

“THE EFFICACY OF FIBRIN GLUE VS SUTURES FOR ATTACHING AMNIOTIC MEMBRANE GRAFT AFTER PTERYGIUM EXCISION – A RANDOMIZED CLINICAL TRIAL”

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ABSTRACT

AIM: To study the efficacy of fibrin glue versus sutures for attaching amniotic membrane graft after pterygium excision- a randomized clinical trial

METHODOLOGY: A total of 50 pterygium patients selected and divided into two groups of 25 each were studied. This study was carried out at Department of Ophthalmology, Santhiram Medical College, Nandyal from January 2014 to April 2015.

RESULTS: Among group 1 mean surgical time was 34.32min compared to group 2 which was 27.24min. Hemorrhage was observed in 4% patient in group 1 whereas in group 2 it was noted among 12% patients at postoperative day one. Displacement of graft was seen in 8% patients in group 2 on week one. Graft edema was present in 4 (18.18%) patients in group 1 and in 3 (13.63%) patients in group 2. Suture granuloma was noted in 2 cases in suture group. Scleral thinning was found in 2 (9.09%) cases in group 1 whereas no such cases were reported in glue group. Conjunctival inflammation (pain, foreign body, lacrimation, discomfort, hemorrhage, graft displacement) were noted to be more among group 1 ($p < 0.05$).

CONCLUSION: The present study showed better efficacy of fibrin glue in amniotic membrane transplant among the patients undergoing pterygium excision, in terms of pain, foreign body sensation, lacrimation and discomfort during blinking and also surgical time.

Pterygium has been described as a triangular wing shaped encroachment of the bulbar conjunctival tissue onto the cornea.¹ It can vary from small, atrophic tissue to large and rapidly growing fibrovascular degenerative lesions that can distort the corneal curvature. In advanced cases, it can obstruct the optical center of the cornea causing visual disturbances.² Pterygium is a common condition in many parts of the world, with reported prevalence rates ranging from 0.3 to 29%.³

The risk factors for pterygium include areas with more ultraviolet radiation,⁵ hot, windy, dry, dusty, and smoky environments.^{4,6} In 1910 Davis was the first to report the use of fetal amniotic membranes as surgical material in skin transplantation.⁷ Since then the use of amniotic membrane in surgery has been expanded. In the 1940s several authors reported the beneficial role of amniotic membrane in treating a variety of ocular surface disorders. The amniotic membrane, as a “transplanted basement membrane”, acts as a new healthy membrane suitable for proper epithelialization. Cryopreserved amniotic membrane produces various growth factors such as basic fibroblast growth factor, hepatocyte growth factor, and transforming growth factor that can stimulate epithelialization.

It has been shown that amniotic membrane induces a down regulation of transforming growth factor β signaling, responsible for fibroblastic activation in wound healing

Hence the present study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing amniotic membrane transplantation and also to compare operative time and post-operative complications.

METHODOLOGY

This randomized controlled trial study was carried out at department of ophthalmology, santhiram medical college, nandyal from january 2014 to april 2015. A Sample size of 50 patients divided into two groups of 25 each were studied.

SELECTION CRITERIA

All the patients with primary pterygium were included and Exclusion criteria include patients with no previous intra-ocular surgery, History of ocular trauma, Ocular surface infection, Patient on any anti-coagulant therapy, Known hypersensitivity to any component of fibrin glue.

METHOD OF COLLECTION OF DATA

After the enrollment, patients were asked for the demographic data such as age, sex, occupation and about the complaints and detailed history was taken regarding the presenting illness.

OCULAR EXAMINATION

Ocular examination such as recording visual acuity with snellen's chart, anterior segment examination was done under slit lamp for the diagnosis of pterygium and grade, type and site were recorded. Pre-operative evaluation included keratometry, measurement of intra-ocular pressure and lacrimal sac patency test. Investigations such as random blood sugar, bleeding time and clotting time were performed.

SURGICAL TECHNIQUE

Under peribulbar block and aseptic conditions the universal wire speculum was inserted and a 11 No. Bard Parker blade was used to excise the pterygium head from the cornea, and the body of the pterygium along with the underlying subconjunctival tissue was removed using Westcott scissors.

The area of the conjunctival defect was measured and a amniotic membrane measuring the same size was obtained. The preferred place of the Amniotic membrane on the ocular surface is the epithelial side up.

GROUP 1

Multiple interrupted 8-0 vicryl sutures were used to attach the amniotic membrane to the underlying episcleral bed.

