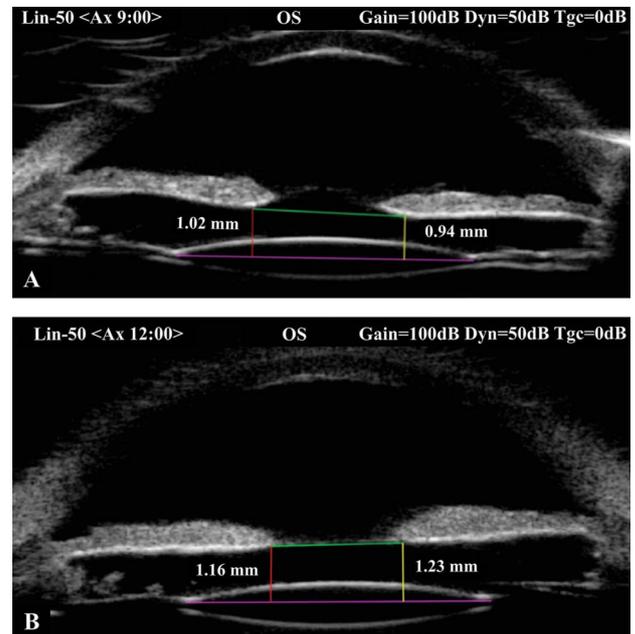


Figure 2. Optic tilt measurement with UBM. The optic tilt was measured by drawing a line along the posterior surface of the iris as a plane of reference (*green line*) and a line along the anterior face of the intraocular lens optic (*purple line*). Using the caliper tool in the UBM system, the distance between these 2 lines was measured in 4 positions: superior (12 o'clock), inferior (6 o'clock), nasal (3 o'clock in the right eye and 9 o'clock in the left eye), and temporal (9 o'clock in the right eye and 3 o'clock in the left eye). The difference between the nasal and temporal distance was defined as the horizontal tilt (A). The difference between the superior and inferior distance was defined as the vertical tilt (B). In this image, the horizontal difference is 0.08 mm, and the vertical difference is 0.07 mm (UBM = ultrasound biomicroscopy).

presented with IOL opacification and 1 patient was affected by anterior segment trauma. One patient was implanted with a toric Carlevalle IOL.

Preoperative, intraoperative, and postoperative data for each patient are reported in Supplemental Table 1 (see Supplemental Digital Content, available at <http://links.lww.com/JRS/A235>). Preoperative UDVA and CDVA were 1.05 ± 0.04 logarithm of the minimum angle of

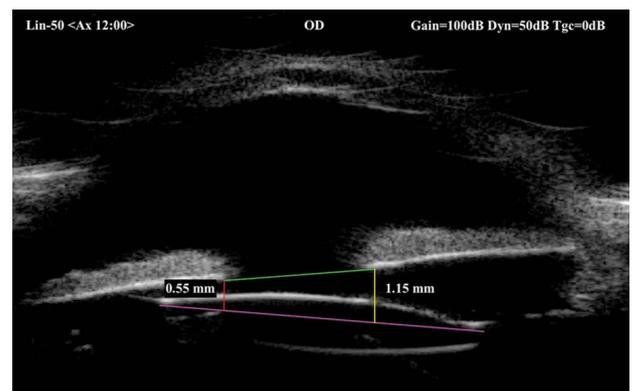


Figure 3. Vertical tilt of the optic plate. The difference between the superior and inferior distance of the optic edges from the posterior iris surface is 0.6 mm, and the optic plate is considered tilted.

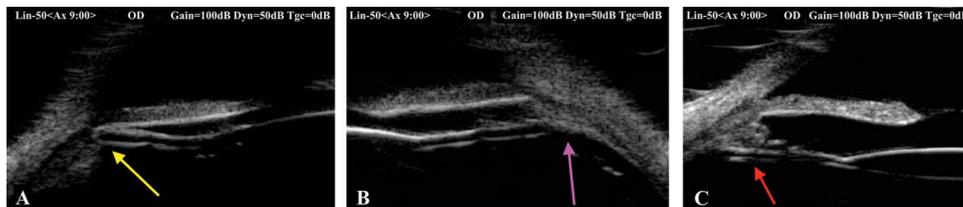


Figure 4. Haptic position: Carlevalle IOL haptics (arrows) passing through the ciliary sulcus (A), through ciliary processes (B), and posterior to the ciliary body (C).

