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Comparative evaluation of the techniques of sutureless scleral fixation of posterior chamber intraocular lenses (SF-IOLs) with and without fibrin glue

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A B S T R A C T

PURPOSE - Clinical comparison between the techniques of sutureless SF- IOLs with and without fibrin glue in patients with deficient/absent capsular support.

METHODS - 40 patients were randomly divided into 2 groups: GROUP A - GLUED IOL– sutureless SF- IOL using fibrin glue. GROUP B- SUTURELESS IOL- sutureless SF-IOL without fibrin glue. Patients were evaluated in terms of surgical time, intraoperative difficulties, and postoperative complications, i.e. healing of the scleral flap, corneal clarity, anterior chamber reaction, post-op visual recovery, induced astigmatism, pupillary abnormalities, IOP changes and Centration of the IOL. Patients were followed up for a minimum of 6 months. Unpaired T test and 2-factor repeated measures ANOVA were used for statistical analysis.

RESULTS- The mean surgical time was longer in glued IOLs (48.50±0.05 min) than sutureless IOL group (43.75±13.06 min). (p=0.361). Postoperatively, the scleral flaps were well apposed and healthy in both groups. A significant rise in post-operative IOP was seen only in the glued IOL group (p=0.049).

CONCLUSIONS - Sutureless SF-IOLs without glue not only avoid the cost of fibrin glue but are equally efficacious. The glued IOL group was associated with an increased incidence of secondary glaucoma, which may be due to multiple surgeries and pre- existing conditions in some patients.

Keywords: Aphakia, Sutureless scleral fixation of IOLS, scleral flaps, scleral tunnel , fibrin glue.

INTRODUCTION

Cataract surgery in patients with deficient capsular/zonular support has always been very challenging. Previously described techniques include Anterior chamber intraocular lenses (AC-IOL)[1]Iris fixated lenses[2,3], Trans scleral sutured PC-IOLs[4] and other adjuncts like Capsule tension rings[5]
and Iris prosthetic devices[6].
However high rate of complications has been reported with all these techniques. Though sutured scleral fixation is well well-recognised technique, there are still chances of dislocation of the lens due to suture breakage/degradation, exposed suture ends resulting in endophthalmitis[7–9] and an increased incidence of retinal detachments[10]

To avoid these, sutureless scleral fixation was described. It was first described by Maggi and Maggi[11] in 1997 and later modified by Gabor and Pavilidis[12] in 2007. The technique of Glued PC-IOLs was introduced by Agarwal et al[13] in 2008, where fibrin glue was used to appose the scleral and conjunctival flap.
However, no comparison of sutureless scleral fixation of PC-IOLs with and without fibrin glue has been done to date.

MATERIAL AND METHODS

This study was conducted on 40 aphakic patients. The study was done after due clearance from the institutional ethics committee. Written informed consent was taken from all the patients. The inclusion criteria comprised aphakia without posterior capsular support, dislocated / subluxated IOL, dislocated /subluxated lens, zonular dialysis (≥180°) / posterior capsular rent (with insufficient capsular support), during cataract surgery (see Fig. 1). The exclusion criteria for the study were - significant corneal opacity that would interfere with visualisation during surgery, bullous keratopathy, endothelial cell count<1000/mm2, uncontrolled glaucoma, uncontrolled anterior/ posterior segment inflammation, any local/systemic contraindication to surgery like scleritis, episcleritis, rheumatoid arthritis, herpes zoster ophthalmicus and patient not willing for surgery or follow. The patients were divided into 2 groups by computer-generated randomisation- **GROUP A (n=20)** - GLUED IOL–Sutureless scleral fixation of IOL using fibrin glue. **GROUP B (n=20)**- SUTURELESS IOL- Sutureless scleral fixation of IOL without fibrin glue. Patients were followed up for min 6 months.

The fibrin glue used was the Reliseal fibrin sealant kit.

