ARTYKUŁ ORYGINALNY ORIGINAL RESEARCH STUDY
DOI: 10.24292/01.OT.311222.6

Sutureless transscleral intraocular lens implantation – own observation study

Małgorzata Marczak, Hanna Jakubowicz-Laska

Department of Ophthalmology and Pediatric Ophthalmology, John Paul II Memorial Subcarpathian Voivodeship Hospital in Krosno
Head: Jacek Brymerski, MD, PhD

HIGHLIGHTS

Sutureless transscleral fixation seems to be quite an effective and safe method of treating aphakia in eyes with deficient capsular support. It allows the duration of the surgery to be shortened in comparison to fixation using sutures. Complications are not very common and mostly reversable. Durability of this method requires further studies.

ABSTRACT

Aim of the study: Presentation of the results of Carlevale™ intraocular lens implantation with a transscleral sutureless fixation method, based on our own experience.

Material and methods: The sutureless transscleral implantation of a Carlevale™ lens was performed in 39 people (40 eyes) with postoperative aphakia after dislocation of lens, including 10 post-traumatic ones, and in one patient with a dislocated transscleral intraocular lens fixated with non-absorbable sutures. Patients were followed for 6 to 18 months.

Results: 80% of patients after surgery achieved visual acuity equal to or better than before surgery (20% achieved Snellen acuity 1.0 without correction). Intraoperative and postoperative complications were observed in slightly more than half of the patients. The most common were: keratopathy, slight bleeding into the vitreous chamber, conjunctival wound dehiscence, and intraocular pressure fluctuations. Most of these complications did not have any lasting consequences.

Conclusions: Sutureless transscleral implantation of an intraocular lens seems to be an effective and relatively safe method of treating aphakia. However, the assessment of the durability of sutureless fixation requires further research.

Key words: Carlevale, sutureless transscleral fixation, secondary intraocular lense implantation, aphakia

INTRODUCTION

In recent years, cataract surgery has been developing intensively. Progress is also being made in the area of intraocular lenses and methods of their implantation. Eye surgeons often face the problem of implanting an intraocular lens in the eye without the posterior capsule support (iatrogenic – during cataract surgery or as a result of trauma). The options left are implantation of the lens into the anterior chamber, iris fixation or transscleral fixation. Currently, there is no evidence for the superiority of any of these methods [1, 2]. The choice of the implantation method and location is difficult and should be based on the indications and the patient's clinical condition (cause of aphakia, age, depth of the anterior chamber, presence of other ophthalmic diseases). Transscleral implantation avoids some of the complications associated with the other two methods, such as the risk of corneal decompensation or angle closure [3]. In cases of the patients described in this study, a Carlevale™ lens with sutureless transscleral fixation was used.

THE AIM OF THE STUDY

The aim of the study is to present our own observations regarding the use of the Carlevale™ lens in treating 39 patients. The minimum follow-up time was 3 months.

MATERIAL AND METHODS

An indication for surgery was postoperative aphakia as a result of dislocation of the natural lens or PCIOL (posterior chamber intraocular lens). The criterion for exclusion of the patient from the procedure was active inflammation and severe keratopathy. We report a retrospective analysis of a group of 39 patients (40 eyes), including 24 men and 13 women. The indication for secondary implantation was aphakia; in 10 cases (25%) it was post-traumatic aphakia. Removal of dislocated lenses and secondary implantation of the Carlevale™ lens was performed:

- simultaneously – in 13 cases (32.5%), including 4 cases with subluxated own lenses and 9 dislocated PCIOLs
- in two stages – in 27 cases (67.5%), including 1 case with removing a dislocated PCIOL with transscleral suture fixation, implanted after traumatic dislocation of the own lens.

The mean time between removal of a lens and secondary implantation was approximately 1 month. In 25% of cases the dislocation was posttraumatic. In 20% of cases, the procedures were performed in two stages, and in 5% – simultaneously. During qualification for surgery, each patient underwent an ophthalmological examination, which included: distance vision acuity (with and without correction), measurement of intraocular pressure (IOP) by applanation tonometry, slit-lamp examination (anterior and fundus), biometric measurement and, if necessary, ultrasound examination in the B-projection of the eye (tab. 1).

TABLE 1

Characteristics of the study group before surgery.

