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Original Research Article

A Comparison of Fibrin Glue with Sutures for Conjunctival Autografts in Pterygium Excision Surgery

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Abstract

Background: A pterygium is a triangular-shaped conjunctival growth that extends onto the cornea, and is usually located nasally. Surgery is commonly used to treat this condition. Pterygium surgery involves excision of the pterygium, and the harvesting of a conjunctival graft from the same eye, which is then placed over the defect. The graft, known as an autograft, is either sutured or opposed with fibrin glue. This study has assessed whether one technique is superior to the other when comparing the patient's post-operative comfort and graft adherence.

Methods: A prospective randomized comparison of 60 patients undergoing primary pterygium surgery in Department of Ophthalmology, BMIMS, Pawapuri, Nalanda between October 2020 and March 2021. A post-operative comfort scale was used to assess foreign body sensation, sensitivity to light, tearing and itchiness. Graft success was defined as a graft that was still adherent at one month following surgery.

Results: Patients in the Tisseel glue group experienced significantly less foreign body sensation (p=0.038) and itchiness (p=0.018) on day-one after surgery, compared to those in the suture group. At one-month follow-up patients had significantly less foreign body sensation (p=0.042), sensitivity to light (p=0.001), and itchiness (p=0.009) in the Tisseel glue group compared to the suture group. Autograft adherence was seen in all 60 patients at the one-month follow-up visit. Both the surgical time and the indirect costs of the procedure were reduced in the Tisseel glue group.

Conclusions: The use of Tisseel glue for attaching autografts in pterygium surgery is an effective method with global autograft success, less post-operative discomfort and shorter operating times.

Keywords: Pterygium, Autograft, Fibrin glue, Tisseel glue

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Introduction

The eye is composed of several layers – with the outermost layers consisting of the cornea and sclera and a conjunctival layer covering the sclera. The cornea is the most anterior portion of the globe; and it is responsible for refracting incoming light onto the back of the eye. The cornea is composed of five different layers: the outer epithelium; Bowman's membrane; the stroma; Descemet's membrane and the inner endothelium.

The cornea is nourished, protected and kept moist by a constant tear film, which is distributed over the smooth regular surface of the cornea every time a person blinks. A pterygium is a conjunctival growth that extends from the nasal conjunctiva over the limbus and onto the cornea [1,2].

As a pterygium grows towards the centre of the cornea (visual axis), it may interfere with the tear-film stability of the eye resulting in a dry eye [3]. Pterygia may compromise a patient's vision by growing into the visual axis of the cornea or by altering the curvature of the cornea (astigmatism), thereby affecting the refraction of light onto the back of the eye [4].

The aim of the study to assess post-operative patient comfort and graft success following conjunctival autografts with sutures compared with Tisseel glue for pterygium surgery, and to identify which procedure was the more cost-effective surgical option.

Material and Methods

This prospective randomized comparative study included 60 patients undergoing primary pterygium excision surgery in Department of Ophthalmology, Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar from October 2020 and March 2021.

Patients with pterygia were selected on presentation to the hospital and assigned a number. The patients were numbered from 1 to 60, in the order of presentation; odd numbers were assigned to the Tisseel glue group and even numbers to the suture group.

A pre-operative interview was conducted to obtain a detailed history of the complaint. A slit lamp examination was performed to determine the pterygium size in millimetres, by measuring from the limbus to the corneal limit of the growth in the horizontal plane. The pterygium was to be graded as follows: Grade I pterygia extend less than 2mm onto the cornea; grade II pterygia extend 2mm to 4mm onto the cornea; and grade III pterygia extend more than 4mm onto the cornea.

The patient was examined to exclude any ophthalmic infection, local or uncontrolled systemic disease or infection.

Inclusion criteria:

- Grade I, II and III pterygia;
- Age >18 years of age;
- No previous pterygium surgery.

Exclusion criteria:

- Patients <18 years of age;
- History of eye trauma or pseudopterygium;
- Intra-ocular and local disease.

