A Comparative Study of Fibrin Glue Vs Vicryl Sutures for Conjunctival Autografting in Pterygium Surgery

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KEYWORDS

Introduction
The term pterygium comes from the ancient Greek pterygos means wing. Pterygium is characterized by a triangular portion of the bulbar conjunctiva encroaching onto the cornea. It is slightly vascular and seen in the intrapalpebral fissure in the horizontal meridian, most often from the nasal side. 1

Clinically pterygium is a fibrovascular wing of tissue extending onto the cornea. Before it enters the optical zone, an advancing pterygium can cause localized flattening of the horizontal meridian of the cornea to the leading apex, resulting in with-the-rule astigmatism. 2

The pterygium belt extends around the world between the latitudes 40° North and 40° South of the equator. 3, 4 The prevalence rate of primary pterygium varies from 0.7 to 31% in various populations around the world. 5 The prevalence of pterygium in South Indian population were 9.5%. 6

The etiology of pterygium occurrence is not clear. Pterygium is more frequently seen in areas with greater ultraviolet radiation 7,8, in hot, dry, windy, dusty, and smoky environments. 9 It is more common in people who have outdoor work in situations with high light reflectivity, including sand and water which enhances the development of pterygium. 10

Independent associations of pterygium with increasing age, male sex, outdoor occupations and systemic factors like blood pressure suggested a complex and multi-factorial aetiology for pterygium to be present. 11

Pterygium is also characterized by corneal epithelial stem cell deficiency at the nasal and temporal limbus. 12

Surgical removal is the treatment of choice. Indications for surgery include visual impairment, restriction of ocular motility, chronic inflammation, and cosmetic concerns. Many surgical procedures and adjunctive techniques (to lower the recurrence rate) have been suggested.

Successful management of pterygium is a constant challenge for ophthalmologists due to high recurrence rate.

 Conjunctival auto grafting after pterygium excision is associated with very low rates of recurrence and complications when compared with other techniques. The surgeon’s skill and experience affect the recurrence rate, which varies between 2% and 39%. 13

Nevertheless, because of graft suturing, this method has the disadvantage of a relatively longer surgery time when compared with the bare sclera technique. The risk of complications such as granuloma formation, giant papillary conjunctivitis and significant patient discomfort was reported after surgery. 14

In most of the surgical procedures patient has post operative redness, pain, watering, photophobia and overall discomfort for longer period due to sutures.

This led to the use of fibrin glue and absorbable 8-0 vicryl suture to attach conjunctival autograft in pterygium surgery. It has been reported that use of this technique reduces redness, pain, watering, post operative inflammation and thereby increases the patient comfort. Conjunctival autograft pasted by fibrin glue reduces the surgical time.

However, the recurrence rates after the use of fibrin glue have been investigated in only a few studies. 15

In the present study, we have selected primary nasal pterygium for pterygium excision with conjunctival autografting by two methods i.e. fibrin glue and 8-0 vicryl and comparison between these two techniques was done.

AIMS AND OBJECTIVES
To compare the efficacy of fibrin glue versus sutures for fixing conjunctival autograft in patients undergoing pterygium excision with respect to

• Operative time
• Pain
• Postoperative ocular signs and symptoms
• Overall patient comfort
• Recurrence of pterygium

Materials and methods
A comparative prospective randomized clinical study was conducted in Department of Ophthalmology, in rural based hospital, from 2009-2011.

This included patients attending Ophthalmology Out Patient Department. The study was done on 57 patients (60 eyes) with primary nasal pterygium. The patients were randomized for fibrin glue (30 eyes) or 8-0 vicryl sutures (30 eyes) for conjunctival autografting. Outcome measures were recorded on days 1, 7, 30, 60 and 180.

Pre operative grading:
Pre operatively pterygium was graded by the grading system developed by Tan and associates in 1997 16 as Grade 1 Atrophic with episcleral vessels under the body of the pterygium not obscured and clearly distinguishable;

Grade 2 Intermediate
Grade 3 Fleshy, episcleral vessels totally obscured.

Post operative grading:
A four point scale from 0 to 3 was used to evaluate and grade pain, lacrimation and discomfort in post operative symptoms.

