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ORIGINAL ARTICLE

Novel modified sutureless, glueless and flapless scleral fixated intraocular lens

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Abstract

Purpose: The purpose of the study was to assess the outcome, complications, and its predictors in novel modified sutureless-glueless-flapless scleral fixated intraocular lens (IOL).

Methods: Prospective study of 86 eyes of 74 patients who underwent sutureless, glueless, and flapless scleral fixated IOL from June 2016 to March 2019. All patients underwent standard scleral fixated IOL without sutures or glue. Pre-operative best-corrected visual acuity(BCVA) and intraocular pressure was assessed. Horizontal corneal white to white (hWTW) diameter and axial length (AL) were assessed. All patients were followed up on day 1, 1 month, 3 months, and 6 months. All patients had a minimum follow-up of 6 months. Post-operative BCVA, intraocular pressure, IOL centration, and IOL-related complications were noted including tilt, decentration, dislocation, haptic extrusion, and optic capture.

Results: Mean age was 66 ± 13.4 years. Eighty-six eyes of 74 patients with aphakia, subluxated IOL, and subluxated crystalline lens were included in the study. The mean pre-operative BCVA was 1.21 ± 2.8 (Log MAR). The mean post-operative BCVA at 6 months was 0.34 ± 0.21 (Log MAR). Significant improvement in mean BCVA was noted at 6 months after the procedure(P=0.011). From the final analysis, 10 eyes were excluded for insufficient follow-up, missing data, or concomitant surgery. There were six eyes excluded for technique modification and two eyes for isolated haptic erosion from the scleral tunnel without lens malposition. From our final analysis of 68 eyes, 8 eyes (12%) developed complications of the IOL. Of these, 3 (38%) eyes underwent surgical intervention. Patients with large hWTW experienced significantly higher rate of complications (P = 0.04). Longer AL was not predictive of higher complication rate (P = 0.08).

Conclusions: Suture or glue is not an absolute must for scleral fixation of an IOL. Sutureless, glueless, and flapless scleral fixation of IOL is a safe surgical option in eyes without capsular support with fewer complications, stable IOL, reduced surgical time, shorter learning curve, good refractive outcome, and without any suture or glue-related complications.

Introduction

In the absence of adequate capsular support/aphakia for posterior capsular or ciliary sulcus intraocular lens (IOL) implantation, there are several options for fixating the lens, including IOL placement in the anterior chamber, or in the ciliary sulcus with fixation to the iris or sclera.[1] Each surgical technique has its advantages and may be associated with technique-related complications.[2-4] Agarwal's glue-assisted posterior chamber IOL implantation technique was first described in December 2007[5] and was a modification of Gabor and Pavlidis original

sutureless fixation technique.[6] While the technique has proven to have excellent results, short-term and long-term complications may occur.[7,8] Hence, we describe a novel modified technique of sutureless, glueless, and flapless scleral fixated IOL, which avoids the complications associate with sutured scleral IOL and glued IOL. We have observed a pattern in which mechanical complications following glued scleral fixated IOLs seem to occur more frequently in eyes with larger horizontal white-to-white (hWTW) and increased axial length (AL) measurements, presumably due to a longer ciliary sulcus distance.[9] We decided to study the role of these anatomical predictors in our modified sutureless, glueless, and flapless scleral fixated IOL.

Methods

Prospective study of 86 eyes of 74 patients from June 2016 to March 2019. All patients underwent sutureless, glueless, and flapless scleral fixated IOL. Study protocol was approved by the Institutional Review Committee, and the study was performed in accordance with the tenets of the Declaration of Helsinki. Informed consent was obtained from all the patients. All patients had a minimum follow-up of 6 months. Pre-operative variables collected included demographics, date of surgery, surgeon, laterality, time from original IOL surgery to any secondary surgery, original IOL model and power, and pre-existing ocular comorbidities. Best-corrected final visual acuity (BCVA) with a Log MAR chart as well as improvement or worsening from pre-operative vision was recorded. The AL, hWTW, and corneal astigmatism were recorded from the IOLMaster™ version 700 (Carl Zeiss Meditec, Oberkochen, Germany). Operative variables recorded included IOL implant model (Sensar AR40e IOL; three piece hydrophobic monofocal), IOL power, surgeon, pre-operative diagnosis, and intraoperative and post-operative surgical complications including IOL-related and other vision-threatening complications requiring additional medical or surgical intervention. All eyes that experienced complications of the implanted IOL were noted. Optic tilt of the IOL was identified by slit-lamp examination, ultrasound biomicroscopy, or anterior segment OCT IOL. Subluxation (defined as a partial displacement of the IOL) and/or IOL dislocation (defined as an IOL which was completely dislocated into the vitreous cavity away from the visual axis) were also recorded .All patients underwent sutureless-glueless-flapless scleral fixated IOL.