Data Analysis: The data was captured in Microsoft Excel 2011 and imported into IBM SPSS Version 20 for further analysis.

Results

Sixty patients, with a median age of 50 years, were enrolled in the study. Forty-two (70%) were female, 18 (30%) were male.

Patients rated their level of discomfort following surgery on a scale of 1 to 4 for foreign body sensation, sensitivity to light, tearing and itchiness, with 1 being indicative of no discomfort, 2 reflecting mild discomfort, 3 for moderate discomfort, and 4 for severe discomfort. The Mann-Whitney U test was used to assess these parameters; the lower the mean rank, the less discomfort the patient had experienced.

Patients in the Tisseel glue group experienced significantly less foreign body sensation and itchiness on the day after surgery, compared to the suture group, with a mean rank of 25.77 versus 35.55 (p=0.038) for foreign body sensation and

25.98 versus 35.33 (p=0.018) for itchiness. Sensitivity to light and tearing showed no statistical difference between the two

groups, with mean ranks of 27.42 versus 33.79 (p=0.620) and 26.84 versus 34.41 (p=0.650), respectively.

Table 1: Comparison of Mean rank in level of comfort day 1 post-operatively

| Groups | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|--------------|------------------------|----------------------|---------|-----------|
| Glue group | 25.77 | 27.42 | 26.84 | 25.98 |
| Suture group | 35.55 | 33.79 | 34.41 | 35.33 |

Similar results were seen at one-month follow-up, with patients in the Tisseel glue group experiencing less discomfort compared to the suture group. Foreign body sensation was statistically lower in the Tisseel glue group compared to the suture group, with a mean rank of 26.40 versus 34.60 (p=0.042), as also were sensitivity to light and itchiness with mean ranks of 24.12 versus 36.88 (p=0.001) and 26.43 versus 34.57 (p=0.009), respectively. The amount of tearing showed no statistical difference between the two groups, showing a mean rank of 29.00 versus 32.00 (p=0.232).

Table 2: Comparison of Mean rank in level of comfort 1 month post-operatively

| Groups | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|--------------|------------------------|-----------------------------|---------|-----------|
| Glue group | 26.40 | 24.12 | 29.00 | 28.50 |
| Suture group | 34.60 | 36.88 | 32.00 | 32.50 |

At the three-month follow-up visit, there were no statistical differences between the two groups, when comparing foreign body sensation (mean rank 30.00 vs 31.00, p=0.317), sensitivity to light (mean rank 30.00 vs 31.00, p=0.317) and tearing (mean rank 29.50 vs 31.50, p=0.154). However, the difference in discomfort attributed to itchiness between the two groups proved to be statistically significant, with mean ranks of 28.50 for Tisseel glue group and 32.50 for suture group (p=0.040).

Table 3: Comparison of Mean rank in level of comfort 3 months post-operatively

| Groups | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|--------------|------------------------|-----------------------------|---------|-----------|
| Glue group | 30.00 | 30.00 | 29.50 | 28.50 |
| Suture group | 31.00 | 31.00 | 31.50 | 32.50 |

Table 4 demonstrates mean comfort scores over the three-month follow-up period in the Tisseel glue group. The lower the mean value, the less discomfort the patient experienced. When analysing, which dimension of discomfort was the most noticeable, Table 4 shows that foreign body sensation caused the most discomfort day-one, and one-month following surgery, when compared to sensitivity to light, tearing and itchiness.

Table 4: Mean Rank of Tisseel glue group-changes in level of comfort on follow-up visits

| Follow up Visit | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|-----------------|-------------------------------|----------------------|---------|-----------|
| Day 1 | 1.80 | 1.20 | 1.60 | 1.30 |
| 1 month | 1.37 | 1.17 | 1.07 | 1.07 |
| 3 month | 1.00 | 1.00 | 1.00 | 1.00 |

The Table 5 demonstrates mean comfort scores over the three-month follow-up period in the suture group. Foreign body sensation caused the most discomfort on day-one and one month following surgery.