resolution (logMAR) and 0.37 ± 0.33 logMAR, respectively. Postoperative UDVA and CDVA were 0.27 ± 0.21 logMAR and 0.09 ± 0.08 logMAR, respectively, at the last follow-up. The postoperative spherical equivalent was close to the desired refractive target in every patient. The mean preoperative astigmatism changed from -1.20 ± 0.85 to -0.90 ± 0.57 D at the last follow-up. The mean ECD decreased from 1671.90 ± 708.57 to 1449.40 ± 637.33 cells/mm³, thus showing an endothelial cell loss of 10.31%; at the last postoperative follow-up, the mean CMT was 273.30 ± 53.88 μ m, compared with the initial 263.60 ± 40.12 μ m. The duration of surgery ranged from 27:00 to 43:00 minutes, with a mean of $33:36 \pm 5:13$ minutes. There were no intraoperative complications. Eight patients had no postoperative complications; 1 patient had cystoid macular edema that resolved after intravitreal dexamethasone implantation; 1 patient had mild vitreous hemorrhage that resolved spontaneously 1 month postoperatively; and 1 patient had an increase in CMT due to an initial epiretinal membrane that worsened 4 months postoperatively, but he was not excluded from the study. No conjunctival erosion or plug externalizations were observed in any patient at the end of the follow-up (Figure 5).

Supplemental Table 2 (see Supplemental Digital Content, available at <http://links.lww.com/JRS/A236>) shows in vivo evaluation data for each patient. At postoperative month 3 follow-up, the mean distance of the IOL optic plate from the

reference plane was 0.86 ± 0.27 mm in the superior position and 0.70 ± 0.28 mm in the inferior position, with a mean vertical tilt of 0.19 ± 0.22 mm, whereas the mean distance was 0.76 ± 0.29 mm in the nasal position and 0.77 ± 0.30 mm in the temporal position, with a mean horizontal tilt of 0.05 ± 0.03 mm. There was no significant horizontal tilt in any patient. Three eyes (30%) had a vertical tilt of more than 0.10 mm. No patient reported postoperative subjective visual symptoms linked to the IOL tilt. Of 20 haptics, 13 (65%) passed through the ciliary sulcus, 4 (20%) posterior to the ciliary body, and 3 (15%) through the ciliary body. Transverse AS-OCT scans showed a correct intrascleral plug position with adequate intrascleral depth. The mean quantity of scleral tissue above the haptic plugs was 247.20 ± 62.82 μ m in nasal sclera and 265.50 ± 30.11 μ m in temporal sclera.

DISCUSSION

Sutureless scleral fixation of IOLs has proven to be a safe and an effective procedure for the management of aphakia. Since it was first described by Gabor et al., many authors have recommended the sutureless scleral fixation technique to avoid suture-linked complications such as erosion and breakage and good postoperative outcomes have been reported.^{6–9,20} However, this technique involves the use of a 3-piece IOL with haptics that are not designed to be intrasclerally fixed, which gives rise to the risk for haptic torsion and IOL tilting.^{10–12}

The Carlevalle IOL is specifically designed for sutureless intrascleral fixation, allowing the optic plate and IOL haptics to be stabilized with intrascleral harpoon plugs. Some authors have reported reduction in the duration of surgery and surgical complexity with this secondary IOL compared with other sutureless techniques and low incidence of IOL tilting and haptic torsion by virtue of the specific 1-piece foldable design.^{15–17} However, no previous studies, to our knowledge, have evaluated the in vivo haptic position and optical plate tilt of the Carlevalle IOL.

In this case series, we used UBM and AS-OCT to evaluate the refractive outcomes and IOL position in 10 aphakic patients undergoing Carlevalle IOL implantation. UDVA and CDVA improved postoperatively in all patients. No patient lost any lines of CDVA during the follow-up. No significant changes were observed in subjective astigmatism, ECD, and CMT values postoperatively in any patient. The surgical technique used was similar to that reported by other authors.^{15–17} The sclerotomies were performed at the 0- to 180-degree meridian in all patients. This might increase the risk

Table 1. Patient demographics.

