

# Trans-scleral plugs fixated IOL: a new paradigm for sutureless scleral fixation



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**Purpose:** To assess the surgical and refractive outcomes of a new technique of sutureless scleral fixation (SSF) using a single-piece foldable acrylic intraocular lens (IOL) (Carlevale).

**Setting:** Department of Translational Surgery and Medicine, Ophthalmology, University of Florence, Careggi, Florence, Italy.

**Design:** Prospective observational case series.

**Methods:** Thirty-two eyes of 32 patients with aphakia, dislocated IOL, or subluxated lens who underwent SSF with a novel single-piece hydrophilic acrylic IOL were studied. Preoperative and postoperative refractive status and complications during and after surgery were recorded. The IOL tilt was evaluated using anterior segment optical coherence tomography (AS-OCT).

**Results:** Twenty-two eyes were IOL/bag luxations, 9 were aphakia, and 3 were subluxated crystalline lens. Mean preoperative corrected distance visual acuity was  $0.46 \pm 0.29$  logarithm of the minimum angle of resolution (logMAR) and

improved to  $0.13 \pm 0.12$  logMAR ( $P < .05$ ) at the 8-month follow-up, with a predictive error spherical equivalent of  $-0.24 \pm 0.81$  diopters (D); the IOL tilt was  $2.08 \pm 1.19$  degrees. One patient (3.1%) experienced transient cystoid macular edema, and 1 (3.1%) experienced vitreous hemorrhage; pigment dispersion with AS-OCT findings of reverse pupillary block was found in 2 (6.2%) eyes. IOL dislocation, conjunctival erosion, and plug externalization were not observed in any eye during the follow-up.

**Conclusions:** SSF using the novel IOL could be a viable option for the management of aphakia, lens subluxation, and IOL–bag complex dislocation with unique characteristics of stability. The advantages of this technique were the absence of haptic manipulation, self-centration, and firm fixation of the IOL.

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Online Video

Intraocular lens (IOL) implantation in the absence of capsular support remains a surgical challenge, especially in the light of patient higher expectations in modern ophthalmic surgery.

Classically, the 3 most widely used approaches are fixation to the iris by suturing or iris claw, anterior chamber IOL, and fixation to the sclera with sutures.<sup>1–5</sup> However, these techniques require wide corneal or scleral incisions, resulting in significant postoperative astigmatism.

Sutureless intrascleral fixation of foldable hydrophilic acrylic 3-piece IOLs inserted through a conventional sub-2.8 mm clear corneal incision is a relatively recent technique introduced by Gabor et al.<sup>6</sup> The glued IOL technique proposed by Agarwal et al. and the flanged intrascleral fixation technique proposed by Yamane et al. are more recent surgical alternatives.<sup>7,8</sup> These techniques allow

sutureless fixation of the 3-piece IOL's haptics into scleral tunnels parallel to the limbus, while minimizing the risk for postoperative astigmatism. However, there are concerns about the centration of the scleral-fixated 3-piece IOL and its long-term stability.

Recently, the introduction of the single-piece sutureless scleral fixation (SSF) IOL (Carlevale, Soleko), implanted using the handshake technique has been proposed as an evolution of sutureless techniques with unique advocated advantages related to the particular shape of the IOL, which is designed to be suspended into the posterior chamber through 2 transscleral plugs. However, there is little literature on this topic.

The purpose of this study was to investigate the surgical and refractive outcomes of an SSF technique using the Carlevale IOL and to compare results with other techniques reported in the literature.

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## METHODS

The study was conducted at Azienda Ospedaliera Universitaria Careggi, Florence, Italy. This was a prospective, observational case series including all patients who underwent secondary IOL implantation with the single-piece acrylic foldable Carlevale IOL for aphakia, subluxated lens, and late IOL–bag complex dislocation. This study was approved by the local research ethics committee in accordance with the principles of the Declaration of Helsinki. Written informed consent for participation was obtained from all patients.

