Comparison of Clinical Results Between a 4-point Scleral Fixation of Intraocular Lenses Using Gore-tex Suture and a 2-point Fixation Using Prolene Suture

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Research Article

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Abstract

Purpose: To compare clinical outcomes between a 4-point scleral fixation of intraocular lenses (IOLs) using Gore-Tex suture or a 2-point scleral fixation using Prolene suture

Methods: In this multicenter, retrospective cohort study, patients were enrolled who had undergone a pars plana vitrectomy and either a 4-point scleral fixation using Gore-Tex suture or a 2-point scleral fixation using Prolene suture. Preoperative biometrics, postoperative refractive outcomes, and postoperative surgical complication rates were evaluated.

Results: Thirty-seven eyes underwent scleral fixation with Gore-Tex suture, while 44 eyes underwent scleral fixation with Prolene suture. Postoperative best corrected visual acuity was 0.20 (± 0.34) in the Gore-Tex group and 0.21 (± 0.28) in the Prolene group (logMAR, 20/32 on the Snellen scale) ($p = 0.691$). No significant difference was found in the average prediction error between the Gore-Tex (-0.13 ± 0.68 D) and Prolene (-0.21 ± 1.27 D) groups ($p = 0.077$). The postoperative complication rate was lower in the Gore-Tex group (17%) than in the Prolene group (41%) ($p = 0.023$).

Conclusion: A 4-point scleral fixation using Gore-Tex suture may be a good alternative to a conventional scleral fixation using Prolene suture for IOL implantations in eyes without capsular support, with a lower risk of postoperative complications.

Introduction

Intraocular lens (IOL) implantation is one of the most important processes during cataract surgery. However, some patients do not have the proper structures to support an IOL due to ruptures in the posterior capsule or zonular weakness. These patients can be treated with insertion of a 3-piece IOL into the sulcus or insertion of a capsular tension ring into the bag if the zonular weakness is limited to less than 120° [1, 2]. However, if severe zonular weakness is observed or IOL dislocation has occurred, other techniques become necessary. In these cases, scleral fixation of the IOL is usually performed [3]. Traditionally, 10-0 or 9-0 Prolene suture has been used for these fixations [4, 5]; however, conjunctival erosion, IOL-pupillary capture, knot exposure, and dislocations due to melting of Prolene can occur with this technique [4, 6–8].

A 4-point fixation with a 4-plate IOL has been reported as a potential alternative procedure [9], with a low risk of postoperative complications [10–13]. However, it is unknown whether this new procedure is superior to the more traditional method. Therefore, in this study, we compared the surgical outcomes and complication rates between a scleral fixation of a 3-piece IOL with Prolene suture and the new 4-point method using Gore-Tex suture.

Materials, Patients, And Methods

This retrospective study included 81 eyes of 81 patients who had undergone surgery between January 2017 and December 2018 at four hospitals (Kong Eye Hospital, Seoul, Korea; Pureun Eye Center, Jeonju, Korea; Moonsan Jaeil Eye Center, Paju, Korea; Myungdong St. Mary Eye Center, Seoul, Korea) and had a minimum follow-up of 6 months. This study adhered to the tenets of the Declaration of Helsinki, and an institutional review board approved this study (KIRB-201901-HR-006-01).

We collected preoperative data, including patient age, sex, and results of a complete ophthalmic examination. Axial length was measured by the IOLMaster 500 (Carl. Zeiss Meditec, Jena Germany). Best-corrected visual acuity (BCVA) was measured using Snellen visual acuity charts and converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analyses.

Surgical Procedures

Either a conventional 3-piece IOL scleral fixation using 10-0 or 9-0 Prolene suture or a 4-point scleral fixation using Gore-Tex was selected alternatively by the surgeons (JMH, DMC, HCK, and DKL). In some patients in whom a 3-piece IOL or a polymethylmethacrylate (PMMA) IOL had become dislocated, the present IOL was fixated using 10-0 or 9-0 Prolene. All procedures were accompanied by a total vitrectomy. For the 3-piece IOL scleral fixation, a docking technique was used [14], and one surgeon (HCK) made scleral flaps for burying of 9-0 Prolene knots.