Age (y)/Sex	Eye	Cause of Aphakia and IOL Explantation	Follow-up (mo)
90/F	RE	Capsular rupture	6
79/M	LE	IOL subluxation	8
81/F	RE	PEX, phacodonesis	3
76/F	RE	IOL subluxation	7
67/M	RE	Ocular trauma	15
73/M	LE	IOL opacification	8
88/F	RE	Subluxated ambroid cataract	15
80/F	RE	Capsular rupture	6
80/F	LE	PEX, phacodonesis	6
74/F	LE	IOL subluxation	13
Mean (SD): 78.80 (6.84)			Mean (SD): 8.70 (4.16)

IOL = intraocular lens; LE = left eye; PEX = pseudoexfoliation syndrome; RE = right eye

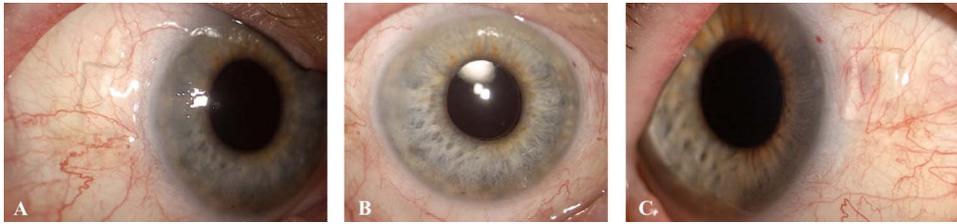


Figure 5. A well-positioned Carlevalle IOL 1 month post-operatively. The temporal (A) and nasal (C) scleral sectors show a good apposition of scleral flaps with overlying conjunctiva, and the IOL is centered (B).

for ciliary nerve damage, but no cases of neurotrophic keratitis were reported in any patients postoperatively. The surgeon used a thin instrument (25-gauge needle) to reduce the possible trauma to the ciliary nerve when performing sclerotomy. One patient received a Carlevalle toric IOL, which is designed to be implanted at 0- to 180-degree meridian to provide customized astigmatic correction. The duration of surgery ranged from 27 to 43 minutes and was shorter than with the scleral fixation IOL technique reported by other authors.^{1,21}

Regarding IOL position, the goal of scleral fixation surgery is to place the optic plate and haptics of a secondary IOL in the ciliary sulcus and secure the haptics of the IOL to scleral tissue. The desired intraocular position is not always achieved. In fact, there is no certainty that the needles will be correctly inserted into the ciliary sulcus when an ab externo scleral fixation technique is performed.²² As reported by previous authors, optic plate tilt can occur in up to 56% of cases, in most cases without affecting the postoperative visual results, and IOL haptics have shown a variable location, with the correct ciliary sulcus position achieved in 37% to 92% of cases.^{10,11,23,24} This variability might be related to the surgeon's personal technique and specific anatomical variants of each operated eye.

In our study, in which we used the UBM examination technique, no patients showed any significant horizontal tilt, and 3 patients (30%) had a vertical tilt not any causing subjective visual aberrations. The mean horizontal tilt was 0.05 ± 0.03 mm, and the mean vertical tilt was 0.19 ± 0.22 mm. Five patients (50%) had both haptics passing through the ciliary sulcus, 2 patients (20%) had both haptics passing posterior to ciliary sulcus, and 3 patients (30%) had 1 haptic passing through the ciliary sulcus and the other through the ciliary body, causing a vertical IOL tilt. These values are lower than those reported in the literature.^{10,11,18,23,24} Because sclerotomies were performed in all cases at 1.5 mm from the posterior surgical limbus, as suggested by numerous authors, an individual anatomical variability presumably explains the different haptic positions.^{9,16,18,25}