Thirty-two eyes of 32 patients who underwent SSF using a Carlevale IOL were included in this study. All patients underwent standard ophthalmologic examination; the data recorded included demographic information, visual acuity, refractive status, and fundus ophthalmoscopy. The mean follow-up period was 10 months (range, 8 to 14 months). Refractive outcomes were analyzed. Refractive prediction error was calculated as the difference between postoperative objective refraction expressed as spherical equivalent (SE) and the predicted SE of the refraction obtained from preoperative biometry (IOLMaster 500, Carl Zeiss Meditec AG) using the Sanders–Retzlaff–Kraff trial formula.

Intraoperative and postoperative complications were recorded. The endothelial cell count was obtained using the Perseus (Costruzione Strumenti Oftalmici) endothelial microscope at the 4- and 8-month follow-up periods. The IOL tilt was evaluated using anterior segment optical coherence tomography (AS-OCT) (MS-39 Costruzione Strumenti Oftalmici).

### Surgical Technique

In all patients, the 0- to 180-degree axis was marked using the slitlamp before surgery to achieve correct centration of the IOL. A 25- or 27-gauge pars plana vitrectomy (PPV) was performed using the Constellation Vision System (Alcon) under retrobulbar anesthesia.

Phacoemulsification with standard corneal tunnel 2.2 mm cataract extraction was performed for the subluxated crystalline lens, whereas in the cases of a subluxated IOL, it was freed from capsular/lens remnants, folded, and extruded from the 2.75 mm corneal tunnel. In all cases, the corneal tunnel was made temporally.

After a limited conjunctival peritomy, 2 partial 4 × 4 mm thickness scleral flaps were made and hinged at the limbus at 0 to 180 degrees. Then, 2 sclerotomies using a 25-gauge needle were placed at 1.5 to 2.0 mm from the limbus in correspondence to the 0- to 180-degree axis. The Carlevale IOL (Figure 1) was injected into the anterior chamber through the previous corneal tunnel (2.75 mm for dislocated lens and 2.2 mm for aphakia and subluxated lens), and the leading plug was grasped with crocodile tip forceps inserted into the vitreous chamber through the sclerotomy and then externalized under the scleral flap in a single maneuver. Then, the trailing plug was grasped and externalized with 2 forceps using the handshake technique; IOL centration was achieved without performing extra intraoperative maneuvers (Figure 2). Scleral flaps and conjunctival wound were sealed with nylon 10/0 and polyglactin (Vicryl) 8/0, respectively; the corneal tunnel did not require any stitches (Video 1, available at <http://links.lww.com/JRS/A26>).

In 12 cases, instead of scleral flaps, the plugs were inserted into 2 self-sealing pockets created with a crescent blade making 2 straight incisions that ran posteriorly from the limbus for 2.0 mm at 0- and 180-degree axis and then dissecting the sclera to make 2 opposite pockets for each side (Video 2, available at <http://links.lww.com/JRS/A27>).

### IOL Tilt Measurement

Spectral-domain AS-OCT (MS-39 Costruzione Strumenti Oftalmici) was used postoperatively to determine the IOL position and tilt. After pupil dilation, a standardized line scan from 0 to 180 degrees and from 90 to 270 degrees centered in



Figure 1. The Carlevale IOL, a single-piece foldable acrylic IOL with 2 transscleral plugs (IOL = intraocular lens).

correspondence to the corneal apex was acquired. The OCT scan image was set in 16.0 mm high-definition mode to obtain a clearer image. Then, the images were processed to evaluate the IOL tilt as already proposed by Yamane et al.<sup>9</sup> A straight line passing through the scleral spur on either side of the image and the horizontal axis of the IOL were marked (Figure 3). The angle between the reference line and the horizontal axis of the IOL was taken to be the IOL tilt. The IOL tilt was measured in both the vertical and horizontal planes. The average of the IOL tilt in the vertical and horizontal planes was defined as the mean IOL tilt.