The surgical technique using Gore-Tex suture has been described previously [10]. Specifically, two corneal peripheral points were marked along a horizontal meridian. A conjunctival peritomy was then performed to expose the bare sclera on the nasal and temporal sides, and minimal cauterization was performed. The four sclerotomy sites were marked at 3.0 mm posterior to the limbus and located 5.0 mm apart from one other at the superior and inferior points [12]. In the initial seven surgeries, a 25-gauge trocar was inserted at a 30–40-degree angle, as described previously, to self-seal the scleral leak [15]. After discussion, the sclerotomies were instead made perpendicularly (90 degree) at these four sites to minimize the track length passing the uveal tissue and to prevent pigment dispersion. Another trocar was inserted inferotemporally as an infusion cannula, and a total vitrectomy was performed.

Next, CV-8 Gore-Tex sutures were passed through the four eyelets of an Akreos AO60 IOL (Bausch & Lomb, Rochester, NY). Either a superior corneal wound or a scleral tunnel wound were made according to the surgeon's preference. Each end of the Gore-Tex suture was passed into the anterior chamber through these wounds and externalized through one of the four sclerotomy sites. The IOL was then folded in half and inserted into the anterior chamber. The sutures were tightened, and the IOL was centered.

During the procedure, it was noted that special attention was required when making a surgeon's knot so as not to create a slippery knot (Figure 1). Since the Gore-Tex material was silky, the knot was slippery, which made it easy to suture too tightly. If this tension was too high, the eyelet of the IOL could be stretched, and a postoperative astigmatism could be induced. The knots were made in either a 3-1-1 or 2-1-1-1 fashion, trimmed, and rotated into the sclerotomy. Special attention was also paid to placing the

knot between the eyelets of the IOL underneath the sclera (see Video, Supplemental Information 1, which shows the whole procedure of Gore-Tex suture).

Postoperative assessments included Snellen VA, slit-lamp biomicroscopy, tonometry, fundus examination, and, if necessary, optical coherence tomography for macular pathologies, such as cystoid macular edema. A manifest refraction was obtained around 3 months postoperatively by qualified technicians who had passed standardized in-office accuracy training.

Our analysis of the surgical results involved several components, including refraction, visual acuity, and complication rates. Eyes with improper keratometric measurements due to corneal opacities from trauma or unknown IOL diopters due to existing IOL, were excluded from refractive evaluations. However, these eyes were included in our analyses of visual acuity and complications.

For refractive error measurements, the formula used for each IOL calculation was based on axial length. For axial lengths of less than 22 mm, the Hoffer Q formula was used, while the Holladay I formula was used for axial lengths between 22 and 26 mm, and the SRK/T formula was used for axial lengths of more than 26 mm [16]. In the Gore-Tex group, each formula was also analyzed separately to evaluate for differences.

A double-angle plot was used to evaluate for astigmatism changes [17]. In this plot, similar patterns of astigmatism were grouped together, with with-the-rule (WTR) eyes grouped together on the left side of the figure and against-the-rule (ATR) eyes grouped together on the right side (Figure 2) [18]. The astigmatism was calculated using an open online tool. (Hill W. Astigmatism double angle plot tool V132. Available at: <https://ascrs.org/tools/astigmatism-double-angle-plot-tool>. Accessed January 2, 2021)

Briefly, the double-angle plot used the following formulas:

$$x = Cylinder * Cos(2 * axis)$$

$$y = Cylinder * Sin(2 * axis)$$

Descriptive statistics are summarized as mean $\pm$ standard deviation. Student's *t*-tests were used to compare the results of the two groups, and chi-squared tests were used to compare the complication rates. Mean absolute errors (MAEs) were compared using a repeated-measures analysis of variance.

Results

A total of 81 eyes from 81 patients were enrolled from the four hospitals. In 44 eyes, scleral fixation was performed using the conventional method with Prolene. In 37 eyes, the IOL was fixed at 4 points using Gore-Tex. Table 1 summarizes data related to patient age, sex, laterality of the operated eye, and surgical indications.

Table 1
Demographic information and surgical indications for patients who underwent IOL scleral fixation.

