TECHNIQUE

Scleral fixation of a single-piece foldable acrylic IOL through a 1.80 mm corneal incision

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A new scleral fixation technique of a single-piece acrylic foldable intraocular lens (IOL) (enVista MX60, Bausch & Lomb, Inc.) through a 1.80 mm corneal incision, using the IOL eyelets as anchoring point, is described. It was a retrospective review of 26 cases. The preoperative mean corrected distance visual acuity was 0.51 ± 0.21 logarithm of the minimum angle of resolution (logMAR). It improved significantly to 0.25 ± 0.27 logMAR ($P < .01$), 0.18 ± 0.16 logMAR ($P < .01$), and 0.17 ± 0.16 logMAR ($P < .01$) (at 1 month, 3 months, and 6 months postoperatively, respectively, repeated measures analysis of variance, $P < .0001$). No astigmatism increase of more than 0.75 diopters was recorded at any time point. In all 26 patients, the IOL was well centered and stable for the entire monitoring period. No complications were observed during follow-up. Scleral fixation of the foldable IOL through a 1.80 mm corneal incision provided excellent IOL stability during the 6-month follow-up of this study and might be an effective and safe surgical technique.

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Online Video

Scleral fixation is one of the most widely used surgical techniques for implanting an intraocular lens (IOL) in the posterior chamber (PC) when capsular support is weak or missing.[1–4] Scleral fixation offers several advantages compared with other techniques used in the absence of capsular support because scleral-sutured PC IOLs do not make contact with the corneal endothelium, iris, or trabecular meshwork, thus reducing the risk of pigment dispersion, iris tissue damage, endothelial dystrophy, and glaucoma. Furthermore, scleral-sutured IOLs provide a barrier function between the anterior chamber and the vitreous cavity.[5–8] The classic scleral fixation technique requires a large sclerocorneal incision of about 6.50 mm to insert the IOL into the PC. Large incisions are typically needed because conventional scleral-fixated IOLs are made of poly(methyl methacrylate), a rigid material that cannot be folded and have a large diameter. Large incisions are associated with many complications, such as intraoperative and postoperative hypotonia, postoperative astigmatism, choroidal detachment, and issues related to wound closure (eg, wound leakage with potential loss of the anterior chamber, suture-induced astigmatism, and higher risk of infections).[9–11] To avoid the complications associated with large scleral incisions, new surgical techniques for scleral fixation using foldable IOLs were developed.[12–19] Foldable IOLs eliminate the need to extend the incision for implantation, thus reducing the final corneal astigmatism and allowing a better visual rehabilitation.[6] The single-piece hydrophobic acrylic foldable IOL (enVista MX60, Bausch & Lomb, Inc.) was introduced in 2012. This IOL is characterized by eyelets located at the junction of the aspheric optic and C-loop haptics that can be used for suture placement (Figure 1). It received the Conformité Européenne marking in August 2010 and was subsequently approved by the U.S. Food and Drug Administration in May 2012. In standard practice, the MX60 IOL is implanted in the capsular bag after phacoemulsification through a 1.80 mm corneal incision. With the standard in-the-bag placement technique, this IOL demonstrated a well-established safety profile.[20] Among many advantages, the MX60 IOL showed stable refractive outcomes and a low incidence of Nd:YAG laser capsulotomies 12 months postoperatively.[21,22] Although this IOL has been designed to be implanted into the capsular bag, its features and physical characteristics might provide good surgical stability and handling during scleral fixation, including a comfortable

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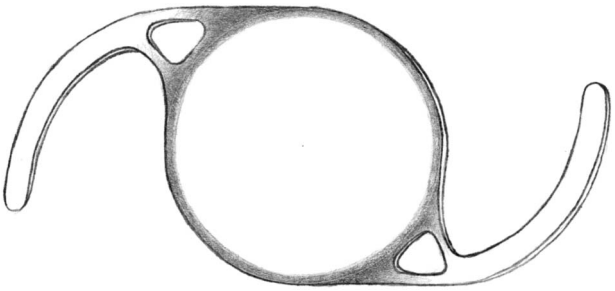

Figure 1. Schematic representation of the MX60 intraocular lens. It is characterized by the eyelets located at the junction of the aspheric optic and C-loop haptics.

intraoperative suture management outcomes of a new surgical technique that allows scleral fixation of a single-piece acrylic foldable IOL through a 1.80 mm corneal incision is presented.