Grade 0: No symptom

Grade 1: Mild discomfort
Grade 2: Moderate discomfort
Grade 3: Severe discomfort

Postoperative ocular signs and symptoms:

Grade 0: None
Grade 1: Mild
Grade 2: Moderate
Grade 3: Severe
Grade 4: Very severe

Operative time:
Operative time was measured as the time taken from the start of the surgery to the end of the surgery. All surgeries were conducted by one surgeon.
Grade 1: Patient had tolerable symptom and present occasionally.
Grade 2: Tolerable symptom present throughout the day or intolerable symptom present occasionally.
Grade 3: Intolerable symptom present throughout the day.

Subconjunctival haemorrhage was graded with a five point scale from 0 to 4. Grades:

Grade 0: None
Grade 1: 25% of the size of the graft
Grade 2: 50% of the size of the graft
Grade 3: 75% of the size of the graft
Grade 4: Haemorrhage involving the entire graft (no subconjunctival vessels visible)

Graft gapping and dehiscence was labelled as absent or present.

INCLUSION CRITERIA:
Patients of 18-60 years of age group of either sex having primary nasal pterygium (progressive or stationary) covering more than 2mm of cornea.

EXCLUSION CRITERIA:
1. Pseudo pterygium
2. Recurrent Pterygium
3. Persons having Pterygium less than 2mm
4. Immune system, eyelid or ocular surface disorder (eg, Blepharitis, Sjögren syndrome, Dry eye)
5. History of ocular surgery
6. History of ocular trauma
7. History of chemical burns

Progressive pterygium is defined as any pterygium wherein over a period of 3–6 months, there was an increase in the size as observed by the patient or as documented in the medical record.

Recurrence is defined as any re-growth of any fibrovascular growth extending across the limbus onto the cornea at the site of surgical excision, the fibro vascular recurrence attaining the same degree of corneal encroachment as the original lesion, or re-growth exceeding 1mm on to the cornea. The onset of recurrence was recorded as the date on which the recurrence was first noted, irrespective of the duration between that visit and the previous visit.

METHODOLOGY
All patients between 18-60 years of age having primary nasal pterygium (progressive or stationary) covering more than 2 mm of cornea were included in the study. A detailed informed consent was obtained from all patients. After complete ocular and systemic history, a thorough ocular examination including visual acuity, refraction, keratometry, ocular movements, fluorescein staining was done to grade the pterygium. A slit lamp examination was done and size of pterygium was measured with a calliper, and a free conjunctival-limbal autograft measuring the same size as the conjunctival defect was obtained from the supero-temporal quadrant of the bulbar conjunctiva. Scissors and conjunctival forceps were used to harvest the free conjunctival-limbal autograft. Meticulous dissection was performed to remove most of the tenons tissue in the autograft. The graft was moved over to the area of the conjunctival defect, with care taken to maintain the limbus to limbus and stromal side down orientation. At this stage, depending on the group in which the patients were allocated to, the auto graft was secured either with multiple interrupted 8-0 Vicryl or /with FG.

In graft to be attached with fibrin glue (Group A), the graft was placed on the cornea with stromal side facing downwards. The graft bed was dried before a drop of reconstituted solution of fibrin glue was put on it. The two components fibrinogen and thrombin solutions were taken in two separate syringes. One drop of each solution was placed on the scleral bed one after the other, and then the conjunctival autograft was slide over immediately to cover the scleral bed. The graft was quickly smoothed out with a non-toothed forceps. Proper care was taken to ensure that the spatial orientation was maintained and that the sides of the graft were opposed to the edges of the recipient conjunctiva and the graft was tucked in the recipient conjunctiva. After drying period of 30 sec, the lid speculum was removed. We used the reconstituted solution in about 3 – 4 patients on same operative day.

For subjects in suture group (Group B), multiple (6-8) interrupted 8-0 vicryl sutures were used to attach the autograft to the underlying episcleral bed. Conjunctival autograft was anchored by two interrupted sutures at the limbus by taking the scleral bite and the remaining part of the conjunctival autograft was sutured to the rest of the conjunctival defect.

At the end of the procedure an antibiotic-steroid ointment was placed and a patch was applied for 24 hours in all eyes.

Various parameters like operating time (starting from placement of lid speculum to its removal at the end of surgery) as well as postoperative symptoms, signs and recurrences were noted for both the groups. Follow up was done on 1st, 7th, 30th, 90th and 180th postoperative day.