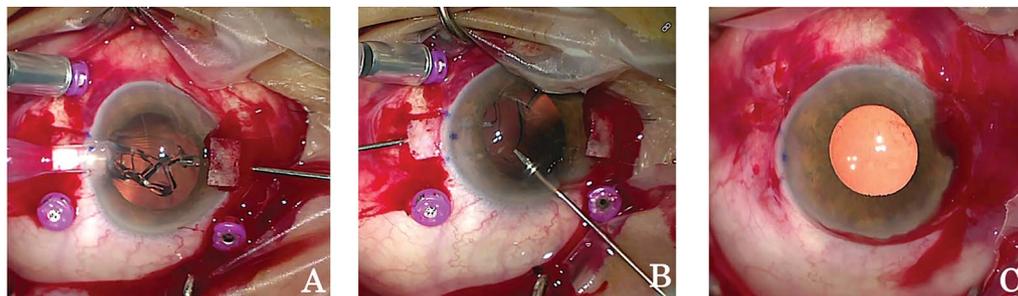
### Statistical Analysis

Statistical analysis was performed using SPSS software (version 26, IBM Corp.). Descriptive statistics were used to summarize mean values and standard deviations of all the numerical data. Pearson coefficient was used as a method to investigate the correlation between variables. A *P* value of less than .05 was considered statistically significant. Visual acuity was converted to a logarithm of the minimum angle of resolution (logMAR) for analysis. Preoperative and postoperative data were analyzed using the paired *t*-test. A *P* value of less than 0.05 was considered statistically significant.

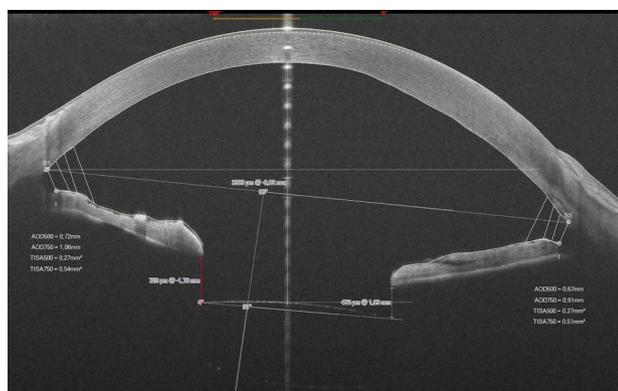
## RESULTS

Patient demographic characteristics are shown in Table 1. The mean age of patients was  $77.2 \pm 7.8$  years (range 45 to 85 years), 21 were male (66%), and 11 were female (34%). Twenty had IOL/bag dislocation (all single-piece soft acrylic IOL), 9 had aphakia, and 3 had a subluxated lens.

The Carlevale lens was fixed well without conjunctival scarring or inflammation (Figure 4). The visual acuity and the endothelial cell density of all eyes were measured before the surgical intervention and during the 4- and 8-month



**Figure 2.** Intraocular lens implantation. *A:* Leading plug grasped by crocodile tip forceps. *B:* Trailing plug externalization. *C:* Final result at the end of the procedure.



**Figure 3.** IOL tilt measurement. The angle between a line passing through the scleral spur and the horizontal axis of the IOL was measured for the horizontal and vertical images of anterior segment optical coherence tomography (IOL = intraocular lens).

follow-up periods (Table 2). Mean preoperative corrected distance visual acuity (CDVA) was  $0.46 \pm 0.29$  logMAR; mean postoperative CDVA improved to  $0.22 \pm 0.18$  logMAR and  $0.13 \pm 0.12$  logMAR at 4 and 8 months, respectively ( $P < .05, P < .01$ ).

Mean corneal endothelial cell density decreased from 2343 cells/mm<sup>2</sup> to 2215 cells/mm<sup>2</sup> and 2208 cells/mm<sup>2</sup> at 4 months and 8 months, respectively, ( $P < .01$ ). The mean IOL tilt was  $2.08 \pm 1.19$  degrees, and the refractive prediction error using the Sanders–Retzlaff–Kraff trial formula was  $-0.24 \pm 0.81$  diopters (D) (Table 3).

Postoperative complications are shown in Table 4. One eye (3.1%) experienced transient cystoid macular edema 2 months postoperatively and was successfully treated with nonsteroidal antiinflammatory eye drops. In 2 (6.2%) eyes, pigment dispersion with AS-OCT findings of reverse

pupillary block was noted 1 week postoperatively, and in both cases, nd:YAG peripheral iridotomy was sufficient to restore the physiological iris profile; however, 1 patient developed intraocular hypertension secondary to pigment dispersion after 7 months, which required the use of antiglaucoma eye drops. Vitreous hemorrhage occurred in 1 (3.1%) eye and resolved spontaneously after 2 weeks. Postoperative hypotony was not observed in any eyes, and plug externalization and conjunctival erosion did not occur during follow-up. After a minimum follow-up interval of 8 months in 32 eyes, there were no cases of retinal detachment, endophthalmitis, or IOL dislocation.

