A comparison of sutureless flanged fixation and 4-point Gore-Tex fixation for scleral-fixated intraocular lenses: a pilot study

Usha K Raina, MD, FRCOphth, Brajesh Kumar, MBBS, MS, Shruti Bhattacharya, MBBS, MS, Varun Saini, MBBS, MS, Shantanu Kumar Gupta, MBBS, MS, and Jawaharlal Goyal, MD

Author affiliations: Department of Ophthalmology, Guru Nanak Eye Centre, Maulana Azad Medical College, New Delhi, India

Published September 24, 2022.

Copyright ©2022. All rights reserved. Reproduction in whole or in part in any form or medium without expressed written permission of the Digital Journal of Ophthalmology is prohibited.

doi: 10.5693/djo.01.2022.08.001

Correspondence: Dr. Shruti Bhattacharya, B21, Ashoka Apartments, Sector 12, Dwarka, Delhi – 110075, India (email: shrutibhattacharya1993@gmail.com).
Abstract

Purpose
Scleral-fixation of intraocular lenses (IOLs) provides an option for eyes that lack sufficient capsular support for in-the-bag IOL placement. The latest techniques for lens fixation include use of a novel suture material, Gore-Tex, and a sutureless method, with flanged intrascleral fixation. The purpose of this pilot study was to compare these methods in terms of anatomic and clinical outcomes.

Methods
A total of 35 eyes of patients 18-60 years of age who presented with aphakia, subluxated lens, or ectopia lentis were randomized into two groups. Group A (15 eyes) underwent flanged intrascleral IOL fixation using the Yamane technique; group B (20 eyes) underwent 4-point transscleral fixation of IOL using Gore-Tex suture. The following parameters were compared between groups on day 1, week 3, and month 6 postoperatively: logMAR uncorrected and best-corrected visual acuity, retinoscopy, IOL centration on slit-lamp biomicroscopy, and IOL tilt on ultrasound biomicroscopy.

Results
Postoperative visual acuity was better in group B: uncorrected, logMAR 0.89 ± 0.22 versus 0.72 ± 0.24 (P = 0.046); best-corrected, logMAR 0.51 ± 0.18 versus 0.37 ± 0.26 (P = 0.016). No significant difference was found in postoperative retinoscopy and astigmatism between groups. IOL tilt (>100 µm) occurred in 8 cases in group A and in 9 cases in group B; 87% in group A and 100% in group B were well centered. Complications in both groups were minimal.

Conclusions
In our small study cohort, both sutureless flanged IOL fixation and Gore-Tex sutured scleral IOL
fixation resulted in excellent visual rehabilitation of patients with aphakia and subluxated lenses. Patients who underwent Gore-Tex suture fixation experienced better postoperative visual acuity, IOL centration, and stability.
Insufficient capsular support for placing an in-the-bag intraocular lens (IOL) can be addressed in different ways. Surgical options include angle-supported anterior chamber intraocular lenses (ACIOLs), iris-fixated anterior or posterior chamber intraocular lenses (PCIOls), and scleral-fixated intraocular lenses (SFIOLs).\textsuperscript{1} Although the literature supports all three options, large multicentric comparative studies are lacking. Some studies suggest that SFIOLs have a better safety profile.\textsuperscript{2}

SFIOLs are broadly of two types: suture-fixated and sutureless intrascleral haptic-fixated IOL. Conventionally, SFIOLs have been sutured to the sclera using double-armed 10-0 or 9-0 polypropylene sutures; however, this technique is associated with long-term risk of suture breakage.\textsuperscript{3} Gore-Tex suture is a nonabsorbable, polytetrafluoroethylene monofilament suture with greater tensile strength that is commonly used for heart valve and vascular procedures, underscoring the resiliency of the suture material.\textsuperscript{4} Gore-Tex possesses the advantages high tensile strength, high visibility due to its white color, minimal inflammatory response, and minimal memory, with no reports of suture degradation, which makes it ideal for use in scleral fixation.\textsuperscript{5}

Recently, sutureless fixation of SFIOLs had been achieved through the use of scleral flaps, limbus-parallel scleral tunnels, or flanged IOL fixation, which has been described by Yamane et al.\textsuperscript{6} However, concerns have been raised about the centration of the scleral-fixated IOLs and their long-term stability. There is paucity of data concerning the postoperative outcomes of sutured versus sutureless scleral-fixated IOLs. To our knowledge, no previous study has compared the outcomes of 4-point scleral fixated IOLs using Gore-Tex suture with sutureless flanged IOL fixation with a 30-gauge double needle technique.