GROUP 2

Three drops of the reconstituted fibrin glue mounted on two separate syringes on a Duploject injection system were then placed on the bare scleral bed, and the graft was immediately slid over the area of conjunctival defect and was quickly smoothed out with a non-toothed forceps so the edges were opposed.

Post operatively in both the groups an antibiotic-steroid combination eye- drop (moxifloxacin 0.3% and dexamethasone 0.1%) were advised for six times a day for two weeks and then tapered off over next four weeks. Lubricating drops (Carboxy methyl cellulose sodium 0.5%) were advised three times a day for six weeks.

All patients were followed on post-operative day one, one week, third week and sixth week and outcome variables are recorded.

RESULTS

Based on the randomization, these patients were divided into two groups as below.

- Group 1; suture glue group: n= 25
- Group 2; fibrin group: n=25

	SUTURE GROUP	GLUE GROUP
No of cases	25	25
male	13	13
female	12	12
Mean age	48.4	51.08
Pterygium grade		
Grade 1	3	3
Grade 2	18	17
Grade 3	4	5
Bilateral	7	6
Unilateral	18	19
Operating time		
21-30	3	21
31-40	22	4

table 1.
assessment of
pain from day

one to six weeks

SIGNS	GROUPS	Pain				Chi Square	P value
		post op day 1	one week	three weeks	six weeks		
ABSENT	SUTURE GROUP	0	15	22	23	5.4314	0.1427 NS
	GLUE GROUP	6	17	23	24		

MILD	SUTURE GROUP	17	10	3	1	1.602304147	0.65886748 NS
	GLUE GROUP	18	6	1	1		
MODERATE	SUTURE GROUP	8	0	0	1	8.8272	0.031679 S
	GLUE GROUP	1	2	1	0		

SIGNS	GROUPS	FB sensation				Chi Square	P value
		post op day 1	one week	three weeks	six weeks		
ABSENT	SUTURE GROUP	0	0	6	17	11.3676	0.009896 S
	GLUE GROUP	1	17	23	25		
MILD	SUTURE GROUP	0	20	17	7	46.2078	< 0.00001 S
	GLUE GROUP	20	7	1	0		
MODERATE	SUTURE GROUP	23	5	2	1	0.8804	0.830149 NS
	GLUE GROUP	4	1	1	0		
SEVERE	SUTURE GROUP	3	0	0	0	-	-
	GLUE GROUP	0	0	0	0		

table 2. assessment of foreign body sensation from day one to six weeks

table 3. assessment of lacrimation from day one to six weeks

SIGNS	GROUP	Lacrimation				Chi Square	P value
		post op day 1	one week	three weeks	six weeks		
ABSENT	SUTURE GROUP	0	4	17	22	4.7509	0.190971 NS
	GLUE GROUP	1	15	23	24		
MILD	SUTURE GROUP	4	20	8	3	19.1316	0.000257 S
	GLUE GROUP	18	9	1	1		
MODERATE	SUTURE GROUP	16	1	0	0	2.6487	0.265972 NS
	GLUE GROUP	6	1	1	0		
SEVERE	SUTURE GROUP	5	0	0	0	-	-
	GLUE GROUP	0	0	0	0		

table 4. assessment of discomfort during blinking from day one to six weeks

SIGNS	GROUPS	Discomfort				Chi Square	P value
		post op day 1	one week	three weeks	six weeks		
ABSENT	SUTURE GROUP	0	0	5	16	3.8401	0.146598 NS
	GLUE GROUP	1	19	24	24		
MILD	SUTURE GROUP	0	12	18	9	39.7059	< 0.00001 S

	GLUE GROUP	19	5	0	1		
MODERAT	SUTURE GROUP	24	13	2	0	1.5627	0.45779 NS
	GLUE GROUP	5	1	1	0		
SEVERE	SUTURE GROUP	1	0	0	0	-	-
	GLUE GROUP	0	0	0	0	-	-

Table 5. Assessment of Hemorrhage from day one to six weeks

		HEMORHAGE			
		post op day 1	one week	three weeks	six weeks
PRESENT	SUTURE GROUP	1	0	0	0
	GLUE GROUP	3	0	0	0
ABSENT	SUTURE GROUP	24	25	25	25
	GLUE GROUP	21	25	25	25

Table 6. Assessment of displacement of graft from day one to six weeks

		DISPLACEMENT				P value
		post op day 1	one week	three weeks	six weeks	
PRESENT	SUTURE GROUP	0	0	0	0	0.1427
	GLUE GROUP	0	2	0	0	

ABSENT	SUTURE GROUP	0	0	0	0	-
	GLUE GROUP	0	0	0	0	

Table 7. Assessment of appearance from day one to six weeks

SIGN	GROUP	appearance				Chi Square	P value
		post op day 1	one week	three weeks	six weeks		
QUIET	SUTURE GROUP	0	7	18	23	9.9674	0.018845 S
	GLUE GROUP	9	21	24	25		
RED	SUTURE GROUP	25	18	7	2	5.1488	0.161218 NS
	GLUE GROUP	16	4	1	0		

DISCUSSION

A number of surgical techniques have been advocated for management of pterygium. Amniotic membrane graft is a simple and safe modality for the management of pterygium.