## DISCUSSION

The intrascleral IOL fixation technique has become a popular procedure because it has several advantages over conventional transscleral suturing of the IOL. All surgical procedures proposed in the literature have been shown to be effective; however, the most relevant issue is related to the stability of the IOL suspended in the eye. Indeed, iris capture of the IOL optic, haptic slippage, and IOL dislocation are all complications described with different percentages in all reports.<sup>10,11</sup> Moreover, the intrascleral fixation of a 3-piece IOL for in-the-bag implantation, although it has been shown to be safe, should also be considered as an off-label procedure.

In this study, we have reported, to our knowledge for the first time, the surgical and refractive outcomes with the use of a new single-piece foldable IOL crafted to be suspended in the eye with 2 transscleral plugs. The prediction error SE found was  $-0.24 \pm 0.81$  D comparable to those found in other reports with sutured and SSF.<sup>12,13</sup>

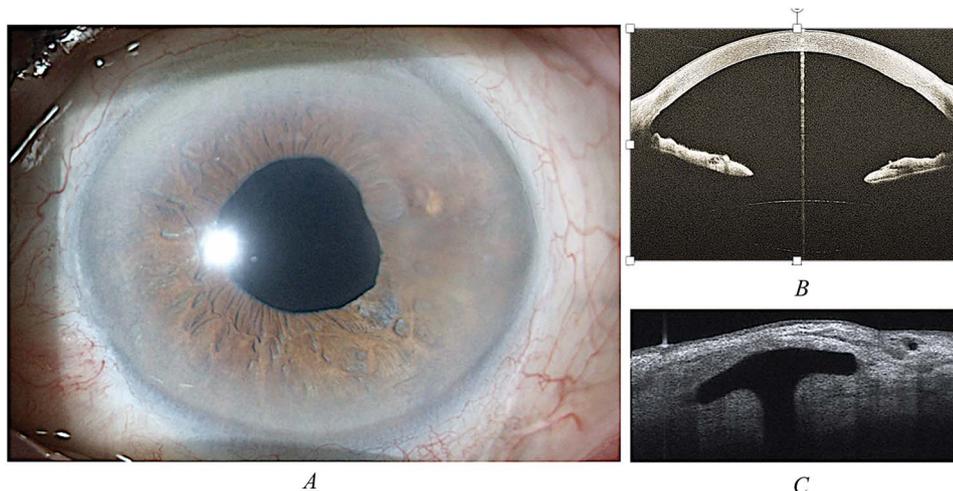
The mean tilt found in our study was  $2.08 \pm 1.19$  degrees; the corresponding mean reported in the literature ranged from  $2.53 \pm 1.43$  to  $5.62 \pm 3.86$  degrees in Yamane's report and  $2.9 \pm 2.6$  to  $3.2 \pm 2.7$  degrees in the glue IOL technique proposed by Agarwal et al.; however, we did not find a statistical correlation between the tilt degree, BCVA, and the refractive status.<sup>8,14</sup> The lowest degree of tilt was on the horizontal axis where the lens was fixed by the plugs ( $P < .01$ ).

The crucial phase of this surgery is the externalization of the leading plug using vitreous forceps together with the injection of the IOL into the anterior chamber; however, manipulating the plug is much more forgiving compared with the haptic of a 3-piece IOL because it can be stressed within a certain limit without deforming; we suppose that

**Table 1.** Patient characteristics.

Number of eyes	32
Age (mean $\pm$ SD y)	77.2 $\pm$ 7.8
Sex (male/female)	21/11
Diagnosis	
Aphakia	9
Dislocated PC IOL	20
Subluxated lens	3
Axial length (mean $\pm$ SD)	24.09 $\pm$ 1.87
Mean follow-up (mo) (range)	(8,15)

PC IOL = posterior chamber intraocular lens



**Figure 4.** Postoperative findings at 4 months. *A:* Slitlamp microscopy image showing no plug externalization or conjunctival scarring/inflammation. *B:* OCT image showing the correct placement of the IOL. *C:* The plug (arrow) of the IOL is fixed under the scleral flap, and no gap in the sclera is seen around the plug by OCT (IOL = intraocular lens; OCT = optical coherence tomography).