The low incidence of Carlevalle IOL tilt is due to the foldable design of the IOL, which can be stretched within certain limits without deforming, as reported by Barca et al.¹⁶ However, these authors assessed the IOL position with AS-OCT, which has a low depth of penetration through tissues. UBM evaluation provides more information regarding the position of this foldable IOL in the posterior chamber, the relationship with the

surrounding structures, and its ability to adapt to different anatomical variants of the ciliary sulcus. In our series, 2 patients had both haptics posterior to the ciliary body, but no significant tilt or deformation of the IOL was observed by UBM (see Supplemental Digital Content, Figure 1, available at <http://links.lww.com/JRS/A232>). These patients both had a white-to-white (WTW) measurement of 11.5 mm and a sulcus-to-sulcus (STS) measurement of 12.05 mm and 12.20 mm, respectively, which was shorter than those in the other patients of our series (see Supplemental Digital Content, Table 2, available at <http://links.lww.com/JRS/A236>). Performing the sclerotomies at 1.5 mm from the posterior surgical limbus might have been excessive in these eyes because the inserted needle was able to penetrate behind the ciliary bodies, resulting in a more posterior IOL position. Because of the design of the Carlevalle IOL, which is soft, extendable, and, therefore, adaptable, this unintentional intraocular position did not affect the shape or functionality of the IOL. On the other hand, 2 patients with no IOL tilt and haptics correctly positioned in the ciliary sulcus showed an excessive anteriorization of the optic plate (see Supplemental Digital Content, Figure 2, available at <http://links.lww.com/JRS/A233>). In these patients, the UBM images showed an alteration of the Carlevalle IOL conformation, with a thinning of the optical plate and stretching of the haptics. These patients had high myopia, with an axial length of 31.60 mm and 27.66 mm, a WTW measurement of 12.6 mm, and an STS measurement of 13.84 and 13.62 mm, respectively; all 3 measurements were greater than those in the other patients of our series (see Supplemental Digital Content, Table 2, available at <http://links.lww.com/JRS/A236>). The Carlevalle IOL has an overall length of 13.2 mm, and being elastic, it can be stretched up to certain limits before deforming. This allows the IOL to adapt to the different lengths of the ciliary sulcus. In the patients concerned, considering 0.8 to 1.0 mm of extension from both sides necessary for intrascleral fixation, the overall length to be covered is over 15 mm, which might exceed the extension capability of the IOL, thus causing excessive stretching of the soft connection mesh. This abnormal traction pushes the optical plate of the IOL forward, causing an alteration of the intraocular conformation and position of the Carlevalle IOL. We could speculate that if the size of the ciliary sulcus is greater than 13.2 mm, that is, greater than the overall length of the IOL, the excessive traction of the soft elastic connection mesh toward the sclera could cause

the anteriorization of the optic plate, with possible IOL deformations, iris chafing, and chronic inflammation. For this reason, the STS distance should be always measured in long eyes before planning surgery. When the STS distance cannot be evaluated, the WTW measurement can be used to obtain an indirect estimate of STS length.^{26,27}

Evaluating the scleral tissue surrounding IOL haptics is useful for checking IOL stability and the risk for haptic extrusion in the scleral fixation technique. The intrascleral haptic depth and plug conformation of the Carlevale IOL was assessed using AS-OCT. Transverse scans on the nasal and temporal scleral sectors showed good integration of the T-shaped plugs within the scleral structure (see Supplemental Digital Content, Figure 3, available at <http://links.lww.com/JRS/A234>). The mean quantity of scleral tissue over the plugs was $247.20 \pm 62.82 \mu\text{m}$ in the nasal sector and $265.50 \pm 30.11 \mu\text{m}$ in the temporal sector, indicating an appropriate intrascleral depth. The solid anchoring of the plugs in the sclera supports the hypothesis that an abnormal traction or stretching of the IOL might affect the optic plate and the flexible connection mesh, predisposing eyes of large dimensions to IOL anteriorization. Further measurements could provide us with insight into the behavior of the Carlevale IOL over time and the possible changes in position and depth of the anchor-shaped plugs.

This study had some limitations, such as the small series of patients enrolled, the inhomogeneous nature of the sample, and the medium/short follow-up. On the other hand, this is the first study, to our knowledge, in which the optic plate, haptics, and intrascleral plugs of Carlevale IOL were evaluated in vivo with UBM and AS-OCT.