Variables	Gore-Tex (N=37)	Prolene (N=44)
Age, years (IQR)	63.9 (54.5–70.5)	62.6 (54.8–69.0)
Gender, n (%)		
Male	30 (81)	33 (75)
Female	7 (19)	11 (25)
Eye operated, n (%)		
Right	20 (54)	25 (57)
Left	17 (46)	19 (43)
Indication, n (%)		
Surgical aphakia	3 (8)	8 (18)
IOL subluxation	25 (68)	29 (66)
Subluxated crystalline lens	4 (11)	6 (14)
Zonular instability (trauma)	5 (14)	1 (2)
Abbreviations: IOL, intraocular lens; IQR, interquartile range		

In the 4-point Gore-Tex group, the logMAR of the BCVA improved from 0.50 (20/63 on the Snellen scale) $\pm$ 0.60 to 0.20 (20/32 on the Snellen scale) $\pm$ 0.34 postoperatively and, in the 2-point Prolene group, from 0.59 (20/80 on the Snellen scale) $\pm$ 0.54 to 0.21 (20/32 on the Snellen scale) $\pm$ 0.28 (Table 2). There were no statistical differences between the two groups in either the preoperative or postoperative BCVAs (p = 0.781 and p = 0.691, respectively).

Table 2
Changes in best-corrected visual acuity in eyes that underwent scleral fixation of IOL.

	Gore-Tex (N=37)	Prolene (N=44)	*P-value
Preoperative LogMAR BCVA	0.50 ± 0.60 (20/63 on the Snellen scale)	0.59 ± 0.54 (20/80 on the Snellen scale)	0.781
Postoperative LogMAR BCVA	0.20 ± 0.34 (20/32 on the Snellen scale)	0.21 ± 0.28 (20/32 on the Snellen scale)	0.691
*P-value	0.000	0.001	
<p>* Calculated using the paired <i>t</i>-test and Wilcoxon's signed-rank test. Statistical significance was defined as <i>P</i> < 0.05.</p> <p>Abbreviations: BCVA, best corrected visual acuity; IOL, intraocular lens; LogMAR, logarithm of the minimum angle of resolution</p>			

Postoperative results related to visual acuity, complications, and refractive results involved different analysis sets (Figure 3).

Analysis of the Target

In the 4-point Gore-Tex group, the IOL was chosen with a slightly myopic target. The predictive refraction was -0.59 ± 0.84 , while the actual postoperative refraction was -0.93 ± 1.71 , which was 0.34 more myopic than the target (Table 3).

Table 3
Refractive results in eyes that underwent scleral fixation of an IOL

	Gore-Tex (N=36)	Prolene (N=40)	* <i>P</i> -value
Mean Spherical Equivalent (D)			
Target	-0.59 ± 0.84	0.20 ± 0.61	
Postoperative	-0.93 ± 1.71	-0.30 ± 1.31	
[†] Prediction error	-0.34 ± 1.53	-0.50 ± 1.28	0.402
* Calculated using the Wilcoxon's signed-rank test. Statistical significance was defined as <i>P</i> < 0.05.			
[†] Prediction error = postoperative spherical equivalent – predicted spherical equivalent (target spherical equivalent)			
Abbreviations: D, diopter; IOL, intraocular lens.			

In the 2-point Prolene group, the IOL was chosen with a slightly hyperopic target. The predictive refraction was 0.20 ± 0.61, while the actual postoperative refraction was -0.30 ± 1.31, which was 0.50 more myopic than the target.

Refractive results were further analyzed in the Gore-Tex group. Different formulas were used based on the axial length. In this analysis, the mean prediction error was -0.132, and the mean absolute error (MAE) was 0.529. The lowest-to-highest order for the MAE was SRK/T (0.482), actual (0.529), Holladay 1 (0.531), and Hoffer Q (0.563). Although there were some differences based on the formula used, 50–58% of cases were within 0.5 D of the target, and 86–92% of cases were within 1 D.

Analysis of Astigmatisms

As shown in Figure 4, some initial cases in the Gore-Tex group showed severe ATR astigmatism. There were no cases of severe astigmatism after the previously described modifications were made to the Gore-Tex surgical procedure.

The preoperative corneal astigmatism was 0.35 @ 83° ± 1.09 D in the Gore-Tex group and 0.19 @ 103° ± 1.35 D in the Prolene group. These axes signified that the astigmatism was within-the-rule (WTR) (see Figure, Supplemental Information 2, which shows the preoperative corneal astigmatism of the two groups). The preoperative corneal astigmatism did not statistically differ between the groups (*p* = 0.898).

In the Prolene group, the mean astigmatism occurred in the direction of against-the-rule (ATR) at about 0.52 D; however, the directions were evenly distributed. The absolute value of the astigmatism was 1.47 ± 0.65. In the Gore-Tex group, the mean astigmatism occurred in the direction of ATR at about 1 D, and the absolute value of the astigmatism was 1.39 ± 0.94 D. In the Gore-Tex suture group, the postoperative astigmatism was significantly reduced after modifications were made to the surgical procedure, with

more than 3 diopters of ATR astigmatism occurring in these initial seven cases. However, after excluding these cases, less astigmatism was observed in the Gore-Tex group than in the Prolene group.

