

Safety and efficacy of fibrin glue versus infinity suture in SICS with extended scleral flap

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Purpose: To study the safety and efficacy of biologic fibrin glue (FG) in comparison with infinity suture in SICS with compromised scleral flap. **Methods:** A retrospective comparative study of patients who were treated with FG (Group A) with 10-0 nylon (Group B) as sealing agent for intraoperative compromised tunnels in SICS. Parameters noted were postoperative inflammation, wound integrity, anterior chamber (AC) depth, intraocular pressure (IOP), and surgically induced astigmatism (SIA) at postoperative day 1, 4 weeks, 6 weeks, and 6 months, respectively. Epi Info 7 software and SIA calculator, Version 2.1 were used to analyze the result. **Results:** We reviewed the two groups of 18 patients each and noted that there was no statistically significant difference in postoperative inflammation ($P > 0.05$), AC depth ($P > 0.05$), and IOP ($P > 0.05$) between both groups at each postoperative visit. One patient in Group A showed postoperative shallow AC and subconjunctival bleb. Exposed sutures causing foreign body sensation had to be removed in five patients in Group B. At the end of 6-month postoperative period, no statistically significant difference was found in SIA ($P = 0.92$) between the two groups. **Conclusion:** Biologic FG can be safely used in securing the compromised scleral incisions in SICS. It also avoids suture-related complications.

Key words: Compromised tunnel, extended scleral flap, fibrin glue, small incision cataract surgery, surgically induced astigmatism, suture

Small incision cataract surgery (SICS) remains the most common method of cataract surgery in the developing world. Its continuing popularity is because of predictable astigmatism, comparable to phacoemulsification in many studies.^[1-3] SICS is also preferred by many surgeons in cases of large nucleus and compromised endothelium.^[4-6] Many of these surgeries are performed by beginners where extended scleral flap, large incisions, torn or buttonholing of scleral flaps are not uncommon complications.^[7] These compromised scleral tunnels lead to postoperative wound leak, shallow anterior chamber (AC), increased risk of postoperative endophthalmitis, and unpredictable astigmatism.^[7-9] This has mostly been managed by putting sutures but sutures are also associated with suture-related complications such as foreign body sensation and possible postoperative wound infection.^[10] Therefore, we aimed to study the safety and efficacy of fibrin glue (FG) and compare it with infinity sutures in cases of SICS with compromised scleral tunnel.

Methods

We did a single-center retrospective analysis of medical records of 679 patients who underwent cataract surgery by manual SICS between September 2015 and April 2017. All cases were operated by a single surgeon. Patients with a history of autoimmune disorders, uveitis, high myopia, and ocular surface disorders were excluded from the study. In

all these cases, straight, cauterized scleral incision of 6.5 mm was planned 1.5 mm away from the limbus. We reviewed those cases where the scleral flap got inadvertently extended, buttonholed, or torn and were managed with FG or infinity sutures [Fig. 1a and b]. We divided these patients into two groups: group A patients had been treated with FG and Group B patients were managed with X-shaped infinity sutures for compromised scleral tunnels.^[11] In all cases, rigid 6.0 mm posterior chamber lens was implanted. Institutional ethics committee approval was obtained.

The primary outcome measures were the effect of FG and infinity sutures on wound closure, postoperative AC depth, and inflammation. Other outcome measures included intraocular pressure (IOP) and surgically induced astigmatism (SIA) at postoperative day 1, 1 week, 4 weeks, 6 weeks, and 6 months, respectively. SIA was calculated by SIA Calculator version 2.1 (Astigmatism calculated as plus cylinder). Data were analyzed by Epi Info 7 software (CDC, Atlanta, GA, USA). Variables were compared using a paired *t*-test.