In conclusion, sutureless scleral fixation with the Carlevale IOL was a safe and an effective procedure for the management of aphakia and showed good postoperative outcomes. Compared with other scleral-fixed IOLs, the Carlevale IOL offered several advantages, including reduction in surgical complexity and in the duration of surgery, low incidence of IOL tilt, and strong attachment of the T-shaped plugs to the sclera, which ensures IOL stability. This IOL has been shown to compensate for slight errors in intraocular implantation and positioning by adapting, up to certain limits, to different anatomical variants of the posterior chamber and ciliary sulcus because of its particular foldable design. Long eyes should be carefully evaluated before IOL implantation by measuring the STS distance or, alternatively, the WTW measurement. When the STS distance is higher than the overall length of the IOL, the Carlevale IOL might be subject to significant deformations. A longer observation period and a greater number of cases will be necessary to understand the influence of anatomical variants on IOL stretching. However, it would be useful to have available Carlevale IOLs with an overall length greater than 13.2 mm to avoid excessive haptic traction and IOL stretching in these anatomical variants.

WHAT WAS KNOWN

- The sutureless scleral fixation (SSF) technique is a safe and an effective procedure for the management of aphakia.
- Three-piece intraocular lenses (IOLs) generally used in the SSF technique are not designed to be fixed in the sclera, increasing the risk for optic plate tilting and haptic torsion.
- The Carlevale IOL is a 1-piece foldable IOL designed for sutureless intrascleral fixation that has shown good postoperative results and a reduction in surgical complexity.

WHAT THIS PAPER ADDS

- Ultrasound biomicroscopy evaluation of the Carlevale IOL showed a low incidence of horizontal and vertical optic plate tilt.
- In long eyes, the sulcus-to-sulcus distance should be carefully measured before Carlevale IOL implantation.
- Anterior segment optical coherence tomography showed secure intrascleral haptic fixation, with good integration of the T-shaped plugs within the sclera.

REFERENCES

1. Wagoner MD, Cox TA, Ariyasu RG, Jacobs DS, Karp CL; American Academy of Ophthalmology. Intraocular lens implantation in the absence of capsular support: a report by the American Academy of Ophthalmology. *Ophthalmology* 2003;110:840–859
2. Por YM, Lavin MJ. Techniques of intraocular lens suspension in the absence of capsular/zonular support. *Surv Ophthalmol* 2005;50:429–462
3. Brunin G, Sajjad A, Kim EJ, Montes de Oca I, Weikert MP, Wang L, Koch DD, Al-Mohtaseb Z. Secondary intraocular lens implantation: complication rates, visual acuity, and refractive outcomes. *J Cataract Refract Surg* 2017;43:369–376
4. Vounotrypidis E, Schuster I, Mackert MJ, Kook D, Priglinger S, Wolf A. Secondary intraocular lens implantation: a large retrospective analysis. *Graefes Arch Clin Exp Ophthalmol* 2019;257:125–134
5. Kim EJ, Brunin GM, Al-Mohtaseb ZN. Lens placement in the absence of capsular support: scleral-fixed versus iris-fixed IOL versus ACIOL. *Int Ophthalmol Clin* 2016;56:93–106
6. Gabor SG, Pavlidis MM. Sutureless intrascleral posterior chamber intraocular lens fixation. *J Cataract Refract Surg* 2007;33:1851–1854
7. Agarwal A, Kumar DA, Jacob S, Baid C, Agarwal A, Srinivasan S. Fibrin glue-assisted sutureless posterior chamber intraocular lens implantation in eyes with deficient posterior capsules. *J Cataract Refract Surg* 2008;34:1433–1438
8. Yamane S, Sato S, Maruyama-Inoue M, Kadonosono K. Flanged intrascleral intraocular lens fixation with double-needle technique. *Ophthalmology* 2017;124:1136–1142
9. Kumar DA, Agarwal A. Glued intraocular lens: a major review on surgical technique and results. *Curr Opin Ophthalmol* 2013;24:21–29
10. Loya N, Lichter H, Barash D, Goldenberg-Cohen N, Strassmann E, Weinberger D. Posterior chamber intraocular lens implantation after capsular tear: ultrasound biomicroscopy evaluation. *J Cataract Refract Surg* 2001;27:1423–1427
11. Kumar DA, Agarwal A, Packialakshmi S, Agarwal A. In vivo analysis of glued intraocular lens position with ultrasound biomicroscopy. *J Cataract Refract Surg* 2013;39:1017–1022
12. Ferguson AW, Malik TY. Pseudophakic posterior iris chafing syndrome. *Eye (Lond)* 2003;17:451–452
13. Taketani F, Matuura T, Yukawa E, Hara Y. Influence of intraocular lens tilt and decentration on wavefront aberrations. *J Cataract Refract Surg* 2004;30:2158–2162
14. Oshika T, Sugita G, Miyata K, Tokunaga T, Samejima T, Okamoto C, Ishii Y. Influence of tilt and decentration of scleral-sutured intraocular lens on ocular higher-order wavefront aberration. *Br J Ophthalmol* 2007;91:185–188
15. Veronese C, Maiolo C, Armstrong GW, Primavera L, Torrazza C, Della Mora L, Ciardella AP. New surgical approach for sutureless scleral fixation. *Eur J Ophthalmol* 2020;30:612–615
16. Barca F, Caporossi T, de Angelis L, Giansanti F, Savastano A, Di Leo L, Rizzo S. Trans-scleral plugs fixated IOL: a new paradigm for sutureless scleral fixation. *J Cataract Refract Surg* 2020;46:716–720
17. Rossi T, Iannetta D, Romano V, Carlevale C, Forlini M, Telani S, Imburgia A, Mularoni A, Fontana L, Ripandelli G. A novel intraocular lens designed for sutureless scleral fixation: surgical series. *Graefes Arch Clin Exp Ophthalmol* 2020