Analysis of Complications

Complications were found in 18 cases in the Prolene group and 6 cases in the Gore-Tex group (Table 4). The most common complication was an increased IOP after surgery, with all of these cases treated with glaucoma eye drops. In the Prolene group, the second most common complication was conjunctival erosion, a suture-related issue. There were also two cases of IOL dislocation, requiring another surgical correction. Three cases had IOL optic capture.

Table 4
Postoperative complications in eyes that underwent scleral fixation of IOL.

Complication, n (%)	Gore-Tex (N=37)	Prolene (N=44)	*P-value
Retinal detachment	0	0	
IOL dislocation	0	2 (5)	
IOL decentration	0	1 (2)	
Suture breakage or erosion	1 (3)	4 (9)	
Pupillary capture of IOL optic	0	3 (7)	
Cystoid macular edema	0	1 (2)	
Ocular hypertension	3 (9)	5 (11)	
Vitreous hemorrhage	1 (3)	1 (2)	
Hypotony	1 (3)	1 (2)	
Endophthalmitis	0	0	
Total	6 (17)	18 (41)	0.023
* Calculated using the chi-squared test.			
Abbreviation: IOL, intraocular lens			

In the Gore-Tex group, the complication rate was significantly lower ($p = 0.023$). There was one patient with vitreous hemorrhage and one patient with hypotony, but all disappeared spontaneously during follow-up. Erosion occurred in one patient in whom the Gore-Tex was inserted inside the sclera and pierced slightly outside the conjunctiva. Although some early cases had pigment on the IOL, there were no effects on vision.

Discussion

A comparison of the clinical outcomes between a 4-point scleral fixation of an intraocular lens using Gore-Tex suture and a 2-point scleral fixation using Prolene suture showed a much lower complication rate with the latter, with equivalent visual acuity.

Gore-Tex is a non-absorbable suture with great durability and tensile strength, allowing it to gain ground as the replacement for Prolene suture [11, 19, 20]. Furthermore, although Gore-Tex is an off-label use for ophthalmic surgery, it has been used in heart surgeries for decades [21]. Vote et al. reported that suture breakage was observed in 27.9% of cases with a mean follow-up of 6 years with 10-0 Prolene suture [6]. Wasiluk et al. reported a 13.8% rate of suture breakage in 29 eyes with a mean follow-up of 63.9 months with 9-0 Prolene suture, suggesting that the incidence of postoperative suture breakage is similar between 9-0 and 10-0 Prolene sutures [22]. Although there is a lack of long-term follow-up results for use of Gore-Tex sutures, short-term and 1-year follow-up results have shown no suture breakage [10, 12, 13, 23]. Indeed, our study showed no suture breakage in the 37 eyes with IOL fixation using Gore-Tex, whereas four cases (9%) in the 44 eyes that underwent IOL fixation using Prolene had suture breakage, with mean follow-up durations of 17 months and 16 months, respectively.

Postoperative visual acuity was good in both groups, and there was no difference in the corrected visual acuity between the two groups. For astigmatism, ATR astigmatism tended to develop more commonly in the Gore-Tex group, which was resolved after modifications were made to the surgical method. Neither direction was more common in the Prolene suture group, with both ATR and WTR occurring.

Our most encouraging finding was that the incidence of complications was greatly reduced in the Gore-Tex group, with complications like optic capture not observed even after mydriasis. Though long-term results after more than 5 years of follow-up have not yet been collected, there have been no reports of scleral breakage during scleral fixations using Gore-Tex, so it is expected that the rate of reoperation for IOL dislocations resulting from suture breakage will be low in this group.

Our study indicated a few important considerations to keep in mind when making knots. The postoperative astigmatism was severe in the initial cases using Gore-Tex suture. The astigmatism was formed in the ATR direction, which can be caused when the IOL pulls the sclera in the 3 and 9 o'clock directions due to the thread being pulled too tightly. Therefore, it is necessary to tie square knots a little loosely.