Table 5: Mean Rank of Suture group-changes in level of comfort on follow-up visits

| Follow up Visit | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|-----------------|-------------------------------|----------------------|---------|-----------|
| Day 1 | 2.27 | 1.60 | 1.93 | 1.77 |
| 1 month | 1.77 | 1.70 | 1.17 | 1.40 |
| 3 month | 1.03 | 1.03 | 1.10 | 1.20 |

Pterygia were graded clinically (Table 1 Clinical grading system of pterygia and associated complications), according to how far they extend onto the cornea. The Kruskal Wallis test was used to ascertain whether the grade of the pterygium would impact on patient comfort following surgical excision; the lower the mean rank, the less the discomfort. However, the numbers of grades I, II and III pterygia were unbalanced and few (grade I= 9 patients, grade II= 34 patients, grade III= 17 patients); and therefore, the Monte Carlo Test was utilized to show any significant differences in comfort between the different grades of pterygia at all follow-up appointments.

Day one following surgery, the mean ranks for foreign body sensation for grades I, II and III pterygia were: 26.72, 30.37 and 34.56 respectively (p=0.491); sensitivity to light: 27.22, 32.39 and 30.15 respectively (p=0.560); tearing: 23.33, 31.33 and 34.38 respectively (p=0.249); and itchiness: 29.11, 32.02 and 29.88 respectively (p=0.828) [Table 6]. Therefore, on day-one following surgery, no significant differences between the level of comfort and pterygium size were noted.

Table 6: Mean Rank of Grade of pterygium and level of comfort day 1 post-operatively

| Grade Pterygium | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|-----------------|-------------------------------|----------------------|---------|-----------|
| Grade 1 | 26.72 | 27.22 | 23.33 | 29.11 |
| Grade 2 | 30.37 | 32.39 | 31.33 | 32.02 |
| Grade 3 | 34.56 | 30.15 | 34.38 | 29.88 |

One month following surgery, the mean ranks for foreign body sensation for grades I, II and III pterygia were: 34.61, 30.85 and 27.62 respectively (p=0.570); sensitivity to light: 32.33, 31.28 and 27.97 respectively (p=0.676); tearing: 27.00, 32.29 and 28.76 respectively (p=0.285); and itchiness: 27.72, 29,79 and 33.38 respectively (p=0.469) [Table 7]. This shows that one month following surgery, no significant difference between the level of comfort and pterygium size was shown.

Table 7: Mean Rank of Grade of pterygium and level of comfort 1 month post-operatively

| Grade Pterygium | Foreign Body Sensation | Sensitivity to Light | Tearing | Itchiness |
|-----------------|------------------------|----------------------|---------|-----------|
| Grade 1 | 34.61 | 32.33 | 27.00 | 27.72 |
| Grade 2 | 30.85 | 31.28 | 32.29 | 29.79 |
| Grade 3 | 27.62 | 27.97 | 28.76 | 33.38 |

It was expected that at three-months follow-up, the grade of the pterygium pre-operatively would still not impact on the patient's level of comfort. At three months, there was no significant difference between the grade of the pterygium and the four dimensions of discomfort: foreign body sensitivity; sensitivity to light; tearing and itchiness, showing p values of 1.000, 1.000, 1.000 and 0.598, respectively.

Discussion

Total 60 patients were recruited for the study. The median age was 50 years, 42 (70%) were females, 18 (30%) were male. A female predominance was noted in this study.

Today, several methods for pterygium surgery are used – from bare scleral techniques to the use of medical and surgical adjunctives [5-7]. Pterygium surgery is commonly performed in this institution, using vicryl sutures to secure the autograft. This technique requires a high level of surgical expertise, and also has several disadvantages.

These include: prolonged surgery time, the possibility of suture-related complications, such as suture granulomas (mass of granulation tissue), abscess formation, tissue necrosis (cell death), giant papillary conjunctivitis; and importantly, the patient may complain postoperatively of ocular irritation including foreign body sensation, pain, redness and itchiness [8,9].