Subjects and Methods
A randomized, prospective, interventional study was conducted over the course of 1 year at Guru Nanak Eye Centre, New Delhi, after receiving approval from the Maulana Azad Medical College Ethical Committee. Informed written consent was obtained from all patients. The minimum required sample size at 5% level of significance and 80% power was calculated to be 219 eyes; for the purpose of this preliminary investigation, we used a convenience sample size of 30 in each group. A total of 35 eyes of patients 18-60 years of age who presented with aphakia, subluxated lens, or ectopia lentis in which intracapsular IOL fixation was impossible were enrolled in the study. Patients with scleral thinning, scleritis, uveitis, secondary glaucoma, any corneal pathology, or any preexisting retinal disorder were excluded. Acceptable patients were randomized into two groups: group A (15 eyes) underwent sutureless flanged intrascleral IOL fixation by double-needle technique as described by Yamane et al, and group B (20 eyes) underwent 4-point transscleral fixation of IOL using Gore-Tex suture. All surgeries were performed by the same surgeon (UKR).

Preoperative workup included uncorrected and best-corrected visual acuity (logMAR), preoperative retinoscopy, automated keratometry, endothelial cell count using specular microscopy, axial length by A-scan, intraocular pressure (IOP) with applanation tonometry, baseline macular optical coherence tomography (OCT), and dilated fundus examination. IOL power was calculated using the SRK-II formula. Phacoemulsification, phacoaspiration, or lensectomy was performed depending on the nature of the crystalline lens, followed by 25-gauge central pars plana vitrectomy and scleral fixation of the IOL. Eyes that were aphakic directly proceeded to scleral fixation of the IOL.

**Surgical Techniques**

Sutureless flanged IOL placement (Yamane technique) proceeded as follows. With a pars plana
infusion in situ, markings were made using a toric IOL marker 2 mm from the limbus for sclerotomies as shown in Figure 1A. A three-piece Sensar AR40e IOL (Abbott Medical Optics, Santa Ana, CA) was inserted into the anterior chamber using an injector, and the trailing haptic was kept outside. An angled sclerotomy was made through the conjunctiva using a 30-gauge thin-wall needle (TSK ultra-thin wall needle; Tochigi Seiko, Tochigi, Japan) and the leading haptic was threaded into the lumen of the needle using 25-gauge microforceps (Figure 1B). A second sclerotomy was then made 180° from the first using a 30-gauge thin-wall needle, and the trailing haptic was inserted into the lumen of the second needle. Both haptics were externalized onto the conjunctiva using the double-needle technique as described by Yamane et al\(^6\) (Figure 1C). The ends of the haptics were cauterized using preheated handheld thermal cautery to make a flange with an approximate diameter of 0.3 mm. The flange of the haptics was pushed back and fixed into the scleral tunnels (Figure 1D).

**Figure 1.** Surgical steps for flanged intraocular lens (IOL) fixation after insertion of a 25-gauge pars plana infusion and creation of entry wounds A, 2 mm marks for 30-gauge needle
insertion B, Tucking of leading haptic. C, Externalization of the haptics using 30-gauge needles D. Both haptics externalized.