In addition, since the IOL is inserted by being folded in half rather than using an injector, small, 2.2 to 3.0-mm incisions are too narrow for IOL insertion and need to be opened to as large as 4.0 to 4.5 mm. As a result, astigmatism can be caused by this wide incision. In our study, a scleral tunnel incision was more effective at reducing astigmatism than a clear corneal incision. After the first seven cases, the degree of astigmatism in the Gore-Tex group was smaller than in the Prolene group.

In Prolene suture cases, it is generally known that conjunctival exposure occurs if sclera flaps are not made. In the case of a Gore-Tex 4-point fixations, it has been reported that there is little risk of thread exposure if the knot is pushed into the sclera. In this study, there was conjunctival exposure in one only Gore-Tex patient in whom the knot did not sufficiently enter the sclera. This knot got stuck in the sclera as it entered, and it ultimately came out again. To solve this problem, it is necessary to firmly push the knot into the sclera and pull the thread from the opposite entry point, so that it is positioned between the two haptics of the IOL inside the sclera.

Although there were no significant effects on vision, the initial Gore-Tex cases showed pigmentary cells on the surface of the IOL after surgery. In this procedure, the Gore-Tex thread passes through the sclera and pars plana. Retinal surgeons usually insert the trocar using a two-direction entry, which creates a long tract between the uveal tissue and sclera [24]. The Gore-Tex is then passed through this long tract and pulled when the IOL is sutured, making it easy for the uvea to wrinkle, which can cause many pigment cells to disperse (Figure 5). Therefore, instead of a two-direction-entry, we pierced the sclera at a right angle to prevent this gap. After this modification, pigmentary cells were reduced. There were also no complications like hypotony after piercing at this right angle because the Gore-Tex thread effectively blocked the incision site.

Scleral fixation with 2-point Prolene suture was performed with a slightly hyperopic target, with the knowledge that the refractive results would be slightly myopic. However, in the case of Gore-Tex 4-point fixations, it was known that the refractive result could be either myopic or hyperopic, so the surgery was planned to be a little myopic. As a result, more myopic results were obtained.

Using a 4-point fixation with Gore-Tex suture can create a more stable IOL fixation because the IOL can be held in four places, and mydriasis is freely possible because no optic capture occurs. Even in patients who have both a retinal detachment and a dislocated IOL, gas tamponade and multiple dilated retinal examinations are possible without any concerns of optic capture or posterior synechia.

This study had several important limitations, including its retrospective study design and its lack of long-term follow-up data. In future studies, we will report on the rate of suture breakage after 5 years of follow-up. In addition, our sample size was relatively small, and the rate of more rare complications could not be assessed. Also, there were variations in the surgical technique after the first seven cases, which is important to consider during analysis of our results.

In conclusion, the visual prognosis with the Gore-Tex scleral fixation method did not significantly differ from the more traditional Prolene scleral fixation method. Although the visual outcome was good with the traditional method, there were issues with optic capture and suture breakage. There was also no significant difference in astigmatisms between the two groups, with better results after our modifications to the Gore-Tex surgical method. This study provides guidance for surgeons choosing to fixate an IOL using Gore-Tex suture.

Declarations

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Financial Disclosures

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Figures

Figure 1

(A) Surgeon's knot; (B) Slippery knot

Gore-Tex suture has a smooth surface that can easily lead to a slippery knot. A slippery knot can be made too tightly, leading to a severe against-the-rule astigmatism.

Double-angle plot

Figure 2

Double-angle plot

In a double-angle plot, with-the-rule (WTR) eyes are grouped together on the left side of the figure, while against-the-rule (ATR) eyes are grouped together on the right side. For example, an eye (A) with a

refractive error of -0.25 Dsph -1.25 Dcyl A170 ° is plotted on the left side (WTR). Another eye (B) with a refractive error of -0.50 Dsph -1.75 Dcyl A92 ° is plotted on the right side (ATR).

Figure 3

Flowchart of patient selection for analyses of visual acuity, complications, and refractive results. IOL, intraocular lens.

Figure 4

Postoperative refractive astigmatisms. (A) Four-point fixation with Gore-Tex. Red circles represent early cases. (B) Two-point fixation with Prolene.

Figure 5

Illustration of trocar insertion using a two-direction entry. The trocar is inserted at an acute angle and then pulled to a right angle, which can induce uvea wrinkling. If the Gore-Tex suture is passed through this trocar, it creates a long track, which can cause many pigment cells to disperse.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [GoreTex2.mp4](#)
- [SupplementalInformation2.pdf](#)