Surgical technique [Figure 1a-1k]

Pre-operative pupil centration marking was done under topical anesthesia. Surgery was done under peribulbar anesthesia. Limited peritomy done in the horizontal meridian on either side of the limbus (1a), 0 and 180° horizontal marking done with 26 gauge needle (1b), after cauterizing the surface bleeders marking was done 2 mm from the limbus (1c), partial-thickness groove made 2 mm from limbus with the help of a scalpel blade and crescent knife (1d), in continuity with groove partial-thickness

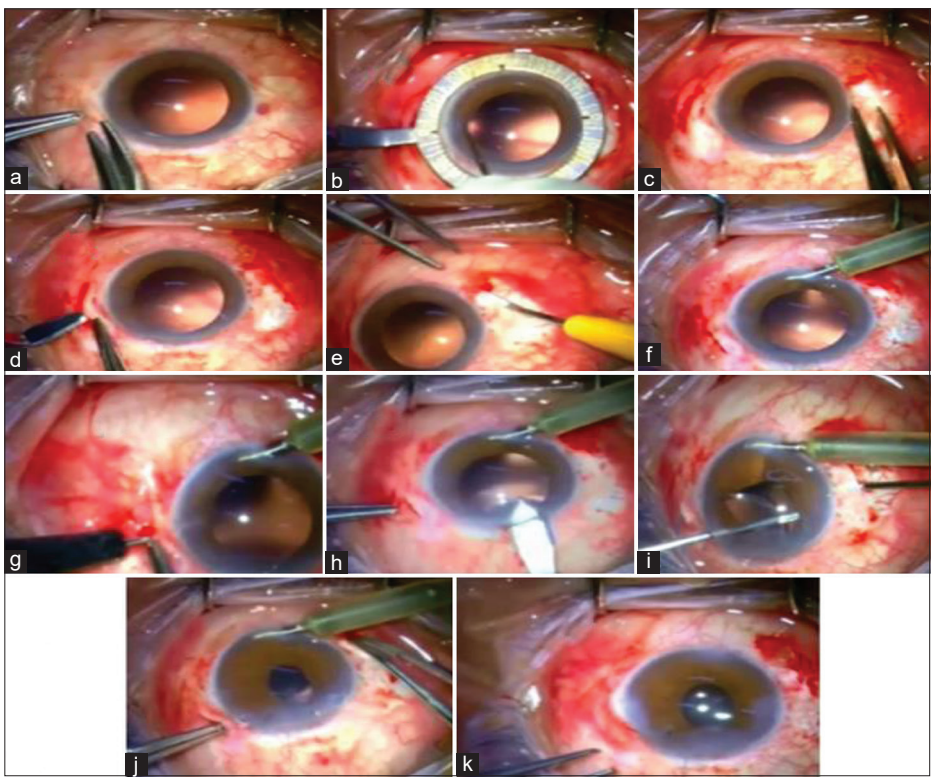

Figure 1: (a-k) Surgical technique – sutureless-glueless-flapless scleral fixated IOL

scleral pockets are done with 1 mm bent keratome for insertion of externalized haptics (1e), anterior chamber maintainer was placed at 6 o'clock limbus (1f), scleral entry was made with 23 gauge trocar in the line of groove along horizontal meridian (1g), clear corneal entry done into anterior chamber (1h), anterior vitrectomy was done, three-piece monofocal hydrophobic IOL was injected into the anterior chamber, externalization of haptics was done with hand shake technique (1i), externalized haptics were tucked into scleral pockets (1j), conjunctiva closed with cauterization, and well-centered IOL noted at the conclusion (1k). We excluded six eyes with technique modifications, such as suture of the haptics to the sclera. Postoperatively, each eye was also examined in the dilated state to assess if tilt or malposition was evident. We defined a large horizontal white-to-white distance as >12 mm, and longer AL as >26 mm, which are consistent with other reports in the literature.[9,10] Statistical analyses were performed using Microsoft Excel to assess for statistical significance using the Fisher's exact *t*-test (two-tailed test with unequal variance) and the Chi-square test. Values <0.05 were determined to be statistically significant.