In the Gore-Tex suturing technique, following conjunctival peritomy and light cautery, superficial 5 mm vertical scleral grooves were made 3 mm from the limbus nasally and temporally, and a pars plana infusion was started. Four 25-gauge sclerotomies were made at the ends of the grooves (Figure 2A). Next, the CV-8 Gore-Tex suture was cut into halves, which were each threaded through the two adjacent eyelets of the Akreos AO60 lens (Bausch & Lomb, Bridgewater, NJ) at equal lengths (Figure 2B) and exteriorized through the corresponding sclerotomies. The IOL was placed in the sulcus (Figure 2C), and the sutures were tied using a 3-1-1 knot technique. The knots were trimmed and rotated into the eye using 25-gauge forceps. The corneal wound was closed using a 10-0 nylon suture and the peritomy was closed with 8-0 polyglactin 910 sutures.
Figure 2. Intraoperative photographs of 4-point IOL fixation using Gore-Tex suture. A, Marking and inserting a 25-gauge anterior chamber maintainer and pars plana infusion. A 5 mm long superficial scleral groove (black arrow) is created using a no. 15 blade, and 25-gauge sclerotomies are made at the ends of the groove (blue arrow). B, Threading of Gore-Tex suture into the eyelets of AkreosA060 IOL. C, All 4 ends of sutures externalized and IOL centered.

Postoperative treatment included systemic antibiotics and analgesics for 5 days and topical steroid and antibiotic drops for 1 month. Uncorrected and best-corrected visual acuity, keratometry, IOL centration on slit lamp examination, and IOL tilt on ultrasound biomicroscopy (UBM) were assessed at 1 day, 3 weeks, and 6 months postoperatively. OCT of the macula was performed to look for postoperative macular edema.

Quantitative variables were expressed as mean ± standard deviation and compared between the groups using the Wilcoxon test or paired t test, as applicable. A P value of <0.05 was considered statistically significant.
Results

The mean age of the patients in group A was 46.67 ± 16.97; of those in group B, 27.15 ± 13.29 ($P = 0.006$). Primary IOL implantation was performed in 51% of eyes; the remaining 49% underwent secondary IOL implantation. The primary IOL implantation was carried out most commonly for ectopia lentis (83%), followed by post traumatic subluxations (17%). The most common indication for secondary IOL was posterior capsular rupture. Baseline patient characteristics and demographics are provided in Table 1.

Postoperative logMAR uncorrected and best-corrected visual acuity, IOP, IOL centration, and IOL tilt in both groups are provided in Table 2. There was no significant difference in uncorrected visual acuity between groups at day 1 postoperatively, but at 6 months group B patients had significantly better visual acuity (0.89 ± 0.22 vs 0.72 ± 0.24). Similarly, the best-corrected visual acuity was better in group B at 3 weeks (0.51 ± 0.18 vs 0.37 ± 0.26) and 6 months (0.49 ± 0.16 vs 0.30 ± 0.22). No significant difference in postoperative retinoscopy and astigmatism between groups was found. Mean IOP at day 1 in group B was slightly higher than in group A, but it was within normal limits in both the groups. There was no significant
difference in the mean horizontal and vertical tilt of IOL between groups as measured by UBM (Figure 3). Significant IOL tilt (>100 µm), as described by Loya et al,⁷ occurred in 8 cases in group A and 9 cases in group B, but the difference between groups was not statistically significant. On slit-lamp examination, none of the patients had a clinically evident IOL decentration in the mesopic pupil. After full pupillary dilatation, 2 eyes in group A and none in group B were found to have mild decentration.