Patient Evaluation and Follow-up
Postoperatively, subjects in both groups were treated with Prednisolone Acetate eye drops four times a day which was gradually tapered over a period of 2 months, Moxifloxacin eye drops three times a day and Lubricating eye gel for one month. All subjects were seen and evaluated on 1 day, 1 week, 1 month, 3 months and 6 months postoperatively. During each post operative visit, slit lamp examination and biomicroscopy was performed for every patient. Standardized digital slit lamp photography was performed.

STATISTICAL ANALYSIS:
A prospective analysis was done on the data. Sample size was 60. The results were tabulated in Excel sheet.

Mann- whitney U test was applied for evaluating post operative signs and symptoms.

A multiple regression analysis was used to evaluate effect of various combined effect of independent factors affecting the duration of surgery.

Results
Demographic profile:
The present study comprised of 57 cases (60 eyes) with primary nasal pterygium.

Duration of surgery:
The data on time required for each surgery was collected during the study. The operative time was segregated according to type of
surgery. Table 1 provides the mean and standard deviation of time taken for the two groups. The summary has been graphically depicted in Diagram 1. To determine if the mean time of surgery in two types differ significantly, *t*-test for independent samples was used. The test revealed significant difference between the two groups (p < 0.001).

Post – operative signs and symptoms:
The response on the severity of six symptoms was also obtained post-operatively for each patient. A four point scale from 0 to 3 was used to measure the response, with 0 indicating less severe while 3 indicating very severe. The interest was to know if type of surgery makes any difference in post-operative symptoms, longitudinally, in statistical sense. Since the response data was on ordinal scale, non-parametric Mann-Whitney U test was used to determine the signicance of difference in the severity of each symptom across two surgery types. The analysis was carried out for different time points.

Table 9 a: Post-operative average severity of symptoms after ‘Day 1’ for the two surgery types

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Mean and percent of patients with positive symptoms</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Symptoms</td>
</tr>
<tr>
<td></td>
<td>Fibrin Glue</td>
</tr>
<tr>
<td></td>
<td>Vicryl Suture</td>
</tr>
<tr>
<td>Pain</td>
<td>0.16 (17%)</td>
</tr>
<tr>
<td></td>
<td>0.17 (17%)</td>
</tr>
<tr>
<td>SCH</td>
<td>0.7 (57%)</td>
</tr>
<tr>
<td></td>
<td>0.83 (60%)</td>
</tr>
<tr>
<td>Lacrimation</td>
<td>0.76 (67%)</td>
</tr>
<tr>
<td></td>
<td>1.83 (100%)</td>
</tr>
<tr>
<td>Discomfort</td>
<td>0.56 (50%)</td>
</tr>
<tr>
<td></td>
<td>1.8 (100%)</td>
</tr>
<tr>
<td>Graft Dehiscence</td>
<td>0.23 (23 %)</td>
</tr>
<tr>
<td></td>
<td>0.13 (13%)</td>
</tr>
<tr>
<td>Post Op gaping</td>
<td>0.2 (20 %)</td>
</tr>
<tr>
<td></td>
<td>0.03 (3%)</td>
</tr>
</tbody>
</table>

On day 1, in vicryl group, among all the post operative signs and symptoms, the mean score of lacrimation and discomfort was 1.83 as compared to 0.76 in fibrin glue which was significantly high (p<0.0001) whereas in the glue group, the mean score of graft dehiscence and post operative gaping was 0.2 as compared 0.03 in vicryl suture group. The mean rating of ‘Fibrin glue’ group was 0.76, while that of ‘Sutures’ was 1.83.