**Table 2. Visual acuity and endothelial cell density.**

Parameter	Mean $\pm$ SD		
	Baseline	4 mo	8 mo
LogMAR CDVA	0.46 $\pm$ 0.29	0.22 $\pm$ 0.18	0.13 $\pm$ 0.12
LogMAR UCVA	1.32 $\pm$ 0.44	0.49 $\pm$ 0.25	0.49 $\pm$ 0.2
Endothelial cell density	2307 $\pm$ 406	2215 $\pm$ 383	2208 $\pm$ 372
Number of eyes	32	32	32

CDVA = corrected distance visual acuity; logMAR = logarithm of the minimum angle of resolution; UCVA = uncorrected visual acuity  
Data are mean  $\pm$  SD.

this may explain the lower degree of IOL tilt observed in our study compared with other reports.

In all surgical techniques already described, a precise and symmetrical parallel limbus scleral tunnel is mandatory to achieve a correct position of the 3-piece IOL, and the manipulation of the haptics is nearly always necessary for IOL centration; all these maneuvers could be cumbersome and could lead to complications that may compromise the success of the surgery. On the other hand, with the Carlevalle lens, the symmetrical position of the sclerotomies alone is sufficient to obtain optimal centration of the IOL optic, and this is also true for different eye sizes because of the particular shape and soft material of the lens, which permits stretching of the connection mesh between the plugs and the optic, without causing IOL optic decentration.

Regarding the stability of the implant, IOL dislocation and pseudophacodonesis were not observed in any eyes during follow-up. Iris capture of the 6.5 mm IOL optic did not occur even in the 2 cases of reverse pupillary block

where AS-OCT demonstrated posterior bowing of the iris in contact with the anterior surface of the lens causing pigment dispersion; after peripheral Nd:YAG iridotomy, the mean iris–IOL distances calculated in both orthogonal planes were 853  $\mu$ m and 904  $\mu$ m, respectively, whereas the endothelium–IOL distances remained unchanged, underlining the firm anchoring of the IOL through the trans-scleral plugs. As a result, we started to perform peripheral iridectomy with the vitrector probe routinely at the end of the surgical procedure.

The Carlevalle lens as a hydrophilic IOL (25% H<sub>2</sub>O) has theoretically a good uveal biocompatibility; clinical evidence of inflammation as aqueous flare and/or cellular deposition on the lens surface was not observed in any eye during follow-up.<sup>15</sup> Using scleral pockets makes surgery faster and completely sutureless; however, the scleral incision should be straight and symmetrical to obtain correct positioning of the sclerotomies and therefore of the plugs.

One of the most frequent early postoperative complications is hypotony secondary to leakage from the corneal tunnel and/or sclerotomies; in our study, it was not observed in any eyes regardless of the use of the scleral flap or pocket and of the gauge of the cannula (25 gauge/27 gauge); we suppose that this is due to the relatively small corneal incision, the complete filling of the 25-gauge sclerotomy by the plug, and also because we usually perform a partial BSS–air change at the end of the PPV procedure.<sup>16</sup>

Although it is not necessary, we performed PPV in all cases to avoid the risk for retinal issues and also because the

**Table 3. Refractive status and IOL TILT.**

Preoperative SE (mean $\pm$ SD)	9.17 $\pm$ 3.32
Postoperative SE (mean $\pm$ SD)	−0.71 $\pm$ 1.21
Refractive PE (mean $\pm$ SD)	−0.24 $\pm$ 0.81
IOL tilt 0 to 180 degrees	1.48 $\pm$ 1.08
IOL tilt 90 to 270°	2.26 $\pm$ 1.13
IOL tilt mean °	2.08 $\pm$ 1.19

IOL = intraocular lens; PE = predeviation error; SE = spherical equivalent

**Table 4. Postoperative complications.**

Complication	Eyes (%)
Vitreous hemorrhage	1 (3.1)
IOP elevation	1 (3.1)
Reverse pupillary block with pigment dispersion	2 (6.2)
IOP elevation	1 (3.1)
Cystoid macular edema	1 (3.1)

IOP = intraocular pressure

balanced salt solution infusion facilitates surgical maneuvers, especially the introduction of the forceps into the sclerotomies.