Table 2. Clinical outcomes in groups A and B

<table>
<thead>
<tr>
<th>Study parameter</th>
<th>Group A</th>
<th>Group B</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA, logMAR, mean ± SD</td>
<td>0.51 ± 0.18</td>
<td>0.37 ± 0.26</td>
<td>0.016</td>
</tr>
<tr>
<td>3 weeks' postop</td>
<td>0.49 ± 0.16</td>
<td>0.30 ± 0.22</td>
<td>0.03</td>
</tr>
<tr>
<td>6 months' post op</td>
<td>0.87 ± 0.23</td>
<td>0.80 ± 0.36</td>
<td>0.216</td>
</tr>
<tr>
<td>UCVA, logMAR, mean ± SD</td>
<td>0.89 ± 0.22</td>
<td>0.72 ± 0.24</td>
<td>0.046</td>
</tr>
<tr>
<td>Tilt, on UBM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>46.7%</td>
<td>55%</td>
<td></td>
</tr>
<tr>
<td>&gt;100 µm H</td>
<td>13.3%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>&gt;100 µm V</td>
<td>0%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>&gt;100 µm H+V</td>
<td>40%</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Centration, on slit-lamp</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Well-centered</td>
<td>86.7%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Slight decentration</td>
<td>6.7%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Marked decentration</td>
<td>6.7%</td>
<td>0%</td>
<td>0.243</td>
</tr>
<tr>
<td>Complications, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>85%</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>Corneal edema</td>
<td>0%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Vitreous hemorrhage</td>
<td>10%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>0%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Haptic dislodgement</td>
<td>5%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

BCVA, best-corrected visual acuity; H, horizontal; LogMAR, logarithm of the minimum angle of resolution; SD, standard deviation; UBM, ultrasound biomicroscopy; UCVA, uncorrected visual acuity; V, vertical.

*P value of <0.05 was considered significant; a value of <0.01, highly significant.
Figure 3. Ultrasound biomicroscopy for measurement of distance of IOL from the iris in the (A) vertical and (B) horizontal meridian.

In our study, 2 patients in each groups had vitreous hemorrhage, which resolved with conservative management within 4 weeks. One patient in group B had retinal detachment 1 month after surgery, which was treated by vitreoretinal surgery, with a final best-corrected visual acuity of 0.2 logMAR. One patient in group B had transient corneal edema, which resolved within 1 week with conservative management, that is, eyedrop and eye ointment sodium chloride given three times a day along with lubricants. In group A, 1 patient suffered from temporal haptic dislodgement, for which IOL explant followed by SFIOL with 4-point Gore-Tex suture fixation was performed, resulting in gain of good visual acuity of 0.0 logMAR. There was no incidence of cystoid macular edema, postoperative hypotony, elevated IOP, pseudophacodonesis, iris capture of the IOL, endophthalmitis, conjunctival granuloma, suture breakage or any suture-related complication, and no incidence of scleral inflammation or scleromalacia during the follow-up period.

Discussion

SFIOLs for eyes with inadequate capsular support is surgically demanding and involves intraoperative manipulation of vitreous base, with potential risk for retinal detachment and vitreous hemorrhage. SFIOL fixation can be sutured or sutureless. The techniques for sutured SFIOLs can broadly be classified into ab externo and ab interno techniques and endoscopy-assisted sutured IOLs. The points of fixation on the haptic can vary from 2-point to 4-point fixation. The 2-point fixation method is more commonly used but has increased incidence of IOL tilt and decentration, which can induce higher-order spherical aberrations. The 4-point fixation method theoretically has decreased risk of lens tilt and decentration.
Studies have shown that the IOL stability depends on the longevity of the suture material. Conventional sutures, such as 10-0, 9-0, and 8-0 polypropylene sutures are prone to erosion and breakage and thus IOL dislocation in the long term, making them unsuitable for use in very young patients. Gore-Tex suture has a higher tensile strength and resilience. Other advantages include its white coloring and greater thickness, providing better intraoperative visualization. Moreover, Gore-Tex material prone to less inflammation because of its inert nature, and its minimal memory makes it easier to manipulate.

Sutureless scleral fixation of PCIOL was first described by Maggi and Maggi in 1997. Sutureless implantation retains the advantages of the SFIOLs while avoiding suture-related complications. Several modifications of sutureless techniques have been introduced since then. These can be broadly categorized into two groups, based on use of a scleral tunnel with or without flaps. In 2007, Gabor and Pavlidis described a technique for embedding the haptics in a scleral tunnel. Since young patients have a higher lifetime risk of corneal decompensation and suture related complications, sutureless scleral tunnel (SST) IOLs appear to be an attractive alternative option. Recently, Yamane et al described a transconjunctival 30-gauge needle–assisted sutureless scleral fixation of IOL, adopted in the current study.