Table 9 b: Post-operative average severity of symptoms after ‘Day 7’ for the two surgery types

<table>
<thead>
<tr>
<th>Day 7</th>
<th>Mean and percent of patients with positive symptoms</th>
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<tr>
<td></td>
<td>Symptoms</td>
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<td></td>
<td>Fibrin Glue</td>
</tr>
<tr>
<td></td>
<td>Vicryl Suture</td>
</tr>
<tr>
<td>Pain</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>SCH</td>
<td>0.13 (10%)</td>
</tr>
<tr>
<td></td>
<td>0.26 (23%)</td>
</tr>
<tr>
<td>Lacrimation</td>
<td>0.1 (10%)</td>
</tr>
<tr>
<td></td>
<td>0.96 (83%)</td>
</tr>
<tr>
<td>Discomfort</td>
<td>0.1 (10%)</td>
</tr>
<tr>
<td></td>
<td>0.93 (77%)</td>
</tr>
<tr>
<td>Graft Dehiscence</td>
<td>0.03 (3%)</td>
</tr>
<tr>
<td></td>
<td>0.03 (3%)</td>
</tr>
<tr>
<td>Post op gaping</td>
<td>0.0 (0 %)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

On post operative day 7, the mean score of lacrimation and discomfort was 0.96 and 0.93 respectively i.e. still there was significant lacrimation and discomfort (p<0.0001) in Vicryl group in comparison to fibrin glue group where the mean score of lacrimation and discomfort decreased to 0.1.

Table 9 c: Post-operative average severity of symptoms after ‘Day 30’ for the two surgery types

<table>
<thead>
<tr>
<th>Day 30</th>
<th>Mean and percent of patients with positive symptoms</th>
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<tbody>
<tr>
<td></td>
<td>Symptoms</td>
</tr>
<tr>
<td></td>
<td>Fibrin Glue</td>
</tr>
<tr>
<td></td>
<td>Vicryl Suture</td>
</tr>
<tr>
<td>Pain</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>SCH</td>
<td>0.03 (3%)</td>
</tr>
<tr>
<td></td>
<td>0.03 (3%)</td>
</tr>
<tr>
<td>Lacrimation</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>0.13 (13%)</td>
</tr>
<tr>
<td>Discomfort</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>0.16 (17%)</td>
</tr>
<tr>
<td>Graft Dehiscence</td>
<td>0 (0 %)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Post Op gaping</td>
<td>0 (0 %)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
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</tbody>
</table>

Two patients in suture group had recurrence i.e. recurrence rate is 6.67% at the 5th post operative visit whereas no recurrence was noted in Fibrin glue group at the end of the study period.

Discussion
In our study of 60 patients with pterygium, excision with conjunctival autografting was done with either fibrin glue or 8-0 vicryl sutures. We aimed at studying the post operative signs and symptoms, operating time, their comfort level and recurrence at 6 months post operative visit.

Duration of surgery:
The duration of surgery was studied in both the groups. We found that the mean time of surgery is significantly more in Vicryl group as compared to the Fibrin glue group.

Koranyi et al in 2004 reported 9.7 minutes (range 6-13) for glue and 18.5 minutes (range 12-30), p<0.001. The study done by Karalezli et al in 2008 reported the mean operative time was 15.7 minutes (range 12-18min) with the SD of 2.4 in fibrin glue group and that in 8-0 vicryl suture group was 32.5 min (range 25-40 min) with the SD of 6.7.

Post operative signs and symptoms:
In our study, we studied post operative signs and symptoms like pain, subconjunctival haemorrhage, lacrimation, discomfort, graft dehiscence and post gaping on 5 post operative visits as 1 day, 1 week, 1 month, 3 month and 6 month.

Pain
In our study, we found that on post operative day 1, pain in fibrin glue group (0.16, 17%) was comparatively less than the vicryl suture group (0.17, 17%) it shows that pain was less in glue group as compared to the suture group. On post operative day 7 and 30, there was no complaint of pain in both of the groups. While in the study done by Koranyi et al in 2004 also confirmed the findings of fibrin glue being better than the suture group in post operative pain, as seen by him on day 0 and first post operative visit (p<0.05).

Subconjunctival haemorrhage
Subconjunctival haemorrhage was graded according to the 5 point scale. On postoperative day 1, subconjunctival haemorrhage in the fibrin glue group was 0.7 (57%) and that of suture group was 0.83 (60%). On day 7, the mean score of fibrin glue was 0.13 (10%) while in vicryl suture is 0.26 (23%) whereas it further reduced to 0.03 (3%) in glue group and 0.03 (3%) in the suture group after 30 days. No significant difference was found in either group by us. According to Srinivasan et al in 2009 the post operative subconjunctival haemorrhage showed no significant difference at postoperative week 1 (mean score -18.82) while in the suture group it was (mean score- 16.18), which is statistically insignificant (p>0.417).