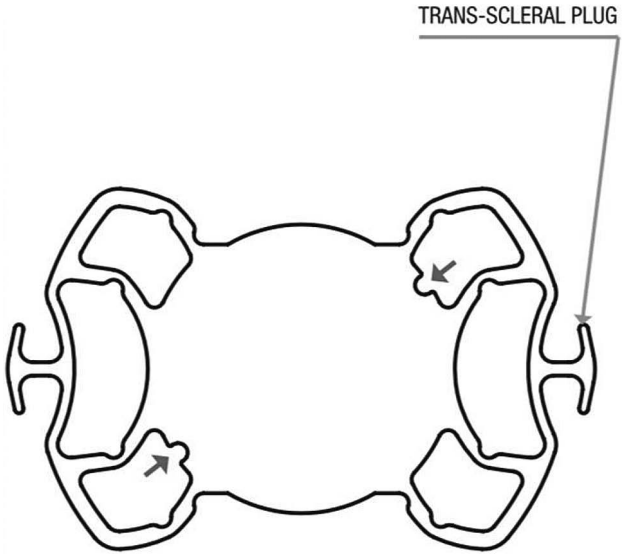
	Range of tested values	Mean sample	Standard deviation
Age of patients (years)	30–88	67.8	±15.25
Preoperative CDVA (decimal equivalent)	0.006–1.0	0.36	±0.28
Preoperative IOP (mmHg)	9–40	18.98	±6.10

CDVA – corrected distance visual acuity.

The choice of lens power was made on the basis of biometric measurements performed with the Lenstar LS 900 device using the Barret formula. In all cases a monofocal Carlevale™ lenses with sutureless transscleral fixation were used. These are one-piece, acrylic, foldable, hydrophilic lenses with a UV filter. The range of available lens powers ranges from -5.00 to +35.00 D [4]. Each lens has a T-shaped plugs on each side, passed through the scleral tunnel, and additional stabilizing elements to prevent lens rotation (fig. 1). What is more, the lenses are equipped with two opposite incisions stabilizing the anterior-posterior position of the implanted lens.

FIGURE 1

Construction of the FIL SSF Carlevale™ lens. Constant A 118.5; diameter 13.2 mm; optical diameter 6.5 mm.



OPERATING TECHNIQUE

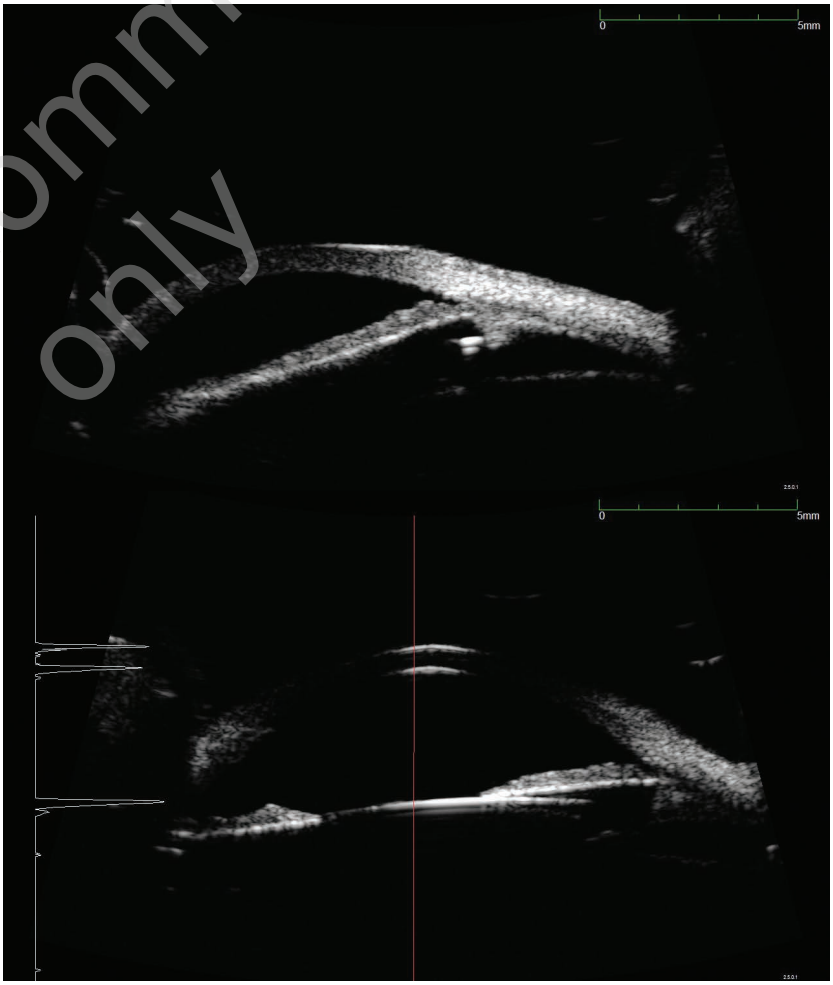
Operations were performed under epibulbar anesthesia with 2.5 ml of lidocaine and 2.5 ml of proxymetacaine. Conjunc-