SURGICAL TECHNIQUE

All surgeries were performed by the same surgeon (P.L.). After administration of peribulbar anesthesia, a 1.80 mm corneal incision was performed at 12 o'clock. Conjunctival peritomy was performed at 3 o'clock and 9 o'clock, and then 2 triangular, partial-thickness scleral flaps were created near the limbus. A double-armed 10-0 polypropylene suture (30 cm ½ circle side cutting AUM-5, straight side cutting SC5 polypropylene blue monofilament, Alcon) was passed from the 9 o'clock scleral flap to the 3 o'clock scleral flap, 1.50 mm posterior to the limbus with an out-in technique using a 27-gauge needle (0.4 × 20.0 mm, Nipro Co). The suture was then drawn out of the corneal tunnel using forceps (eg, 25- or 27-gauge Eckardt forceps) (Figure 2). The suture loop thus formed was inserted into the injector cartridge (Viscoject Bio 1.8, Carl Zeiss Meditec AG). The suture was cut, and the 2 suture ends were tied to the IOL eyelets. The IOL was then injected into the eye through the 1.80 mm corneal incision using a modified cartridge while tension was applied to the other ends of the sutures. The IOL was spread and centered, and the 10-0 polypropylene suture ends were fixed to the sclera. The scleral flaps were repositioned, and the conjunctiva was sutured (Video 1, Supplemental Digital Content, available at http://links.lww.com/JRS/A34).

Baseline and follow-up data were analyzed using repeated measures analysis of variance, with Greenhouse-Geisser correction and a significance level of 5%. Serial comparisons were performed using the Dunnett multiple comparisons test.

Results

A total of 26 eyes (26 patients) were enrolled in the study from the Department of Medicine-Ophthalmology at the University of Udine and from the Istituto Europeo di Microchirurgia Oculare from June 2014 to June 2017. This study was conducted in compliance with the tenets of the Declaration of Helsinki and approved by the institutional review board. Written informed consent was taken from all

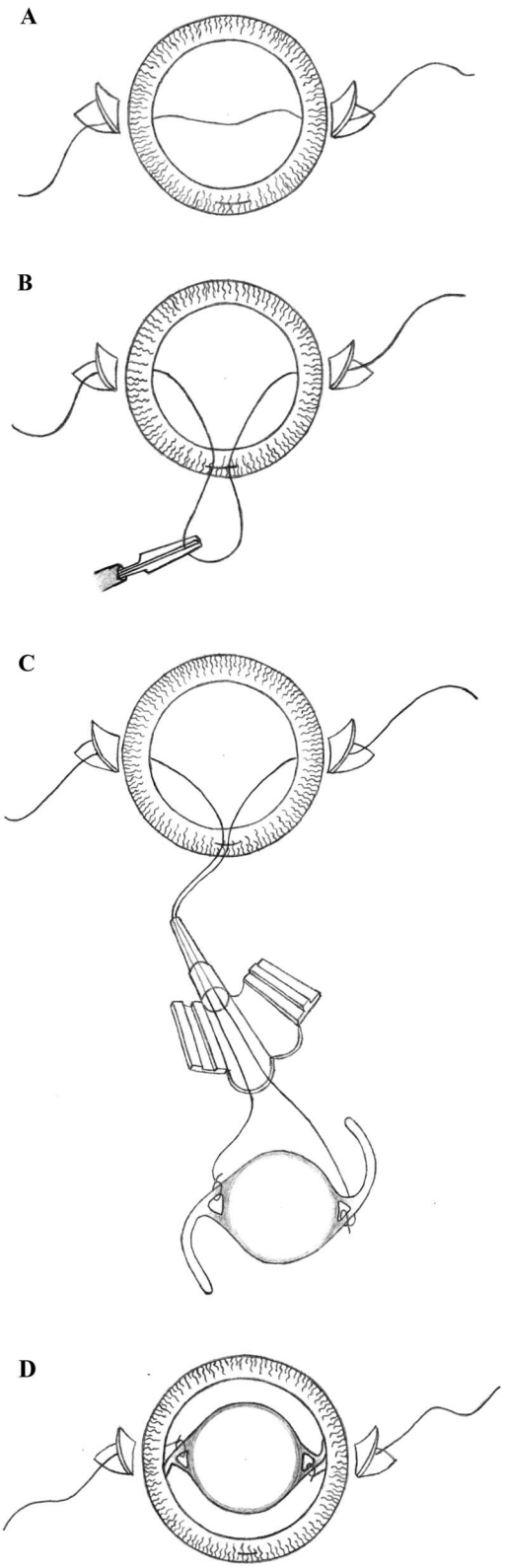

Figure 2. Graphical representation of the surgical procedure for scleral fixation of the MX60 IOL through a 1.80 mm corneal incision. *A*: A polypropylene suture is passed from 9 o'clock scleral flap to 3 o'clock scleral flap. *B*: The suture is drawn out from the 1.80 mm corneal tunnel using forceps. *C*: The IOL is loaded onto the cartridge and then implanted in the posterior chamber. *D*: The IOL is centered using the polypropylene suture ends (IOL = intraocular lens).

patients. Included were patients who underwent scleral fixation of a MX60 IOL through a 1.80 mm incision because of post–cataract surgery aphakia with an inadequate capsular support and a subluxated and luxated crystalline lens because of ocular trauma.