Patients were evaluated in terms of surgical time, intraoperative difficulties, postoperative complications like healing of the scleral flap, corneal clarity and anterior chamber reaction, post op visual recovery &induced astigmatism, pupillary abnormalities, IOP changes and centration of IOL. (on table and post op). The statistical tests used were - Unpaired T test and 2-factor repeated measures ANOVA. The technique of sutureless scleral fixation of Glued PCIOLS was done, as described by Agarwal et.al[13](2008). After doing the conjunctival peritomy and making the scleral flaps(see Fig. 3), an intralamellar scleral tunnel underneath the flap was made with a 26G needle (tip was dipped in gentian marker to mark the site of the tunnel). The tunnel was 1.5 - 2mm long, was parallel to the limbus in a direction downwards (for the nasal flap) and upwards (for the temporal flap). Vitrectomy via the pars plana or anterior route was done.The anterior chamber was maintained by an infusion cannula and an AC maintainer, respectively.

Then, two straight sclerotomies with a 20G MVR blade were made about 1 mm from the limbus under the existing scleral flaps. A superior clear corneal incision was prepared for introducing the IOL (See Fig. 4). The IOL was implanted through the corneal incision behind the iris, and the trailing haptic was fixated into the incision. The tip of the leading haptic was advanced till it was visualised in the mid-pupillary area and was grasped with the forceps 23 G vitrectomy forceps, which were introduced through the temporal sclerotomy. It was pulled through the sclerotomy and externalised under the scleral flap. The externalised haptic was then stabilised by the assistant or by tying 3.0 silk at its tip. Similarly, the trailing haptic was externalised through the other sclerotomy (nasal) under the scleral flap. The haptic tips were tucked into the intralamellar scleral tunnel at the point of externalisation of the haptics.

The reconstituted fibrin glue was then injected under the scleral flaps by an applicator. Local pressure was given over the flaps for 10-20 seconds for the formation of fibrin polypeptides. The Corneal wound was closed with 10.0 nylon. The conjunctiva was closed with fibrin glue. The fibrin glue used was the Reliseal fibrin sealant kit. It is available as a 0.5ml/1ml pack.

In the second group, fibrin glue was not used for the flap and the conjunctival closure. The scleral flaps were closed with 10.0 monofilament, and the conjunctiva was closed with 6.0 Vicryl.

The surgical time was measured from the end of the vitrectomy till the end of the surgery (conjunctival closure). All the intraoperative difficulties and complications were noted and compared.

RESULTS

The average age of the patients in group A (54.35±13.45 years) was lower than in group B (62.40±13.68 years). The male-to-female ratio was nearly equal in both groups. The most common indication of surgery was Aphakia with no posterior capsule (see Fig.1). Large PC rent or inadequate PC was the second most common indication of surgery. The pre-operative parameters were - UCVA, BCVA, IOP, ACD, AC reaction, Iris & pupillary changes, endothelial cell count & corneal thickness, gonioscopic findings,

Vitreo-retinal changes and CMT. There was no significant difference between the two groups.

The mean surgical time was more in the glued IOL (48.50±0.05 min) than sutureless SF-IOL group (43.75±13.06 min). (p=0.361)

In some cases of glued SF-IOL, extra time was taken because one application didn't cause closure of the flaps, and glue had to be applied 2 or 3 times.

Post-operative BCVA (See fig. 2) was ≥ 6/18 in 35% of patients in group A and 30% patients of group B. Mean BCVA in group A was 0.667±0.24, and in group B was 0.685±0.23. The difference was not significant (p = 0.853). In group A of glued IOLs, only two patients (10%) had visual recovery of 6/9 or better (See Fig. 2). The results are contrary to the study done by Kumar et al (2010). They reported a visual acuity of 6/9 or better in 50.9% patients following glued IOLs.

Postoperatively, the scleral flaps were well apposed and healthy in both groups. However, subconjunctival migration of the IOL haptic was seen in 1 patient of group B at 3 months, which was uneventfully repositioned.