FG is a biological, nonirritating substance that is absorbed in a few days, inducing collagen formation and cross-linking

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and thus promoting natural wound healing. The fibrin sealant (Reliseal, Reliance Life Sciences, India) consists of two components: sealer protein/apoprotein and thrombin/CaCl₂ solution. It is available as a kit containing freeze-dried powder, freeze-dried thrombin, calcium chloride, and apoprotein solution. As the two components combine during application, the sealant consolidates and adheres to the site of application. The tensile strength of a clot formed with fibrin seal is approximately 200 g/cm² (17 kPA). The clotting procedure is fast, with firm adhesion in 3 to 5 s. FG can also be used on wet tissue surfaces.^[12] The FG was applied using a double syringe that allows the two sealant components to be thoroughly mixed with one hand immediately before wound closure. A thin film of FG was applied to the posterior part of the scleral pocket along its entire length. The conjunctiva was also fixed onto the sclera with drops of FG. After the glue is applied, fibrin consolidates in a few seconds. The wound was kept dry to enhance the adhesive strength of fibrin.^[10]

Results

We analyzed 36 patients (18 patients in each group), with mean age 64 ± 4.8 years in Group A and 61 ± 3.7 years in Group B ($P > 0.05$). Mean size of incision was 7.48 ± 0.31 mm (range 6.9–8.0 mm) and 7.6 ± 0.19 mm (range 6.7–8.2 mm) in Group A and B, respectively ($P > 0.05$). We observed that postoperative mean central anterior chamber depth was 3.24 ± 0.44 mm in Group A while it was 3.30 ± 0.15 mm in Group B in all postoperative follow-up visits ($P > 0.5$). Comparison of inflammation scores, AC cells, and flare showed no statistically significant difference between the two groups at any of the postoperative visits ($P > 0.05$). IOP measured by noncontact tonometer was 14.0 ± 2.8 mmHg

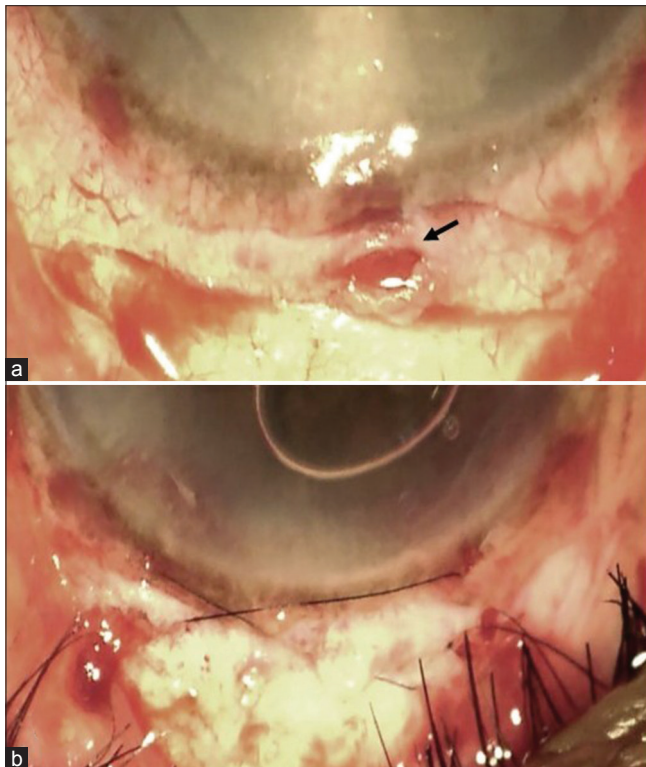


Figure 1: (a) Intraoperative photograph shows buttonhole in sclera flap (black arrow) and (b) management by infinity suture