Patients were evaluated at baseline, days 1 and 7, and months 1, 3, and 6 postoperatively. Preoperative conditions, surgical times, duration of follow-up, and the results of the surgery in terms of corrected distance visual acuity (CDVA), postoperative astigmatism, centering and stability of the IOL, and intraoperative and postoperative complications were recorded.

All 26 patients completed the 6-month follow-up schedule. Clinical characteristics, preoperative diagnoses, and comorbidities are summarized in Table 1.

Ten patients required additional posterior and/or anterior segment procedures at the time of the scleral IOL fixation procedure, such as phacoemulsification of the luxated lens and anterior or posterior vitrectomy. The mean surgery time for all 26 patients was 58 ± 18 minutes (range 35 to 80 minutes), whereas for patients requiring only the scleral fixation procedure, it was 42 ± 10 minutes (range 35 to 60 minutes). The mean CDVA improved significantly postoperatively ($P < .0001$). CDVA changes are summarized in Table 2. In all 26 patients, the IOL was well centered and stable for the entire follow-up period (Figure 3).

No astigmatism increase of more than 0.75 diopters was recorded at any time point. Cystoid macular edema, choroidal detachment, vitreous hemorrhage, or other complications were not observed during the follow-up.

DISCUSSION

In the absence of adequate capsular support, different techniques can be used for IOL implantation, such as implantation in the anterior chamber, iris fixation, or scleral fixation. Implantation of the anterior chamber IOL is a simple surgical technique, but it is associated with an increased risk of corneal decompensation, glaucoma, cystoid macular edema, and uveitis–glaucoma–hyphema syndrome.[2–4,23] The iris-sutured lenses increase the risk of iris atrophy, uveitis, and cystoid macular edema.[3,6] Scleral fixation is one of the most used techniques when an adequate capsular support is not present, because of a lower incidence of complications and greater stability of the IOL when compared with other techniques.[24] Although it provides a good safety profile, complications such as erosion of sutures, cystoid macular edema, vitreous hemorrhage, dislocation of the IOL, retinal detachment, and side effects related to large incisions have been observed.[25]

Table 1. Baseline characteristics.

Characteristic	n = 26
Age (y, mean ± SD) (range)	69.3 ± 13.1 (50, 89)
Female sex (n, %)	10 (38)
CDVA, logMAR (mean ± SD) (range)	0.51 ± 0.21 (0.8, 0.1)
Comorbidities (n, %)	8 (31)
Dry AMD	3 (12)
Glaucoma	2 (8)
Proliferative DR (laser-treated)	1 (4)
Alcohol-related optic neuropathy	1 (4)
Adult-onset foveomacular vitelliform dystrophy	1 (4)
Preoperative IOP (mm Hg, mean ± SD) (range)	15.8 ± 2.3 (10, 21)
SE (D, mean ± SD) (range)	+9.2 ± 5.3 (−1.5, +22)
Indication of surgery (n, %)	
Postoperative aphakia (after previous surgery)	18 (69)
Traumatic lens subluxation/luxation	2 (8)
PCR (at the time of surgery)	6 (23)

AMD = age-related macular degeneration; CDVA = corrected distance visual acuity; DR = diabetic retinopathy; logMAR = logarithm of the minimum angle of resolution; PCR = posterior capsule rupture; SE = spherical equivalent

To reduce the complication rate, several variants of the classical scleral fixation technique have been developed, mostly directed at reducing the incision size.[3,22,26]

In 2015, Yang et al. described for the first time the results of surgical scleral fixation of the MX60 IOL, using the eyelets located at the optic–haptic junction for suture placement. The IOL was threaded with sutures, folded in half, and inserted with forceps into the anterior chamber through a 3.50 mm corneal incision. Their technique allowed for reporting an easy centration of the IOL and a stable IOL position. A transient postoperative hypotony was noted in 7% of cases.[22]

Recently, Morkin and Patterson proposed a new IOL insertion method, using injector systems, allowing a 2.75 mm corneal incision using an hydrophilic acrylic IOL (Akreos A065, Bausch & Lomb, Inc.) prethreaded with sutures and mounted in a cartridge (Monarch III system, Alcon). The authors reported that the benefits of inserting the IOL with an injector system and through a smaller wound include less surgically induced astigmatism and faster rehabilitation time, with a presumed low incidence of hypotony and other complications.[27]

Here, we describe a modified technique that uses the MX60 IOL and an injector system with many advantages. This foldable IOL allows implantation through a 1.80 mm corneal incision and shows a greater stability because of 4 support points: 2 sutures fixed to the eyelets and 2 haptics placed in the ciliary sulcus.[22] This is also supported by our results in that no IOL decentration or dislocation was observed. In addition, no intraoperative or postoperative complications were reported. To our knowledge, this is the first report to describe a scleral fixation technique using a corneal incision inferior to 2.0 mm. This technique does not represent a complex procedure and can be easily and quickly learnt by ophthalmic surgeons.