18. Marianelli BF, Mendes TS, de Almeida Manzano RP, Garcia PN, Teixeira IC. Observational study of intraocular lens tilt in sutureless intrascleral fixation versus standard transscleral suture fixation determined by ultrasound biomicroscopy. *Int J Retina Vitreous* 2019;5:33
19. Ang M, Baskaran M, Werkmeister RM, Chua J, Schmidl D, Aranha Dos Santos V, Garhöfer G, Mehta JS, Schmetterer L. Anterior segment optical coherence tomography. *Prog Retin Eye Res* 2018;66:132–156
20. Kumar DA, Agarwal A, Prakash G, Jacob S, Saravanan Y, Agarwal A. Glued posterior chamber IOL in eyes with deficient capsular support: a retrospective analysis of 1-year post-operative outcomes. *Eye (Lond)* 2010;24:1143–1148
21. Bellucci R, Pucci V, Morselli S, Bonomi L. Secondary implantation of angle-supported anterior chamber and scleral-fixated posterior chamber intraocular lenses. *J Cataract Refract Surg* 1996;22:247–252
22. Sugiura T, Kaji Y, Tanaka Y. Anatomy of the ciliary sulcus and the optimum site of needle passage for intraocular lens suture fixation in the living eye. *J Cataract Refract Surg* 2018;44:1247–1253
23. Manabe S, Oh H, Amino K, Hata N, Yamakawa R. Ultrasound biomicroscopic analysis of posterior chamber intraocular lenses with transscleral sulcus suture. *Ophthalmology* 2000;107:2172–2178
24. Sewelam A, Ismail AM, El Serogy H. Ultrasound biomicroscopy of haptic position after transscleral fixation of posterior chamber intraocular lenses. *J Cataract Refract Surg* 2001;27:1418–1422
25. Lewis JS. Ab externo sulcus fixation. *Ophthalmic Surg* 1991;22:692–695
26. Hashemian SJ, Mohebbi M, Yaseri M, Jafari ME, Nabili S, Hashemian SM, Hashemian MS. Adjustment formulae to improve the correlation of white-to-white measurement with direct measurement of the ciliary sulcus diameter by ultrasound biomicroscopy. *J Curr Ophthalmol* 2017;30:217–222
27. Ghoreishi M, Abdi-Shahshahani M, Peyman A, Pourazizi M. A model for predicting sulcus-to-sulcus diameter in posterior chamber phakic intraocular lens candidates: correlation between ocular biometric parameters. *Int Ophthalmol* 2019;39:661–666

Disclosures: None of the authors has a financial or proprietary interest in any material or method mentioned.



First author:

Alessandro Mularoni, MD

Department of Ophthalmology, Istituto per la Sicurezza Sociale, San Marino State Hospital, Cailungo, Republic of San Marino