(range 8–20 mmHg) in Group A while it was 13.9 ± 2.1 mm Hg (range 9–19 mm Hg) in Group B in all postoperative visits and the difference was not significant ($P = 0.61$). IOP was within normal limits in all cases on each visit in both groups except in one case in Group A where shallow AC was noted on postoperative day 1. The presence of a subconjunctival bleb was noted in the same patient at the end of 1 week. Subsequently, it was managed by wound revision and applying a single anchor suture. In Group A, there was an increase in the mean SIA from 1st day (mean SIA $1.78 \pm 1.30 \times 178^\circ$) to 7th postoperative day (mean SIA $3.07 \pm 1.37 \times 175$) ($P = 0.008$). However, on excluding the patient with subconjunctival bleb formation, the mean SIA was 2.42 ± 0.74 ($P = 0.06$) at the end of 1 week, and this value has been used for SIA analysis [Table 1]. In Group B, mean SIA decreased from 1st postoperative day (mean SIA 1.99 ± 1.33) to end of 6 weeks (1.72 ± 1.22) ($P = 0.65$). At the end of 6 months, mean SIA was not significantly different from 1st postoperative day in both groups. There was no complaint of any discomfort in any patient in Group A. Five patients in Group B complained of foreign body sensation. On examination, exposed knots were seen along with associated conjunctival hyperemia [Fig. 2]. It was managed by giving lubricant drops till they were removed at the end of 1st month.

Discussion

SICS with extended or buttonholed scleral flap has usually been managed by nylon sutures. However, sutures are associated with many complications such as foreign body sensation and possible postoperative wound infection. On the other hand, cyanoacrylate glue is not favored as it forms a solid, impermeable mass *in situ* which acts as a foreign body causing giant papillary conjunctivitis and corneal neovascularization.^[13] Unlike cyanoacrylate glue, FG forms a uniform seal along the length of the wound edge and hence provides greater postoperative comfort to the patient with fewer complications.^[14] Although FG has been used in scleral pocket phacoemulsification for controlling SIA in previous studies,^[12] literature search regarding the use of FG in extended or buttonholed scleral pocket incision in SICS revealed no such study.

Alvarado Valero *et al.* evaluated the histological inflammatory activity on scleral tissue with bioadhesives such as fibrin and cyanoacrylate glue and demonstrated that on day 30, both fibrin and cyanoacrylate adhesives had generated a greater inflammatory response than sutured and unsutured techniques for closure in their cases.^[15] Kim *et al.* documented that although cyanoacrylate glue initially demonstrates a strong adhesive quality, it causes a severe inflammatory response that inhibits

Table 1: Statistical analysis of astigmatic changes in Postoperative visits

Postoperative period	Mean SIA (plus cylinder)		P value
	Group A (Fibrin glue)	Group B (suture)	
Day 1	1.78 ± 1.30	1.99 ± 1.33	0.62
1 Week	2.42 ± 0.74	1.89 ± 1.09	0.06
4 Week	1.67 ± 0.75	1.75 ± 1.26	0.81
6 Weeks	1.56 ± 0.69	1.72 ± 1.22	0.62
6 Months	1.73 ± 0.77	1.76 ± 1.23	0.92

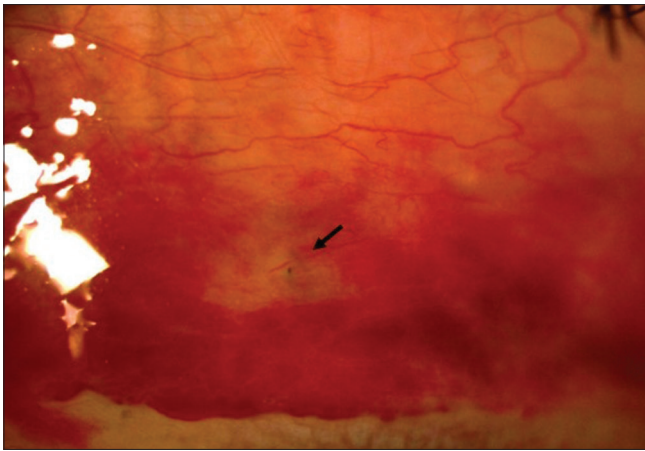


Figure 2: Postoperative photograph demonstrates exposed suture

subsequent collagen remodeling. Hence, they concluded that fibrin tissue adhesives may have an application as adjunctive means of closing scleral tunnel incisions.^[16] Buschmann used fibrin intraocularly to close traumatic defects of the lens capsule without reporting any side effects.^[17] In our study, however, postoperative inflammation was minimal in all eyes.

