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ORIGINAL ARTICLE

A Modified Four-point Scleral Fixation of Intraocular Lens in Aphakic Eyes without Adequate Capsular Support

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Background: Polypropylene is a commonly used suturing material for intraocular lens (IOL) scleral fixation, but a high breakage rate after several years of follow-up is reported. Meanwhile, Gore-Tex has been a popular artificial material in ophthalmic surgery. **Aim:** This pilot study investigated the safety and efficacy of a modified surgical technique for scleral fixation of a four-point, close-loop haptic IOL using Gore-Tex as the suture material for aphakic patients without adequate capsular support. **Methods:** A modified IOL scleral fixation technique was developed using a four-point, close-loop haptic IOL and Gore-Tex as the suture material. Patients undergoing the operation between March 2018 and May 2019 at one center were included in the study. The preoperative uncorrected distance visual acuity (UDVA) with spectacles and postoperative UDVA with an IOL were compared as the main outcome. Follow-up time was 17–43 months. **Results:** A total of 10 eyes of 10 patients were enrolled, including 3 with iatrogenic IOL dislocation, 3 with iatrogenic lens drop, 2 with traumatic lens dislocation, and 2 with late in-the-bag IOL dislocation. The mean age was 70.8 ± 12.11 years. The mean UDVA, evaluated by the logarithm of the minimum angle of resolution, was decreased from preoperative 1.89 ± 0.28 to postoperative 0.58 ± 0.70 ($P < 0.001$). No complications were reported except in one case with a postoperative corneal ulcer which healed after antibiotic treatment. **Conclusion:** The favorable outcome suggests Gore-Tex sutures as a safe and stable material for IOL scleral fixation. Prospective studies with a larger sample size would be necessary for more details on the safety and efficacy of the Gore-Tex suture in IOL scleral fixation.

Key words: Gore-tex, intraocular lens, scleral fixation, suture, visual acuity

INTRODUCTION

Intraocular lens (IOL) implantation in patients with compromised or no capsular support has been challenging. Numerous different designs of IOL, suturing materials, and surgical techniques such as angle-support anterior chamber (AC) IOL, iris-claw IOL, iris-suture IOL, scleral-suture IOL, and intrascleral sutureless IOL fixation have been developed for this kind of situations.[1-4] A review of 189 citations related to IOL implantation in the absence of capsular support concluded that the available surgical approaches and IOL types appear to provide comparable or equivalent positive visual and safety outcomes.[5]

Among the available surgical techniques, scleral fixation of IOL is relatively common and applicable in most situations because of its relatively simple and straightforward design.[4] Many surgeons prefer 10-0 polypropylene (prolene) to be the suturing material for IOL scleral fixation because its needles are suitable for performing tucking techniques during IOL fixation. However, it seems to be fragile with a high breakage rate after several years follow-up.[6,7] On the other hand, Gore-Tex has been a popular artificial material in the field of surgery in recent years.[8-12] The ophthalmic use of Gore-Tex suture was first reported by Nottage *et al*. in 2009[13] and has become more and more popular thereafter.[14-17] The aim of this study is to

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investigate the safety and efficacy of Gore-Tex sutures for scleral fixation in IOL surgery performed in aphakic patients without capsular support. Favorable outcomes supported Gore-Tex as a useful suture material in scleral fixation.

MATERIALS AND METHODS

Study design

This was a retrospective study of consecutive patients undergoing a modified IOL scleral fixation technique using NeoEye four-point close haptic IOL (PT. Rohto Laboratories, Jakarta, Indonesia) and Gore-Tex (W. L. Gore and Associates, Newark, DE) as a suture material between March 2018 and May 2019 at our hospital. The protocol for this study was reviewed and approved by the Institutional Review Board of Tri-Service General Hospital, Taipei, Taiwan (TSGHIRB No.: B202005067). All included patients provided signed informed consent to have their pre-, intra, and postoperative results evaluated in this study. All methods were performed in accordance with the ethical standards of the responsible committee on human experimentation and with the Declaration of Helsinki 1975.