tival incision was made 10–14 mm from the limbus. Then the Tenon's capsule was removed from sclera and the blood vessels were coagulated. Two opposing 4 × 4 mm scleral flaps were made between 8.30 and 9.30 and between 2.30 and 3.30, at 2/3 of the scleral thickness, with the base towards the limbus. A solution of lidocaine with phenylephrine and tropicamide was administered into the anterior chamber. Then, depending on the indications, the dislocated lens was removed, and anterior vitrectomy was performed if needed. The Carlevale™ lens was prepared in an injector; a viscoelastic was administered into the anterior chamber. Then using a 15° knife or dagger knife, a tunnel into the posterior chamber was made under the scleral flaps (2 mm from the limbus, through the pars plana). Through a 2.7 mm corneal incision, the lens was slowly inserted into the anterior chamber until the fixation plug developed and was then pulled through the tunnel using crocodile forceps and fixed under the scleral flap. A second haptic was then similarly attached (at 9.00 and 3.00) to fix the lens in the posterior chamber. Later, the viscoelastic was removed, an antibiotic was administered to the anterior chamber, the 10/0 sutures were placed on the scleral flaps, and an 8/0 on the conjunctival wound. Finally, the corneal ports were sealed and an a subconjuntival injection of antibiotic-glucocorticosteroid solution was administered. The time of each operation was about 45 minutes. All patients were operated on by the same surgeon. After the procedure, all patients received treatment to the operated eye (antibiotic, glucocorticosteroid, non-steroidal anti-inflammatory drug, moisturizing drops), modified during the follow-up depending on the clinical condition.

All described patients remained under ophthalmological care for a period of 3 to 18 months after the operation (examination at discharge from the hospital, 1st ambulatory examination – after 7 days, 2nd examination – one month after surgery, 3rd examination – after 3–6 months. Each examination included: distance visual acuity test using Snellen charts, slit-lamp examination of the anterior segment and fundus, IOP measurement by applanation, ultrabiomicroscopy of the anterior segment of the eye (UBM) if needed (fig. 2). Also conjunctival sutures were removed.

FIGURE 2

In the UBM examination, the position of the lens and the fixation haptics was checked (in the sulcus or through the processes of the ciliary body).



Changes in follow-up examinations in the first month after surgery are presented in figures 3 and 4.

RESULTS

The most common intraoperative complications included:

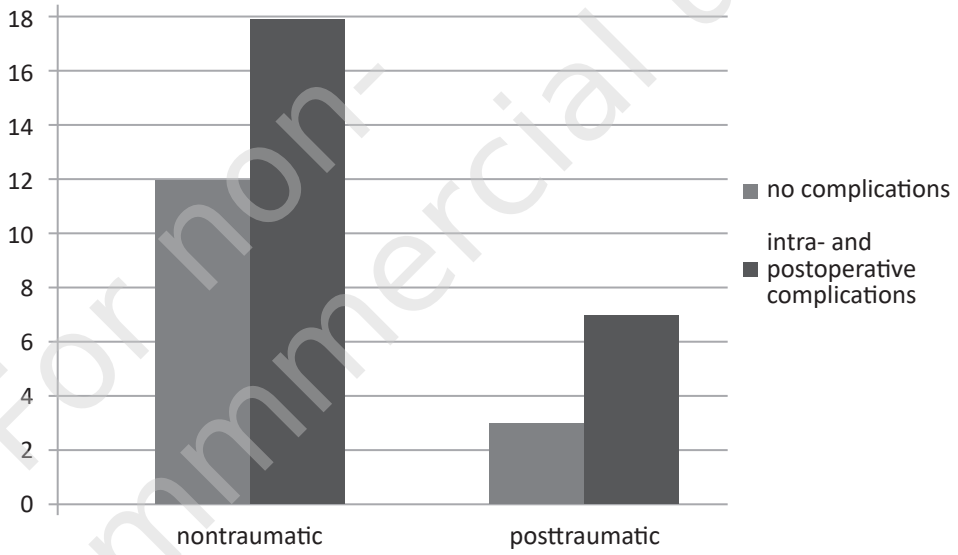
- anterior chamber hemorrhage (AC hemorrhage) (12.5% of cases)
- vitreous hemorrhage (25% of cases).