In conclusion, SSF using a Carlevalle IOL implanted with the handshake technique might represent a valid option for the management of aphakia, IOL–bag complex dislocation, and lens subluxation, with unique characteristics of stability. The advantages of this technique are the absence of haptic manipulation, the self-centration, and the firm fixation of the lens. Moreover, considering that a high degree of IOL tilt increases the incidence of astigmatism and coma, in our opinion, the advantages of a low degree of IOL tilt and the possibility of achieving good centration may be useful to obtain good refractive outcomes in eyes with high corneal astigmatism, above all using the toric version of this IOL.<sup>17</sup> Further studies with more patients and longer follow-ups are needed to corroborate these initial results.

#### WHAT WAS KNOWN

- Sutureless scleral fixation (SSF) of a 3-piece intraocular lens (IOL) has become a popular procedure because it has several advantages over conventional transscleral suturing of the IOL; however, the most relevant issue is related to the long-term stability.

#### WHAT THIS PAPER ADDS

- SSF using a Carlevalle IOL represents what could be a valid new option for the treatment of aphakia, lens subluxation, IOL/bag dislocation with unique characteristics of stability.
- The particular shape of the Carlevalle IOL designed to be suspended in the eye through 2 transscleral plugs facilitates the correct centration of the IOL and also provides a low tilt degree.

#### REFERENCES

1. Yazdani-Abyaneh A, Djalilian AR, Fard MA. Iris fixation of posterior chamber intraocular lenses. *J Cataract Refract Surg* 2016;42:1707–1712
2. De Silva SR, Arun K, Anandan M, Glover N, Patel CK, Rosen P. Iris-claw intraocular lenses to correct aphakia in the absence of capsule support. *J Cataract Refract Surg* 2011;37:1667–1672
3. Güell JL, Barrera A, Manero F. A review of suturing techniques for posterior chamber lenses. *Curr Opin Ophthalmol* 2004;15:44–50
4. Dadeya S, Kamlesh, Kumari Sodhi P. Secondary intraocular lens (IOL) implantation: anterior chamber versus scleral fixation long-term comparative evaluation. *Eur J Ophthalmol* 2003;13:627–633
5. Malbran ES, Malbran E Jr, Negri I. Lens guide suture for transport and fixation in secondary IOL implantation after intracapsular extraction. *Int Ophthalmol* 1986;9:151–160
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. Yamane S, Inoue M, Arakawa A, Kadonosono K. Sutureless 27-gauge needle-guided intrascleral intraocular lens implantation with lamellar scleral dissection. *Ophthalmology* 2014;121:61–66
10. Kawaji T, Sato T, Tanihara H. Sutureless intrascleral intraocular lens fixation with lamellar dissection of scleral tunnel. *Clin Ophthalmol* 2016;10:227–231
11. Jacob S. Intrascleral IOL fixation. *Asia Pac J Ophthalmol (Phila)* 2017;6:381–387
12. 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
13. Kumar DA, Agarwal A, Agarwal A, Chandrasekar R, Priyanka V. Long-term assessment of tilt of glued intraocular lenses: an optical coherence tomography analysis 5 years after surgery. *Ophthalmology* 2015;122:48–55
14. Agarwal A, Jacob S, Kumar DA, Agarwal A, Narasimhan S, Agarwal A. Handshake technique for glued intrascleral haptic fixation of a posterior chamber intraocular lens. *J Cataract Refract Surg* 2013;39:317–322
15. Özyol P, Özyol E, Karel F. Biocompatibility of intraocular lenses. *Turk J Ophthalmol* 2017;47:221–225
16. McKee Y, Price FW Jr, Feng MT, Price MO. Implementation of the posterior chamber intraocular lens intrascleral haptic fixation technique (glued intraocular lens) in a United States practice: outcomes and insights. *J Cataract Refract Surg* 2014;40:2099–2105
17. Lawu T, Mukai K, Matsushima H, Senoo T. Effects of decentration and tilt on the optical performance of 6 aspheric intraocular lens designs in a model eye. *J Cataract Refract Surg* 2019;45:662–668

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