Fibrin glue is safe and effective method for amniotic membrane transplantation in primary pterygium excision. The use of fibrin glue to attach is as stable as those secured with sutures and also produce significantly less inflammation, less discomfort and less operative time.

In the present study equal distribution of males 52% and females of 48% in both the suture and fibrin group. Mean age group among group 1 was 48.4yrs and group 2 was 51.08yrs.

C Kucukerdonmez et al, Turkey¹⁰, mean age group in fibrin group was 52.7± 9.8 yrs and in suture group was 54.2± 11.3 yrs

In this study Mean operating time in glue is 27.24 min and in suture group it is 34.32 min.

Mahdy RA et al¹¹, Egypt, demonstrated that there was a statistically significant decrease in surgery time in the fibrin glue group (the procedure took 17 min) relative to the sutured group (28 min; p < 0.05).

C Kucukerdonmez et al¹⁰, Turkey, average operation time in the fibrin glue and suture groups were 11.2±2.4 min (mean±SD) and 18.7±2.2 min, respectively (P=0.018)

In the present study on post-operative. Moderate pain was reported 32% in group 1 and 4% in group 2 (p=0.03).

In the present study, the foreign body sensation in group 2 (glue) was absent among 4% patients on day one whereas in group 1 (suture) all the patients (100%) complained about moderate

foreign body sensation on day one (p 0.009)

lacrimation was mild 16%,80%,32% and 12% during post operative day one, week one, week three and six among the patients with group 1 respectively while in group 2, it was noted as 72%,36%,4%,4% respectively (p=0.00025)

In group 1, moderate discomfort during blinking was reported by 96% patient on day one and 4% had severe pain while 76% of group 2 were reported with mild pain and 20% had moderate and 4% had no complaints (p <0.00001).

C Kucukerdonmez et al¹⁰ Turkey, showed significantly lower post-operative scores for all symptoms (pain, epiphora, foreign body sensation, and irritation) were found in the fibrin glue group compared with the suture group at days 1, 7, and 14 after surgery (P<0.05) depending on the Five point scale assessment.

Mahdy R.A¹¹, showed that both postoperative pain and discomfort were noted significantly less often in the fibrin glue group. Complications were also decreased in the fibrin glue group.

In the present study suture granuloma was noted in 2 cases in suture group, so we have removed the sutures and increased frequency of topical steroids. The granuloma resolved within 3 weeks.

Dong Yub Kwab et al¹² Korea, granuloma in one eye (4.3%) in the fibrin glue group, granuloma in three eyes (15%) in suture group.

In the present study, among the suture group one case(4%) and among fibrin group three cases (12%) were observed to have normal conjunctiva growing over the attached amniotic graft which was suggestive of conjunctival recurrence at the third follow up that is 3 weeks post-operative.

Dong Yub Kwab et al¹² Korea, showed conjunctival recurrence was noted in four eyes (17.4%) and fibrovascular tissue invading the cornea (corneal recurrence) was noted in two eyes (8.7%) in the fibrin glue group. Conjunctival recurrence was noted in five eyes (25%) and corneal recurrence was noted in one eye (5%) in the suture group.

. **Ma et al**¹³ have found that single-layered amniotic membrane was able to reduce the recurrence to 12.5%, which was comparable with our study.

CONCLUSION

Fibrin glues have been used in many of ophthalmic procedures such as conjunctival closure in strabismus, vitreo retinal and glaucoma surgery. Because of its biological and biodegradable properties, fibrin-based adhesives may be used to attach the amniotic membrane graft without inducing inflammation. This study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing amniotic membrane transplantation and also to compare operative time and post operative complications.

This one and half year randomized controlled trial on 50 patients with primary pterygium was conducted at Department of Ophthalmology, Santhiram Medical College, Nandyal during the period of January 2014 to April 2015. Based on randomization, these patients were divided into two groups namely, Group 1 (Suture group: n=25) and Group 2 (Fibrin glue group: n= 25).

This study showed better efficacy of fibrin glue in amniotic membrane transplant among the patients undergoing pterygium excision, in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Except the recurrence it significantly reduced the surgical time with fewer post-operative complications.

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