In the current study, well-formed AC was found in all cases of both groups except one case in Group A FG where the patient had shallow AC on postoperative day 1 and showed the presence of a subconjunctival bleb on day 7. As per medical records, this patient had premature entry into AC. We presume that this event could be due to aqueous leak leading to decreased adhesive strength of FG. Subsequently, this patient was managed by applying a single suture. Alió *et al.* tested the efficacy of synthetic, biological bioadhesives and 10–1 nylon anchor suture for incision closure in scleral tunnel phacoemulsification in 126 eyes with high myopia (axial length >28.0 mm) and noted that in the fibrinogen group, 3 eyes developed postoperative hypotony requiring reclosing of the incision with sutures and 5 eyes developed intraoperative hypotony requiring suture closure.^[18] Perhaps, the presence of low scleral rigidity in high myopia makes FG unable to provide the required tensile strength to the wound margin.^[19] On the basis of our clinical finding and results of above-mentioned study, we can suggest that in cases of premature entry into AC and in high myopia, sutures may be applied in the first attempt itself.

Some studies analyzed the tensile strength of glue (biological and synthetic) and compared it with sutures in scleral pocket incisions. Shigemitsu and Majima demonstrated that both cyanoacrylate and FG had tensile strength comparable to the sutures used in cataract surgery.^[20] Henrick *et al.* analyzed the use of biologic glue in posterior beveled and scleral pocket incisions for cataract surgery in fresh cadaveric eyes and closed them with nylon sutures, glue, or a combination of both and concluded that biologic glue was an alternative to suture closure of scleral pocket cataract incisions.^[21]

In our study, at the end of 6 months, mean SIA was against the rule (ATR) in both the groups, and the difference between Group A (1.73 ± 0.77) and Group B (1.76 ± 1.09) was not significant ($P = 0.92$). However, in Group A, SIA increased from day 1 to day 7 even after excluding the case with subconjunctival bleb ($P = 0.06$). This increase in mean SIA could

be due to wound slide and the fact that clot organization takes 2 weeks to complete after glue application. Thereafter, mean SIA showed decline till end of 6 weeks. In Group B, mean SIA decreased from day 1 to 6 weeks which was not statistically significant. However, ATR in this group was higher than the study by Mallik *et al.* at 6 weeks (0.1 ± 0.20).^[11] This could be due to increased length of scleral incision and extended or buttonholed scleral flap in our cases. There was no significant difference in SIA between Group A and B at any postoperative visit in our study. Mester *et al.* discussed astigmatism after phacoemulsification with scleral pocket incision using small incision technique with fibrin adhesive for wound closure and concluded that SIA was smaller in the fibrin group (vector analysis: 0.80 D) than in the single-stitch group (vector analysis: 0.99 D).^[12] On the contrary, we observed higher mean SIA in both the groups. This could be because our cases had a compromised tunnel with large wound size (6.7–8.2 mm) as compared to their study (5.5–6 mm). Mean SIA in our Group A (FG) was more than suture group at the end of 6 months as compared to Mester *et al.*, which could be due to a presumed presence of wound slide in our FG group. However, this difference at the end of 6 months was not significant in our study ($P = 0.92$).^[12] Alió *et al.* noted that the difference in mean SIA at 3 months between the bioadhesive groups and the suture group was not significant in their cases which is similar to our finding.^[18]

None of the patients in Group A had any complaints of discomfort. Suture had to be removed in five patients in Group B due to marked FB sensation and conjunctival hyperemia. McClellan *et al.* found evidence on scanning electron microscopy of surface disintegration of 10–0 nylon sutures after 3 months.^[22]

Our study was limited by small number of patients. Cost of FG can be a limiting factor. We propose a prospective study on more number of patients.

Conclusion

Biologic FG can be safely used in securing the scleral pocket incision in SICS when there is extended scleral flap or buttonholing of the scleral flap. It strengthens the incision margin, prevents unpredictable astigmatism, and does not cause untoward inflammation. It also avoids suture-related complications.

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Conflicts of interest

There are no conflicts of interest.

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