Patients with lens drop, lens dislocation (ectopia lentis), or IOL dislocation caused by poor or absent capsular support or weakness of zonule (e.g., more than half of ciliary zonules are broken) who had been indicated for secondary IOL implantation surgery were recruited. Inclusion criteria were patients diagnosed with traumatic lens dislocation, postphaco complications (iatrogenic PC rupture; lens drop), or in-the-bag IOL dislocation for whom placement of IOL in the capsular bag or sulcus was not appropriate, or in whom more than half of ciliary zonules were broken. The uncorrected distance visual acuity (UDVA) with speculate, evaluated with the logarithm of the minimum angle of resolution (logMAR), before and after scleral fixation were collected. Complications in follow-up duration were also noticed. All data were retrospectively analyzed.

Surgical procedures

A total of 10 eyes of 10 patients (7 men and 3 women) underwent combined pars plana vitrectomy (PPV) and scleral fixated posterior chamber IOL implantation using CV-8 Gore-Tex suture. ROHTO Neo Eye foldable IOLRF-31 PL, a hydrophilic acrylic IOL, was used for all cases. The surgical technique was modified by Khan *et al.* (2018). Key procedures are demonstrated in the accompanying supplemental digital content [Supplementary Video 1]. For each patient, a toric lens marker was used to mark the corneal limbus at two points in the horizontal plane 180° apart. Nasal and temporal conjunctival peritomies were created; hemostasis was maintained using external cautery. A standard infusion line for PPV was installed. The two remaining trocars were placed superotemporally and superonasally to the marked horizontal axis, 2 to 3 mm posterior to the limbus, using a straight-in, nontunneled approach. The introducers were then used to construct two additional sclerotomies, each 4 mm from one of the superonasal and superotemporal trocars while maintaining the same 2- to 3-mm distance from the limbus [Figure 1].

Standard PPV was then performed. This technique is compatible with 23G, 25G, or 27G instrumentation. The AC was entered through a clear corneal incision created using a phaco keratome blade and then enlarged slightly. A previously constructed incision can be used if cataract extraction was recently performed. The AC is stabilized using a viscoelastic substance while the infusion line is clamped. Next, the CV-8 needles of the 8-0 polytetrafluoroethylene (PTFE) Gore-Tex suture were removed, and the suture was cut into halves. Each suture end was threaded through two adjacent eyelets of the ROHTO Neo Eye RF-31 PLIOL. The suture was passed through the first IOL eyelet from anterior to posterior and then through the corresponding second eyelet from posterior to anterior. This pattern was repeated on the contralateral side of the IOL. In a hand-to-hand technique, the two nasal or two temporal ends of the PTFE suture are passed into the AC and pulled out of the corresponding sclerotomy using intraocular forceps.

The ROHTO Neo Eye RF-31 PLIOL was then folded along its long axis using Kelman-McPherson or similar forceps and introduced into the AC. Once in the eye, the IOL was placed into the posterior chamber, and each remaining end of the PTFE suture was grasped and externalized through the respective sclerotomies using MaxGrip (Alcon, Vernier, Geneva, Switzerland) or similar forceps. All four ends of the