Ganekal et al compared visual outcomes in sutured SFIOLs with glued SST IOLs and found that results were comparable in both groups. However, complications, such as postoperative inflammation and glaucoma were nearly doubled in the sutured SFIOL group. Similarly, a study by Haszcz et al comparing scleral fixation using Hoffman pockets and sutureless intrascleral haptic fixation technique found no differences in visual outcomes. Sinha et al compared the clinical outcomes of transscleral suture fixated IOLs with sutureless intrascleral haptic fixated IOL, with 20 eyes in each group, and concluded that the latter provided
more stable fixation, better visual outcome, and fewer complications compared with the sutured scleral fixated IOL. They found that postoperative visual acuity was significantly better in the sutureless intrascleral haptic fixated group and that refractive astigmatism, corneal astigmatism, IOL tilt, pseudophacodonesis, and macular thickness were all greater in the sutured IOL group. This may be because they adopted the 2-point fixation technique in their sutured SFIOL group.

Sindal et al\textsuperscript{21} compared the intermediate-term anatomic and visual results of SFIOL implantation using 4-point suture fixation versus transscleral sutureless fixation. The baseline characteristics and final visual outcomes in the sutured scleral-fixated IOL group and sutureless scleral-fixated IOL group were comparable, and both techniques appeared to be equally good in eyes with surgical or post-traumatic aphakia.

In our study, the mean age of the patients in group A was 46.67 ± 16.97; of those in group B, 27.15 ± 13.29. This difference may be attributed to the face that it was a prospective study, and patients were enrolled and randomized into either group, over the course of the study. The postoperative visual acuity was better in the Gore-Tex group than in the flanged IOL group. Retinoscopy, astigmatism, and IOP did not differ significantly between groups. The rates of decentration and tilt of IOL were higher in group A, possibly because of distortion of the haptics of the IOL, but this did not translate into any significant difference in the postoperative astigmatism between groups. Recently, CT Lucia 602, with its silicone acrylate optic and polyvinylidene C loop haptic, has emerged as a popular option for the Yamane technique because of the haptic strength, strong scleral attachment, and resistance to breakage,\textsuperscript{22} unfortunately, this was unavailable in India at the time of our study. Sutured SFIOL resulted in a more stable and centered IOL fixation, which may be attributed to the 4-point fixation of the IOL. The rate of complications was low in both the groups proving both techniques to be
relatively safe. The flapless nature of the surgeries and the use of 25- and 30-gauge sclerotomies enhanced the safety profile of the procedures and made them less invasive. There was no incidence of scleral inflammation or scleromalacia, and this may be attributed to the fact that no scleral flap was raised and that sutureless 25- and 30-gauge sclerotomies were performed. The strengths of our study included its prospective nature, the performance of all the surgeries by a single experienced surgeon, and strict postoperative follow-up. Limitations include the relatively small sample size.

To our knowledge, few studies have compared sutured versus sutureless fixation of SFIOLs, and no prior study has compared the outcomes of Yamane’s flanged IOL fixation technique with 4-point fixation using Gore-Tex suture. Despite the small sample size, our study highlights the advantages of the latter technique in terms of visual acuity, IOL tilt, IOL centration, and IOL stability. Moreover, we believe that the sutured technique is easier to master than the Yamane technique, which has a steep learning curve.

In conclusion, both the sutureless technique and the 4-point fixation using Gore-Tex suture offer excellent visual rehabilitation with minimal complication rates. In our study cohort, the Gore-Tex sutured group had better postoperative visual acuity, IOL centration, and stability. Studies with larger sample sizes and longer follow-up periods are needed draw more definitive conclusions.

**Literatures Search**

PubMed was searched in May 2022 for English-language results for the period 2019-2022, using the following terms: *SFIOL, Yamane, Gore-Tex, sutureless scleral tunnel, scleral-fixed IOL, and 4-point fixation.*
References


9. Schechter RJ. Suture-wick endophthalmitis with sutured posterior chamber intraocular