We used a polypropylene suture, which is the most commonly used suture material for scleral-fixated IOL techniques. However, concerns regarding suture breaking and degradation have been raised in the past. In a recent article, Kokame et al. showed that scleral fixation with a 10-0 polypropylene suture provides an excellent long-term fixation of PC IOLs. IOLs remained well stabilized and positioned at the last follow-up in 116 (98.3%) of 118 eyes with a mean follow-up of 6 years. The maximum stable follow-up

Table 2. Visual acuity changes.

Paremeter	Baseline	Month 1	Month 3	Month 6	Repeated Measures ANOVA
CDVA, logMAR (mean ± SD)	0.51 ± 0.21	0.25 ± 0.27	0.18 ± 0.16	0.17 ± 0.16	
CDVA, logMAR (range)	0.8, 0.1	0.5, 0	0.4, 0	0.4, 0	
P value		<.01	<.01	<.01	<.0001
Astigmatism, D (mean ± SD)	1.5 ± 1.3	1.1 ± 0.8	1.0 ± 0.7	1.1 ± 0.7	
Astigmatism, D (range)	0, 2.75	0, 3.00	0, 2.50	0, 2.50	
P value		NS	NS	NS	NS
IOP, mm Hg (mean ± SD)	15.8 ± 2.3	16.2 ± 2.5	16.0 ± 2.5	15.3 ± 2.2	
IOP, mm Hg (range)	10, 21	12, 21	12, 18	11, 20	
P value		NS	NS	NS	NS

ANOVA = analysis of variance; CDVA = corrected distance visual acuity; IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; NS = not significant

with 2 intact fixation sutures was 24.75 years.[28] The Gore-Tex suture could become a valuable alternative to the polypropylene suture. However, at the moment, the largest case series describing the use of the Gore-Tex suture for scleral fixation has a relatively short follow-up (325 days). Moreover, the authors themselves underline that the use of the Gore-Tex suture in the eye is currently off-label.[29]

This study has some limitations, including a small sample size and a relatively short postoperative follow-up period. Important complications, such as suture erosion, IOL dislocation, and tilting, might be observed in a longer follow-up period.

Scleral fixation of the MX60 IOL through a 1.80 mm corneal incision might be an effective and safe surgical technique that provides excellent stability of the IOL, although the follow-up of this study is relatively short (6 months). Compared with other scleral fixation techniques, it allows IOL implantation through the smallest corneal incision reported in the literature, to our knowledge. Studies with a larger sample and a longer follow-up period are needed to determine the safety and long-term efficacy of the surgical technique described in this article.

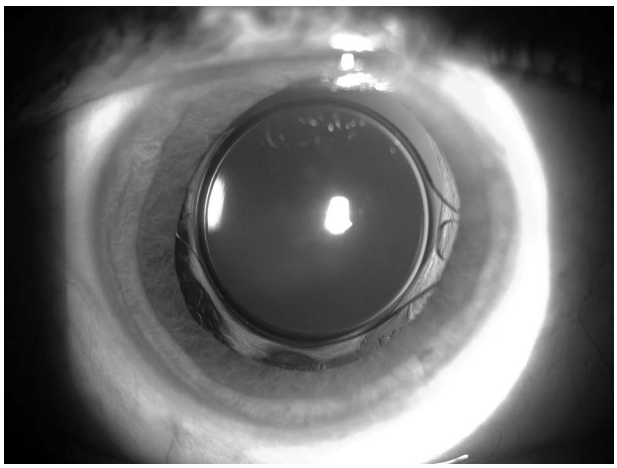

Figure 3. Slitlamp photograph of a scleral-fixated, well-centered MX60 intraocular lens at 6 months postoperatively.

WHAT WAS KNOWN

- Scleral fixation is a widely used technique for intraocular lens (IOL) implantation. The use of foldable IOLs eliminates the need for large incisions, thus reducing the incidence of postoperative astigmatism and facilitating a faster healing.

WHAT THIS PAPER ADDS

- To our knowledge, this is the first report to describe a scleral fixation technique using a corneal incision inferior to 2.0 mm.
- Because many complications of scleral fixation are related to a large incision, this technique might provide better outcomes.

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