A quantitative summary of individual intraoperative and postoperative complications is presented in figure 4.

Corneal complications regressed to first follow-up in all cases. Post-operative wounds healed properly after additional sutures were applied, in one case it was necessary use the amniotic membrane. Hemorrhages resolved in all cases during the follow-up period. Normal IOP values were achieved during the follow-up period in almost all cases. 1 patient with post-traumatic glaucoma before surgery,

FIGURE 3

The number of intraoperative and postoperative complications in non-traumatic and post-traumatic patients.



Post-operative side effects observed during post-operative follow-up included:

- descemet membrane folds (20% of cases)
- keratopathy (25%)
- IOP fluctuations (17.5%): an increase above 21 mmHg was observed in the perioperative period in 12.5% of cases (5 patients, including 3 with treated high IOP before surgery). In 2 patients (5%) IOP over 30 mmHg maintained at all 3 follow-ups; hypotonia occurred in 2 cases (5%)
- dehiscence of the conjunctival wound in 17.5% of cases (and in 1 case the formation of a scleral fistula under the conjunctiva)
- protrusion of one part of the fixing haptic from the scleral pocket (haptic visible under the conjunctiva) – in 1 case (2.5%).

None of the described patients developed postoperative macular edema or uveitis–glaucoma–hyphema syndrome, although there are reports of these complications [5–8].

developed an advanced neuropathy despite treatment. In 2 patients hypotension led to choroidal detachment. In one of them, it resolved until the third inspection. In the second case, hypotonia and choroidal detachment persisted, preventing usable visual acuity. The average IOP before surgery was approximately 19 mmHg, and 17 mmHg 3 months after surgery. Keratopathy was slightly more common in uninjured eyes; these patients had usually simultaneous dislocated lens removal and Carlevale™ implantation. Fluctuations of IOP and related complications were more common in eyes after injuries. There were no other significant differences in the incidence of complications between posttraumatic and nontraumatic eyes (fig. 5). There were also no other significant differences in postoperative complications between patients who underwent simultaneous lens removal and secondary implantation and those who underwent these operations in 2 stages.

The mean preoperative visual acuity was 0.3–0.4 (decimal equivalent), and postoperative 0.5–0.6 (tab. 2).

FIGURE 4

Detailed quantitative summary of the most common intraoperative and postoperative complications.