Significant shallowing (See Table 2) of the post op anterior chamber depth was seen in both groups. However, the difference between the two groups was not significant (p = 0.73). Cornea cleared in 2-3 weeks in both groups. (A= 3.95±2.8 wks, B= 3.35±2.1 wks, p = 0.453). Persistent corneal edema was seen in 10% patients of group A & 5% patients of group B.
There was a significant increase in corneal thickness post-surgery in both groups. (p=0.005). However, there was no intergroup difference (p=0.741).
At 3 months, 2 patients of group A developed PBK and 1 patient of group B developed a retrocorneal membrane.
Endothelial cell loss (See Table 3) was higher in group A than Group B, but the difference was not significant (p = 0.472). A significant rise in post op IOP (See table 4) was seen only in the glued IOL group (p=0.049).
Postoperative inflammation (See table 5) persisted between 2-3 weeks in the two groups (p = 0.361). The mean duration was 2.80±0.62 & 2.75±0.16 weeks in groups A & B.
90% and 75% in group A & B, respectively, had irregular pupils prior to surgery. The causes were vitreous in A.C., PAS and sector iridectomy.
100% patients in group A and 85% patients in group B had irregular pupil after surgery. The causes for the same were sphincter tears & iris injury. There was no significant difference in pre and post CMT between the two groups. 2 patients in each group had IOL decentration (See Figs 4 & 5).
In group A, decentration was seen at 4th and 12th post op weeks.
In group B, decentration was seen 8th and 12th post op weeks
The decentration in all the patients was mild and did not affect vision.

DISCUSSION

Intraocular lens implantation in the absence of capsular support forms one of the most difficult aspects for visual rehabilitation following complicated cataract surgery. IOL can be implanted in cases of incomplete zonular/capsular support by using Capsular tension rings[5],Cionni's ring[6], and capsular tension segment.
In cases of total capsular absence, various techniques described are anterior chamber intraocular lens[1], iris fixated lenses, iris claw lenses[14] and scleral fixated intraocular lenses.