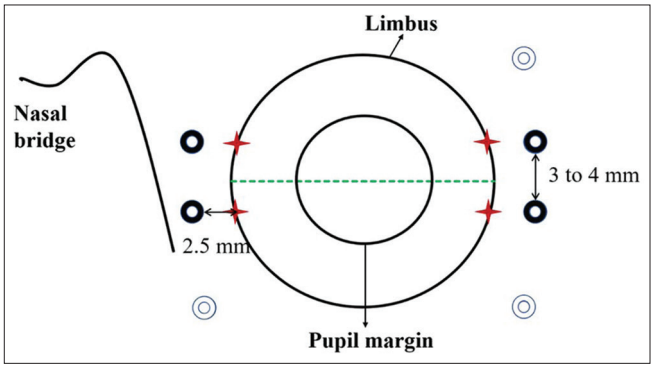

Figure 1: Illustration of sclerotomy sites when using a horizontal axis. The four filled circles indicate sclerotomy sites with 25 G cannula, each located 2.5 mm from the limbus. The three empty circles indicate sclerotomy sites with 23 G cannula, which are also standard sites for pars plana vitrectomy. The longitudinal distance between two adjacent 25 G cannula is 3–4 mm, depending on patient's eye size. The dashed line indicates the horizontal toric-marked axis

PTFE suture were then pulled, and tension was balanced to ensure that the IOL was well centered. The trocars were then removed, and sutures were tied using a 3–1–1 or adjustable slip-knot technique. The knots were trimmed, and nasal and temporal knots were buried into the sclerotomies that previously housed the trocars. The viscoelastic material was removed, and the corneal wound was closed using a 10-0 nylon suture. The overlying conjunctival peritomy was then closed, making sure the PTFE suture was completely covered. The operation takes 40–60 min.

Statistical analysis

Mann–Whitney test was used for data analysis. Continuous variables are expressed as means with standard deviation. All statistical analyses were performed using IBM SPSS Statistics software, version 22 (IBM Corp. Armonk, NY, USA). A two-tailed $P < 0.05$ was established as statistical significance.

RESULTS

Baseline characteristics of patients who underwent scleral fixation of IOL are summarized in Table 1. A total of 10 eyes of 10 patients were included, 3 were diagnosed with iatrogenic IOL dislocation, 3 with iatrogenic lens drop, 2 with traumatic lens dislocation, and 2 with late in-the-bag IOL dislocation [Supplementary Table 1]. The mean age at surgery was 70.8 ± 12.11 years (range 57–90 years), and 70% (7/10) were male. The mean follow-up duration was 32.7 ± 10.9 months (range 17–43 months). Three patients had a history of ophthalmic disorders, including optic atrophy, orbital wall fracture, and macular hole [Supplementary Table 1]. No remnant capsule bag was observed in the preoperative eye of an 83-year-old male patient with iatrogenic IOL dislocation, as shown in Supplementary Figure 1.

Table 1: Patient's baseline characteristics

	ALL (*n*=10)
Total eyes	10
Age, years	
Mean±SD	70.8±12.11
Range	57–90
Sex	
Male	7
Female	3
Relevant ophthalmic history	
Optic atrophy	1
Macular hole	1
Preoperative VA logMAR	
Mean±SD	1.88±0.27
Range	1.30–2.30
Postoperative VA logMAR	
Mean±SD	0.58±0.69
Range	0–1.85
Duration of follow-up, days	
Mean±SD	232.5±173.96
Range	15–450

VA=Visual acuity; SD=Standard deviation; logMAR: Logarithm of the minimum angle of resolution

Change in logMAR after scleral fixation was observed in all included patients, which decreased from 1.89 ± 0.28 preoperatively to 0.58 ± 0.70 postoperatively ($P < 0.001$). The pre-and postoperative logMAR in different diagnostic subgroups are listed in Table 2. One case reported postoperative corneal ulcer. However, this patient with iatrogenic IOL dislocation exhibited meibomian dysfunction and an injured corneal before the surgery, and the corneal ulcer healed after antibiotic treatment. No other complications were observed in the remaining nine patients during the follow-up period.

DISCUSSION

In the present study, we report a modified IOL scleral fixation technique using NeoEye four-point close haptic foldable IOL and CV-8 Gore-Tex suture in patients with compromised or no capsular support. Favorable outcomes were reported, including improved UDVA and no complications in most patients except one case who developed a nonsuture-related corneal ulcer cured after antibiotic eye-drop treatment.