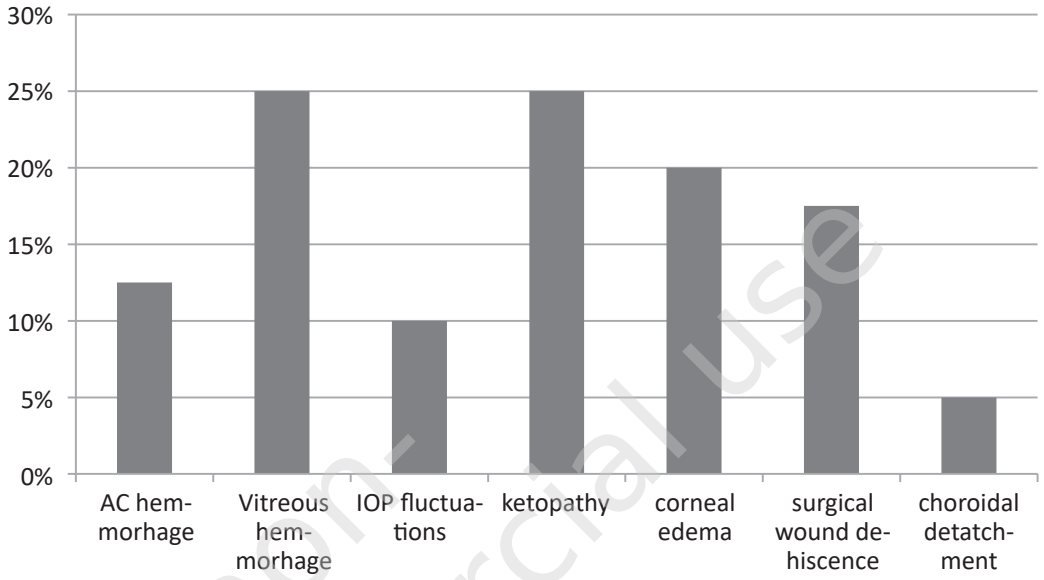
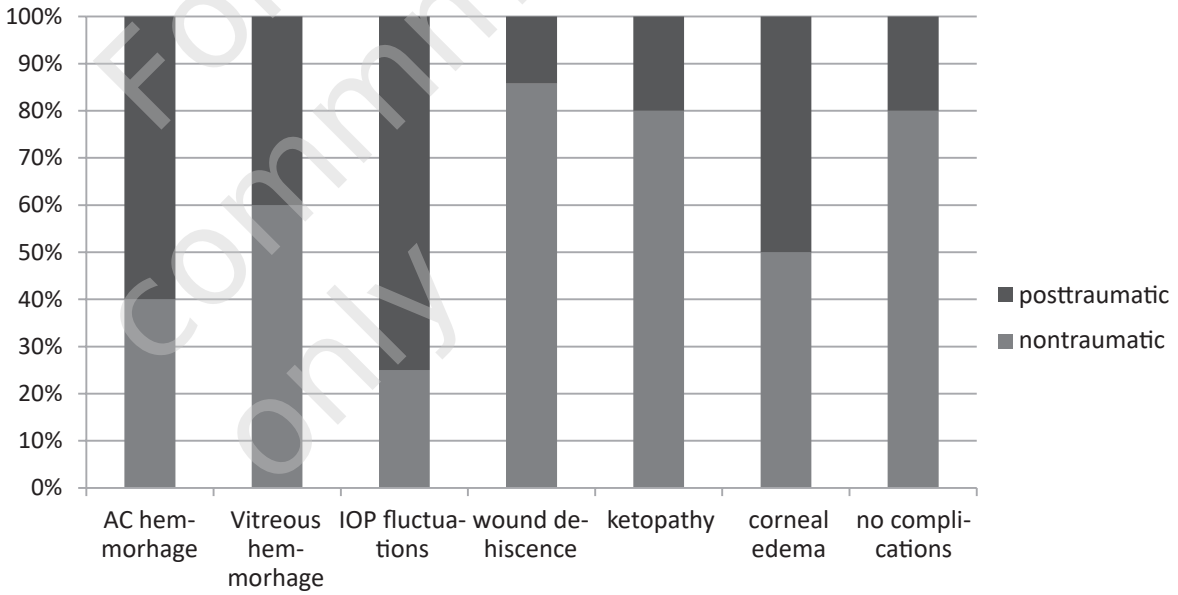


FIGURE 5

Comparison of complications rates in traumatized and non-traumatic eyes.



Visual acuity improved after surgery in 27 cases (67.5%) or remained at the preoperative level (tab. 3). In 2 cases, visual acuity decreased as a result of neuropathy caused by IOP disorders. Visual acuity of 1.0 was achieved after surgery in 20% of cases. Visual acuity above 0.5 was achieved in 62.5% of the subjects. In 1 patient, the best corrected visual acuity (BCVA) was below 0.1 after the observation period.

TABLE 2

Characteristics of the study group in the postoperative period.

	Tested value range	Mean sample	Standard deviation
UDVA 3 months postoperatively (decimal equivalent)	0–1.0	0.55	±0.31
IOP on the 1st day postoperatively (mmHg)	7–44	19.40	±7.29
IOP 3 months postoperatively (mmHg)	3–38	17.05	±5.94

UDVA – uncorrected distance visual acuity.

TABLE 3

Quantitative summary of patients and their postoperative visual acuity (UDVA after at least 3 months follow-up).