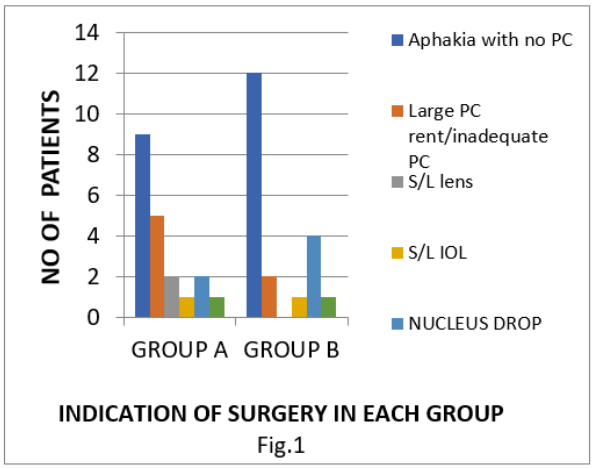
Various complications have been reported with ACIOLs, like corneal decompensation[1], glaucoma[14], iris tuck and iris chafing[7], erosion of haptic into the ciliary body and angle recession[7], subclinical uveitis[1] and Cystoid Macular edema[15]
Even scleral-fixated IOLs were shown to have complications. Scleral fixated IOLS (SF-IOLs) are associated with an increased incidence of endophthalmitis, especially due to exposed ends of suture. Uthoff et al[16] (1998), showed suture erosion(17.9%), cystoid macular edema(5.8%), retinal detachment(1.4%), vitreous haemorrhage(1.0%) and uveitis(0.5%) in a 1 year post operative outcome of scleral fixated IOLs.
To avoid suture-related complications, the concept of sutureless scleral fixation was given by Maggi and Maggi[11] In 1997 and later by Gabor and Pavilidis[12]. A technique of Glued IOLs was described by Agarwal et al in 2008[13]. In this technique, they tucked the haptics of the IOL into the intralamellar scleral tunnel and the scleral flaps were sealed by quick-acting fibrin glue.
There was significant improvement in the pre-operative & post-operative uncorrected visual acuity in each of our study groups (p=0.000). These findings in our study are consistent with the results of other studies on SF-IOLs. Evereklioglu et al[15] (2003), Lee et al[17] (2003), Johnston et al[18] (2000), Kumar et al[19](2010) have all reported an increase in visual acuity following trans scleral fixation of PC-IOLs. In group B of glued IOLs, only two patients (10%) had visual recovery of 6/9 or better.
The results in our study are contrary to the study done by Kumar et al[19] (2010), who reported much better visual results in their patients. They reported a visual acuity of 6/9 or better in 50.9% patients following sutureless scleral fixation of glued IOLs. This difference may partly be explained by a larger sample size of 53 patients in their study as compared to only 20 in our study. Also 3 of 20 patients in group B (glued) had poor post-operative visual recovery, 2 of whom developed pseudophakic bullous keratopathy and one had undergone pars plana vitrectomy with silicon oil injection for retained intra-ocular foreign body, prior to SF IOL implantation. However, he developed re-detatchment following oil removal. Subsequently, his retina settled after silicone oil re-injection, but vision improved only to 1/60. Post-operative high intraocular pressure was seen in 20% in group A and 15% in group B, in the first post-operative week. The rise in IOP was marginally significant in group A (p=0.049) only, on comparison of pre & post-operative intra-ocular pressure in each group, In a similar study on glued IOLs, Kumar et al[19] did not find significant IOP change post-operatively in their study group (p=0.447). Chakrabarti et al[20] (2011) did not report a single case of post-operative high IOP in their study on sutureless IOLs. Our findings are contrary to theirs as we found post-operatively increased IOPs in 15% patients in group C (sutureless).
The high post-operative IOPs in our cases may be due to increased manipulation during surgery, leading to increased inflammation, hyphema (5%)and vitreous haemorrhage (6.67%) in some patients. Some patients already had high IOP preoperatively (2 in group A).

All these patients were managed medically by systemic and topical antiglaucoma drugs. However,2 patients developed persistent secondary glaucoma for which trabeculectomy was done, and one patient required cyclocryotherapy even after trabeculectomy for control of glaucoma. The post-operative endothelial cell count was found to decrease from pre-operative values in both groups. However, this decrease was not statistically significant (p=0.109)
In a similar study on glued IOLs, Kumar et al[19] (2010) found a significant decrease in the postoperative specular counts in glued IOL patients. However, in our case, the decrease did not reach statistical significance because of a small sample size.
A theoretical risk of transmission of viral infections from the fibrin glue has been described in the literature; however, infection was not seen in any of the patients in the follow-up.

CONCLUSIONS

Sutureless SF-IOLs without glue not only avoid the cost of fibrin glue but are equally efficacious and also avoid the theoretical risk of transmission of viral infections from tissue derivatives.

The incidence of secondary glaucoma was higher in the Glued IOL group in our study, which might be due to multiple surgeries and pre-existing conditions in some patients.



INDICATION OF SURGERY IN EACH GROUP
Fig.1

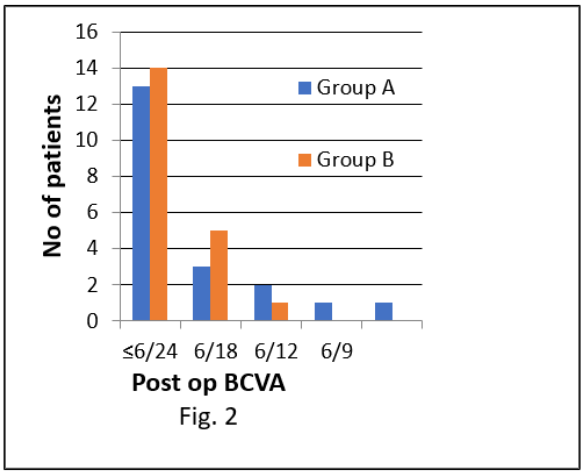


Fig. 2

Table 1: Complications in Both Groups

List of Complications	Group A	Group B
IOL haptic slippage/breakage	9	7
Increased corneal haze during surgery	6	5
Haemorrhage	1	6
Problems due to intraoperative hypotony	4	5
Glue-related problems	4	0
Iris injury during surgery	1	4
Difficulty in making flaps	1	3
Centration problem	3	0