Lacrimation 0.76 (67%) patients in the glue group had complain of lacrimation whereas in suture group 1.83 (100%) nearly all patients complained of lacrimation, which statistically signifies the dominance in the suture group (p<0.0001). 0.1 (10%) patients of glue group and 0.96 (83%) in suture group had complained of lacrimation on day 7, which is statistically significant (p<0.0001). Analysis done on patients on day 30, revealed absolutely no complaint of postoperative pain in glue group(0%) while the suture group 0.13(13%) patients had lacrimation. In his study Karalezli et al 2008 also concluded the less complaints of the lacrimation in glue group against the suture group.

Discomfort
We found that 0.56 (50%) patients complained of discomfort in glue group whereas 1.8 (100%) patients had post operative discomfort in vicryl group (p<0.0001) on day 1. Karalezli et al in...
Graft dehiscence
0.23 (23%) patients complained of post operative graft dehiscence in glue group whereas 0.13 (13%) patients in vicryl group had post operative graft dehiscence on day 1. On 30th post operative day graft dehiscence in both the groups was not found.

Koranyi et al in 200417 found no transplant loss or dislocation in his cases in both the groups.

Post operative gaping
On post operative day 1, 0.2 (20%) patients had post operative gaping in glue group whereas 0.03 (3%) patients in suture group had post operative gaping. On subsequent visits that is on post operative day 7 and 30, after correction there was no gaping seen (p = 0.047), which is statistically significant.

Recurrence
The recurrence rates were studied at 3 and 6 month post operatively. It was found that 2 patients in suture group showed recurrences (6.67%) on 6th month post operatively whereas no recurrence was found in the glue group. Koranyi et al in 200417 reported recurrence rate of 8% in glue group and 4 in the suture group (4%) were seen in a post operative period of 2 – 3 months. Koranyi et al in 200518 reported recurrence rate of 5.4% in glue group (14/258 patients) and 13.8% (17/123 patients) in suture group which occurred within 6 months of surgery.

Post operative complications
Post-Operative Complications of pterygium excision are uncommon, and are generally related to the surgical technique but the post operative complications of the pterygium surgery are common and closely studied. In our study, the patients were followed up to 6 months post operatively. In 2009, Sinivasan et al 19 in his study of pterygium excision reported excessive bleeding, button hole of the conjunctiva graft, perforation of the globe with the suture needle, and injury to the medial rectus muscle. Other complications such as pyogenic granuloma, dellen, persistent epithelial defects are not uncommon, but these may be easily treated with no significant long-term sequelae.

Conclusion
60 eyes of 57 patients were included in the study which was randomized into two groups,

- In this study, pterygium excision with conjunctival autograft was attached with either fibrin glue or 8-0 vicryl sutures.
- We found that 56 patients (93%) had symptoms due to pterygium since last 36 months.
- The mean time of surgery is significantly more in vicryl group as compared to the fibrin glue group. T-test revealed significant difference between the two groups (p < 0.001) which is statistically significant.
- On all 5 different postoperative days complaint of pain was less in glue group in comparison to the suture group
- Analysis done using 5 point scale revealed considerably lower complaints of subconjunctival haemorrhage in the glue group against the suture group and subconjunctival haemorrhage disappeared early in glue group as compared to the suture group which took more time to subside.
- Postoperative lacrimation in the glue group was less whereas in suture group, nearly all patients had the complaint of lacrimation.
- Discomfort in the form of itching and foreign body sensation experienced by the patient was less in glue group and it resolved early. While in suture group the discomfort was present for a quite a longer time and resolved late and in some cases suture removal was done.
- Graft dehiscence was noted more in the glue group patients than the suture group and after correction no dehiscence was seen.

- Postoperative wound gaping was seen more in the glue group while it was negligible in the suture group.
- Two patients in suture group had recurrence i.e. recurrence rate is 6.67% at the 5th post operative visit whereas no recurrence was noted in fibrin glue group at the end of the study period.
- Fibrin glue is better than 8-0 vicryl sutures as
- Less operative time
- Less postoperative ocular signs and symptoms
- Better patient comfort
- No recurrence
- No systemic complications due to the use of fibrin glue were noticed in our study.

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4) Cameron M. Pterygium throughout the world. Springeld, IL: Charles C Thomas, 1965