Postoperative UDVA (decimal equivalent)	1.0	0.5–0.9	0.1–0.4	< 0.1
Number of cases (%)	8 (20%)	17 (42.5%)	14 (35%)	1 (2.5%)

CONCLUSIONS

Secondary IOL implantation using Carlevale™ sutureless scleral fixation lenses is a relatively new method with promising results. It can be successfully used in patients after eye injuries. Sutureless fixation allows to shorten the operation time, and the construction of the lens ensures its stable position and prevents rotation [9]. However, some skills and experience is needed to create the scleral pockets and appropriate transscleral tunnels necessary for proper lens attachment. It seems the construction of the plugs will allow to avoid the complication of suture breakage, which occurs in traditional transscleral fixation. However, a longer, long-term observation will be needed to assess the durability of this fixation. Previous studies comparing transscleral fixation using sutures with the sutureless method did not show any advantage of either method [10]. The sutureless method seems to be a good choice in the treatment of aphakia in patients with glaucoma, shallow anterior chamber and low endothelial cell density.

The most common complications, which are keratopathy and corneal edema, disappear shortly after surgery. Unfortunately, this method, like transscleral fixation with sutures, is not free from the risk of vitreous hemorrhage. Other more serious complications are relatively rare, which makes implantation of a sutureless transscleral fixation lens a relatively safe and effective method of treating aphakia. However, the assessment of its usefulness in relation to other methods of aphakia treatment requires even longer observation studies.

Figures: Figure 2. – FIL SSF Carlevale™ lens product data sheet, other figures – own materials.

CORRESPONDENCE
Hanna Jakubowicz-Laska, MD
Department of Ophthalmology and Pediatric Ophthalmology,
John Paul II Memorial Subcarpathian Voivodeship Hospital in Krosno
38-400 Krosno, ul. Korczyńska 57
e-mail: haniajakubowicz@gmail.com

ORCID
Małgorzata Marczak – ID – http://orcid.org/0000-0002-1450-3835
Hanna Jakubowicz-Laska – ID – http://orcid.org/0000-0001-7358-472X

References

1. Wagoner MD, Cox TA, Ariyasu RG et al.; American Academy of Ophthalmology. Intraocular lens implantation in the absence of capsular support: a report by the American Academy of Ophthalmology. Ophthalmology. 2003; 110(4): 840-59. http://doi.org/10.1016/s0161-6420(02)02000-6.
2. Dick HB, Augustin AJ. Lens implant selection with absence of capsular support. Curr Opin Ophthalmol. 2001; 12(1): 47-57. http://doi.org/10.1097/00055735-200102000-00009.
3. Tang Y, Xu J, Chen J et al. Long-Term Destiny of Corneal Endothelial Cells in Anterior Chamber Intraocular Lens-Implanted Eyes. J Ophthalmol. 2020; 2020: 5967509. http://doi.org/10.1155/2020/5967509.
4. Soleko IOLDivision. Charakterystyka produktu, karta katalogowa FIL SSF Carlevale Lens.
5. Vaiano AS, Hoffer KJ, Greco A et al. Long-term Outcomes and Complications of the New Carlevale Sutureless Scleral Fixation Posterior Chamber IOL. J Refract Surg. 2021; 37(2): 126-32. http://doi.org/10.3928/1081597X-20201207-02.
6. Fiore T, Messina M, Muzi A et al. A novel approach for scleral fixation using Carlevale lens. Eur J Ophthalmol. 2021; 31(6): 2947-54. http://doi.org/10.1177/1120672121991358.
7. Georgalas I, Spyropoulos D, Gotzaridis S et al. Scleral fixation of Carlevale intraocular lens: A new tool in correcting aphakia with no capsular support. Eur J Ophthalmol. 2022; 32(1): 527-33. http://doi.org/10.1177/1120672121992978.

8. Rouhette H, Meyer F, Pommier S et al. FIL-SSF Carlevale intraocular lens for sutureless scleral fixation: 7 recommendations from a serie of 72 cases. MICA study (Multicentric Study of the Carlevale IOL). J Fr Ophtalmol. 2021; 44(7): 1038-46. http://doi.org/10.1016/j.jfo.2021.05.002.
9. Mularoni A, Imburgia A, Forlini M et al. In vivo evaluation of a 1-piece foldable sutureless intrascleral fixation intraocular lens using ultrasound biomicroscopy and anterior segment OCT. J Cataract Refract Surg. 2021; 47(3): 316-22. http://doi.org/10.1097/j.jcrs.0000000000000444.
10. Sindal MD, Nakhwa CP, Sengupta S. Comparison of sutured versus sutureless scleral-fixated intraocular lenses. J Cataract Refract Surg. 2016; 42(1): 27-34. http://doi.org/10.1016/j.jcrs.2015.09.019.

Conflict of interest:
None.

Financial support:
None.

Ethics:
The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.