Table 2: Anterior Chamber Depth

Mean ACD(in mm)	Group A	Group B
Pre op	3.69±0.5	3.69±0.4
Post op	3.2±0.5	3.3±0.4

Table 3: Corneal Endothelial Cell Count

Endothelial cell Count (cells/mm²)	Group A	Group B
Pre op	1836±361	1778±116
Post op	1713±127	1730±121

Table 4: Post-operative IOP

Post-Operative IOP	Group A (N%)	Group B (N%)
Low	2 (10%)	0
Normal	15(75%)	16 (80%)
High	3 (15%)	4 (20%)

TABLE 5: DURATION OF INFLAMMATION

DURATION OF INFLAMMATION	Group A N (%)	Group B N (%)
<2 WEEKS	5 (25%)	9 (45%)
>2 WEEKS	15 (75%)	11(55%)

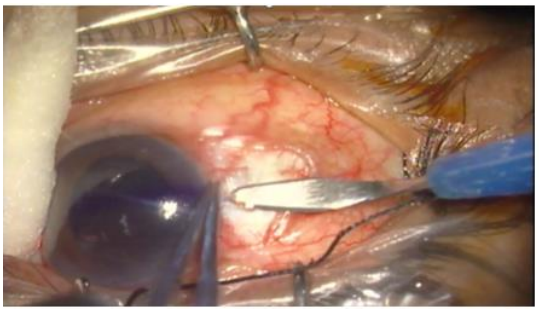


Fig. 3: Creation of Scleral Flaps

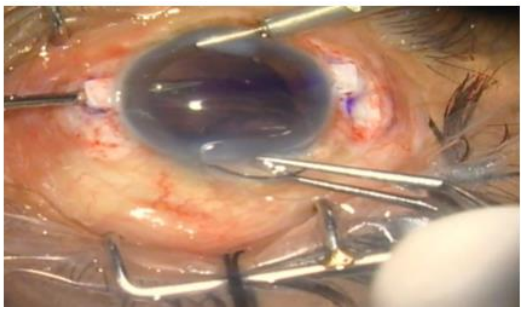


Fig.4 : Insertion of IOL

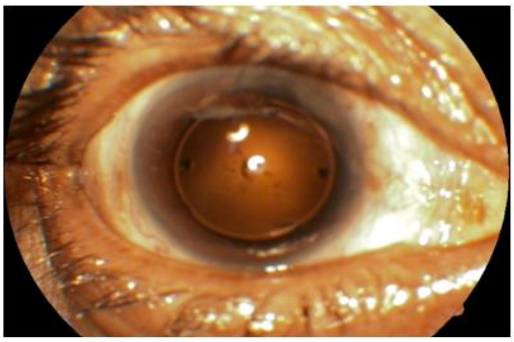


Fig 5: Normal Centration of IOL

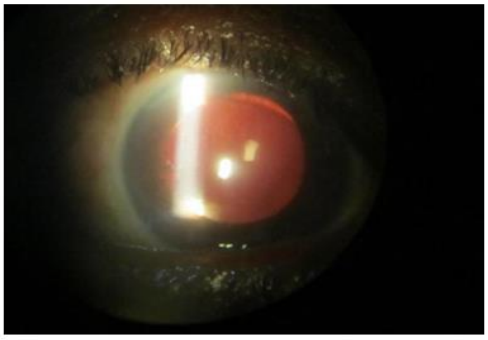


Fig. 6: Mild Inferior Decentration of IOL

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