An upregulation in the inflammatory response around vicryl sutures in the conjunctiva seems to be responsible for these adverse events [10]. Therefore, by replacing the sutures with Tisseel fibrin glue; it would be expected that the graft would adhere and the post-operative discomfort and other complications associated with the suture material could well be alleviated.

Tisseel fibrin glue is registered with the Medical Control Council as a blood fraction, which is used to achieve haemostasis, to seal or glue tissues, and to support wound healing. The use of ocular tissue adhesives was proposed in 1963; and in the late 1970s, fibrin adhesives became commercially available in Europe [11]. Their use in included Ophthalmology conjunctival wound closure. cataract surgery, oculoplastic and orbital surgery, repair of leaking blebs, lamellar keratoplasty and amnion patching. The "cut-and-paste" method used by Koranyi *et al.* comprises the use of Tisseel tissue glue to secure the autograft; and it was developed to reduce post-operative patient discomfort, and to reduce surgical time [12].

Uy et al. later also found fibrin glue to be a safe and effective method for attaching autografts, as well as reducing surgical time and post-operative patient discomfort and more recently, Nieuwendaal et al. reported the use of Tisseel glue to be a safe, easy and effective technique for attaching the autograft with low recurrence rates [13].

There have been no studies prior to this one at St John eye Hospital regarding the use of adjunctives in pterygium surgery. The possibility of a safe, easy and effective surgical technique that could reduce patient discomfort, surgical time and costs in our institution was the driving force behind this prospective, randomized, comparative study.

Pterygium excision was performed using the technique described by Starck *et al*. The autograft was adhered with either Tisseel fibrin glue or vicryl sutures. Overall, patients in the Tisseel glue group on day-one and one-month following surgery were more comfortable than those in the suture group. The conclusion in this study that Tisseel glue significantly reduces post-operative discomfort is consistent with the literature [8-10,13-15].

The size or grade of a pterygium is related to the extent to which it encroaches on the cornea; and it was thereby assumed that the greater the surface area of cornea involved in the procedure, the greater the postoperative discomfort. However, in this study, the grade of the pterygium did not impact on the amount of post-operative discomfort at any of the follow-up appointments. This observation was also noted in a study by Bahar *et al.*, where regression analysis failed to show any correlation between pterygium size and discomfort [15].

Koranyi et al. reported no autograft losses or dislocations in their study that compared glue and sutures to attach conjunctival autografts in pterygium excision surgery [12]. In this study, autograft success was defined as a graft that was still adherent and intact at one-month follow-up. This study showed a 100% graft success in both groups of patients; and it highlights the fact that both techniques are effective for securing the autograft in pterygium excision surgery. Recurrence is a common complication of pterygium surgery; and the success of this surgery is based on avoiding this complication. Recurrence rates vary in the literature, based on the surgical expertise, the surgical technique, and the adjunctives used.

Conjunctival autografting, regardless of the material used, following pterygium surgery has been associated with lower recurrence rates of 2% to 9 %.14 Hirst et al. reported a larger variability in recurrence rates of 2% to 39% when using glue-assisted conjunctival autografts [5]. In this study, recurrence was seen in seven (11.7%) patients: four (6.7%) patients in the glue group, and three (5%) in the suture group. These recurrence rates are consistent with the literature. However, the small sample size and the duration of the follow-up need to be taken into consideration when interpreting the data.

When assessing the cost-effectiveness of a procedure, it is conventional to distinguish between the direct costs and the indirect or productivity costs, associated with the intervention, as well as what are termed intangibles, which, although they may be difficult to quantify, are often consequences of the intervention, and should therefore be included in the cost profile [16,17].

Conclusion

This comparison of the use of Tisseel fibrin glue and vicryl sutures in pterygium excision surgery showed that patients post-operatively in the Tisseel glue group were significantly more comfortable than those in the suture group. Graft success was documented in all patients of both surgical groups. Tisseel fibrin glue is, therefore, considered an effective method for attaching conjunctival autografts; and it also offers the benefit of less postoperative discomfort, shorter operating times, and reduced overall costs for the procedure.

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