Results

Mean age was 66 ± 13.4 years. There were 86 eyes of 74 patients who underwent sutureless-glueless-flapless scleral fixated IOL procedures performed between June 2016 and March 2019. There were 58 male and 16 female patients. The pre-operative diagnoses for requiring secondary scleral fixated IOL surgery in our study group are listed in Table 1. The mean pre-operative BCVA was 1.21 ± 2.8 (Log MAR). The mean post-operative BCVA at 6 months was 0.34 ± 0.21 (Log MAR). Significant improvement in mean BCVA was noted at 6 months after the procedure (*P*=0.011). Postoperatively, the mean spherical refraction was −0.040 ± 1.06D (range −1.75 D–+1.25 D), with a mean total astigmatism of −0.42 ± 1.20 D (range −2.00–+2.00 D), a mean corneal astigmatism of −0.14 ± 1.24 D (range −1.75–+2.0 D), and a mean spherical refractive equivalent of −0.32 ± 1.36 D. The mean difference between total and corneal astigmatism in these eyes was −0.06 ± 0.84 D (range −1.50–+2.00 D), which may indicate that the IOL-induced astigmatism was minimal. We excluded six eyes that underwent additional concomitant ocular procedures such as corneal transplantation

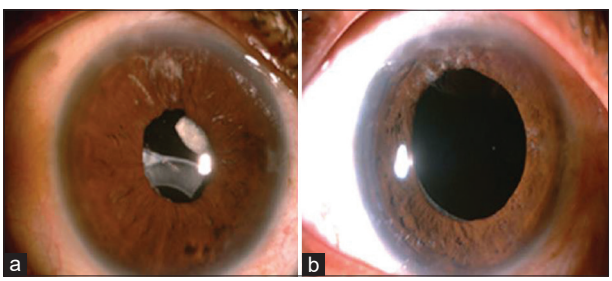

Figure 2: (a,b) Pre-operative subluxated intraocular lens (IOL) capsular bag complex and post-operative well-centered IOL

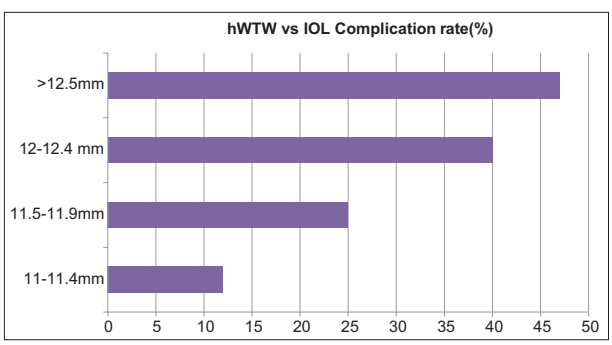

Figure 3: Horizontal corneal white to white versus intraocular lens complications

Table 1: Characteristic, indications, outcome, and complications in study patients

Characteristics	(*n*=68)
Age (years)	66±13.4 years
Male:female	58:16
Pre-operative BCVA (mean Log MAR)	1.21±2.8
Mean AL (mm)	24.2±1.2 mm
Mean hWTW (mm)	11.9±1.3 mm
Mean pre-operative IOP	13.8±2.9mm Hg
Mean post-operative IOP	14.5±3.8 mm Hg
Etiology for secondary scleral fixated IOL (%)	
IOL subluxation – Late endocapsular (trauma/pseudoexfoliation)	11 (16)
IOL subluxation – After previous secondary fixation	4 (6)
ACIOL exchange	7 (10)
Subluxated crystalline lens	8 (12)
Aphakia requiring secondary IOL	38 (54)
Post-operative BCVA (mean Log MAR)	0.34±0.21
Mean post-operative astigmatism	−0.06±0.84 D
Time from first surgery to IOL (years)	4.5±1.2
Complications (number of eyes) (%)	
Self-resolving hyphema	3 (5)
Corneal striae	2 (3)
Raised intraocular pressure	7 (10)
Anterior chamber reaction	2 (3)
IOL tilt	2 (3)
IOL subluxation	1 (1)
Optic capture	1 (1)

BCVA: Best-corrected visual acuity, hWTW: Horizontal corneal white to white, AL: Axial length