Suturing materials for scleral-fixated IOL have been studied and debated for decades. The most common suturing material used in IOL fixation is probably 10-0 prolene. This suture was convenient for surgeons who prefer intraocular needle-tucking techniques and was deemed to provide good long-term fixation of IOLs.[11] However, more and more reports have shown that the suture breakage rate may be as high as 24%–28% within 10 years.[14] Gore-Tex suture has been commonly used in nonophthalmic surgeries for decades. Nottage *et al*.[13] and Khan *et al*.[14-16] have reported an external scleral fixation of IOL or PPV combined with scleral fixation of IOL using Gore-Tex sutures with favorable outcomes. Long-term refractive outcomes after 4-point scleral fixation combined PPV and scleral fixation, and transscleral fixation of capsular tension rings with IOL using Gore-Tex sutures were also favorable.[8,11,17-21] These studies showed that Gore-Tex suture was well tolerated with no suture-related complications such as breakage, erosion, IOL dislocation, IOL tilt, endophthalmitis, or persistent postoperative inflammation noted at a minimum

Table 2: Visual acuity (logarithm of the minimum angle of resolution) outcomes

	Overall	Iatrogenic IOL dislocation	Iatrogenic lens drop	Traumatic lens dislocation	Late in-the-bag IOL dislocation
Preoperative VA	1.89±0.28	1.93±0.18	1.85[b]	1.58±0.39	2.08±0.32
Postoperative VA	0.58±0.70	0.75±0.98	0.36±0.30	0.19±0.05	1.04±1.15
n	10	3	3	2	2
P[a]	0.001				

[a]Mann–Whitney test between preoperative and postoperative VA, [b]SD value was not available because preoperative logMAR values in the iatrogenic lens drop subgroup were all 1.85. Differences between preoperative and postoperative logMAR for overall and four diagnostic subgroups. Statistical significance: $P<0.05$. IOL=Intraocular lens; VA=Visual acuity; SD=Standard deviation

of 1-year follow-up.[8,11,13-21] Similarly, in the present study, the UDVA in all patients was improved postoperatively. Severe intraoperative or postoperative complications were not observed in the majority of cases, except one patient reported a corneal ulcer which was healing well after using antibiotics eye drops. Our results also support Gore-Tex as a well-tolerated suture material for scleral fixation.

Various IOLs can be used for secondary IOL implantation, including AO60 IOL,[8,11,17,18,20] Alcon CZ70BD,[8] and Neo EyeRF-31 PL IOL. In particular, Khan *et al*.[14-16] reported that the AO60 IOL is stable as a result of its four-point fixation and the ability to use a small corneal incision, but opacification may occur on exposure to gas or air due to its hydrophilic acrylic nature. On the other hand, the CZ70BD has become popular, but it has only two eyelets and only fits the two-point fixation technique.[4] In the present study, the hydrophilic acrylic Neo Eye RF-31 PL IOL was used because of its advantages of stable four-point fixation and that it also can be folded along its long axis, contrary to an IOL with a small scleral tunnel (3.5 mm corneal incision width). Notably, for the 10 patients in the series, fluid-air exchange was avoided and no opacification occurred.

In the present study, modification of the scleral fixation of the IOL technique described by Khan *et al*.[15] involved the introduction of extra sclerotomy sites, including four sites corresponding to the four corners of IOL and 3 PPV sites. Compared to Khan's study, which only used 4 IOL corner sites, the modified design enabled us to examine the posterior chamber and retina condition after tying up the IOL, offering procedural advantages as well as supporting successful outcomes.

Among secondary IOL fixation approaches, retropupillary iris fixation and intrascleral IOL fixation are mostly used. Both provide good stability and favorable outcomes. Retropupillary iris fixation is of shorter operation time[8] than intrascleral IOL fixation, but ~ 30% of patients may develop complications including iris atrophy, disenclavation, and transient elevation of intraocular pressure in 2–5 years. By contrast, intrascleral IOL fixation has a similar physiological location, so the above complications are avoidable. Various modified techniques are developed and can be generally classified into sutured and sutureless. Sutured techniques may manifest suture-related problems such as inflammation, suture degradation, and delayed IOL dislocation caused by suture breakage or exposure.[18,19] Sutureless techniques do not have these suture-related complications but may develop haptic damage and dislocation from the intrascleral tunnel. In our study, there were no postoperative complications except one patient with corneal ulcer in the follow-up time of 1–3 years. Given that the suture breakage rate was up to 28% within 10 years,[14] a continuing follow-up for longer than 5 years may be required to ensure the safety of the Gore-Tex suture.

Limitations

This study has several limitations. First, it is a retrospective, single-center study with a small sample. Retrospective analysis does not allow ruling out selection bias and causation cannot be inferred. A comparison group was also lacking in this study. Second, preoperative UDVA with spectacles (not contact lenses) and postoperative UDVA with an IOL were compared as the main outcome. Third, although ROHTO Neo Eye RF-31 PL IOL provides stable four-point support, hydrophilic IOL may not be an ideal choice as a trans-scleral fixation of IOLs for vitreoretinal surgery in the future because of its increased risk of opacification during fluid-air exchange.

CONCLUSION

Postoperative UDVA was improved in all included patients undergoing a modified fixation technique for IOL using Gore-Tex suture material. Gore-Tex sutures appear to be safe and stable in the scleral fixation of IOL. An additional prospective study with a larger sample is needed to confirm the findings of the present study.

Data availability statement

The data that support the findings of this study are available from the corresponding author, Dr. Yun-Hsiang Chang, MD in Department of Ophthalmology, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan, upon reasonable request.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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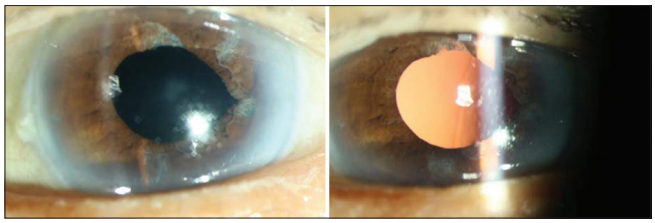
SUPPLEMENTARY TABLE

Supplementary Table 1: List of cases

Case	Gender	Right/ Left	Age	Diagnosis	History	Preoperative UDVA	Postoperative UDVA	Follow-up (months)	Complications	Op date
1	Male	Left	79	Iatrogenic IOL dislocation	Optic atrophy	2.3	1.85	43	Corneal ulcer	March 22, 2018
2	Female	Left	90	Iatrogenic lens drop	Nil	1.85	0.3	42	Nil	April 21, 2018
3	Female	Left	57	Iatrogenic lens drop	Nil	1.85	0.09	42	Nil	May 03, 2018
4	Male	Right	64	Traumatic lens dislocation	Nil	1.85	0.22	41	Nil	May 31, 2018
5	Female	Left	63	Traumatic lens dislocation	Orbital wall fracture	1.3	0.15	37	Nil	September 11, 2018
6	Male	Right	85	Iatrogenic lens drop	Nil	1.85	0.69	36	Nil	October 04, 2018
7	Male	Right	60	Late in-the-bag IOL dislocation	Nil	2.3	1.85	32	Nil	February 12, 2019
8	Male	Left	66	Late in-the-bag IOL dislocation	Macular hole	1.85	0.22	18	Nil	April 25, 2019
9	Male	Right	61	Iatrogenic IOL dislocation	Nil	1.85	0	19	Nil	March 12, 2019
10	Male	Left	83	Iatrogenic IOL dislocation	Nil	1.85	0.39	17	Nil	May 07, 2019

UDVA=Uncorrected distance visual acuity; IOL=Intraocular lens

SUPPLEMENTARY FIGURE



Supplementary Figure 1: Illustration of aphakia in an 83-year-old male patient with iatrogenic intraocular lens dislocation. No remnant capsule bag was observed