or glaucoma surgery. An additional four eyes had <6 months follow-up hence excluded. We also excluded six eyes with technique modifications such as suture fixation of the haptics, as well as two eyes with isolated haptic slippage from the scleral tunnel without subsequent IOL malposition. Of the remaining 68 eyes, 6 eyes (9%) developed complications of the IOL. The most common IOL complications were optic tilt two eyes, subluxation one eye, and optic capture in one eye. Of these eyes with IOL complications, one eye was surgically corrected, and none of the eyes underwent more than 1 corrective procedure. The most common reasons for surgical intervention were subluxation or tilt [Figure 2]. UBM measured mean vertical tilt values were 0.22 ± 0.19 mm and the mean horizontal tilt values were 0.25 ± 0.16 mm. One eye with optic capture was treated in the office with dilation resulting in resolution of the optic capture. More than >50% of complications occurred in the early post-operative period (within 6 weeks after the IOL procedure). Other early complications such as hyphema, corneal striae, and anterior chamber reaction were seen in three eyes, two eyes, and two eyes, respectively, and all the eyes recovered with topical medications. None of the eyes had post-operative posterior segment complications except for vitreous hemorrhage in two eyes which resolve spontaneously over a period of 2 weeks. The mean pre-operative intraocular pressure was 13.8 ± 2.9 mmHg. Seven eyes had raised intraocular pressure and were treated with topical anti-glaucoma medication, average post-operative intraocular pressure was 14.5 ± 3.8 mmHg. Patients with larger hWTW (>12 mm) experienced significantly more complications (44%, $P = 0.05$), and there was an increase in complication rate with increasing hWTW [Figure 3]. There were eight eyes with an AL >26 mm. Of these, the complication rate was 28%. Of the remaining 60 eyes with AL <26 mm, the complication rate was only 22% ($P = 0.08$). A total of 62 eyes (91%) achieved the same or better vision than preoperatively ($P = 0.001$).

Discussion

In the absence of adequate capsular support for IOL implantation, there are numerous options for secondary lens fixation. Scleral fixation provides an additional alternative to anterior chamber, iris fixated, and transscleral sutured IOL techniques and allows the surgeon to place the lens posterior to the iris in the sulcus and avoids the iris-related complications.[1-5,7] In general, the IOL centration appears excellent and it is presumed that the thickness and strength of haptic fixation will be less likely to suffer the mechanical breakdown seen in suture techniques overtime. The short-term results of this technique have been promising. However, the glue-assisted technique is not without lens related and other complications and the length of follow-up compared to scleral sutured patients is far shorter.[[8,11-14]

IOL-related complications are more frequent in eyes with a larger hWTW and a longer AL.[8] It is noted that haptics will be placed under more stretch in these cases and that there are shorter externalized haptics to thread into the scleral tunnel. In larger eyes, haptic slippage may occur because of inadequate length of haptic exteriorized through the sclerostomy and from the tension placed on the haptic with subsequent recoil after tunneling. IOL tilt may occur as it is more difficult to orient the haptics in the correct plane to avoid tilt when there is less haptic available to thread into the tunnel. Optic capture may be due in part to an anterior shift or vaulting of the optic forward when the haptics are put on stretch when tunneled into the scleral pockets. Many 3-piece IOLs have anterior angularization of the haptics from 5 to 10° which will be lost when the haptics are put on stretch.

Studies have shown variability in measuring sulcus diameter depending on imaging modality.[9,15-17] Measuring WTW distance using optical biometry (i.e., IOLMaster™) has been shown to be accurate and reproducible.[18] As some studies have shown a correlation between ciliary sulcus diameter and hWTW,[16] we believe that hWTW may be reflective of the distance the haptics need to travel to be externalized through the sclerostomy.[16] There is debate as to whether or not the hWTW is correlated with axial myopia. Some studies have shown that high axial myopia and WTW are inversely proportional,[18] while others suggest that the longer AL in myopes is associated with an increase in all dimensions of the eye.[19-21] Our study did not show a strong correlation between hWTW and AL, and AL was not significantly predictive of IOL complications. There are several modifications that may be considered in cases of large hWTW. The literature suggests that the horizontal WTW distance is greater than the vertical WTW distance.[22-24] One potential modification is orienting the haptics vertically in patients with large hWTW diameters.[22] In two separate studies, Jacob *et al*. and Narang and Agarwal suggested anteriorizing the sclerostomy sites bringing them closer to the limbus, thereby shortening the distance the haptics need to stretch and providing more haptic length for tunneling.,[25,26] Our practice has been using the Sensar AR40e IOL due to its PMMA haptic material and haptic design. We have not noted a decrease in optic capture, haptic deformation, haptic breakage, and kinking with Sensar AR40e IOL. In conclusion, our technique of scleral fixated IOL had less complications, stable IOL fixation, reduced surgical time, shorter learning curve eyes, good refractive outcome, and without suture or glue-related complications. Large eyes with >12 mm hWTW experienced higher rates of IOL-related complication. In these eyes, we suggest modification in surgical technique similar to glued IOL. Longer AL did not contribute to IOL-related complications. Future comparative randomized trials are needed to determine the long-term outcome and safety of our technique in comparison with other methods of scleral fixated IOL.

Conclusions

Sutureless-glueless-flapless scleral fixation of IOL is a safe surgical option in eyes without capsular support with fewer complication, stable IOL, reduced surgical time, shorter learning curve, good refractive outcome, and without any suture or glue-related complications.

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