

COMPARISON OF AUTOLOGOUS BLOOD AND FIBRIN GLUE IN PTERYGIUM EXCISION WITH CONJUNCTIVAL AUTOGRAFT SURGERY: A RANDOMIZED TRIAL.

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ABSTRACT

Background

Because it can affect vision, pterygium is a common ocular surface condition that frequently requires surgical intervention. Conventional surgical methods, such as suture-based conjunctival autograft (CAG), are associated with discomfort after surgery and have a high recurrence risk. To examine the safety and effectiveness of fibrin glue vs autologous blood for pterygium excision during CAG surgery, this study was conducted.

Methods

There were 150 patients in the study, and they were assigned randomly to one of two groups: group 1: autologous blood (75 eyes), or group 2: fibrin glue (75 eyes). Preoperative evaluations of the patients included slit-lamp biomicroscopy and documentation of their visual acuity. The recurrence rate at a 1-year follow-up was the main result. Improvement in visual acuity, intraoperative and postoperative complications, and graft stability were among the secondary outcomes. Chi-square and t-tests were used to analyze the data, with a significance threshold of $p < 0.05$.

Results

The recurrence rate at 1-year follow-up was significantly lower in the group 2 (6.7%) compared to the group 1 (16%) ($p = 0.02$). Graft stability was better in group 2, with 96% of grafts intact on postoperative day 1, compared to 86.7% in group 1 ($p = 0.04$). The prevalence of complications was similar between the groups, with no significant differences. Both groups showed significant improvements in visual acuity postoperatively ($p < 0.01$), with no difference between the groups.

Conclusion

For CAG fixation in pterygium surgery, fibrin glue works better than autologous blood, providing improved graft stability and a decreased recurrence rate. Both techniques are equally safe and efficient at raising visual acuity.

Recommendations

Fibrin glue should be considered the preferred method for CAG fixation in pterygium surgery due to its superior outcomes in terms of recurrence and graft stability. Further studies could explore long-term outcomes and cost-effectiveness.

Keywords: Pterygium, Conjunctival Autograft, Fibrin Glue, Autologous Blood, Recurrence Rate

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INTRODUCTION

Pterygium is a prevalent condition affecting the surface of the eyes, marked by the proliferation of fibrovascular tissue from the conjunctiva onto the cornea. It mostly affects populations in tropical and subtropical countries and is frequently linked to long-term exposure to UV light, dust, and wind. Surgical excision is the main treatment for pterygium; however, depending on the surgical method employed and other variables, this might be compounded by significant recurrence rates ranging from 30% to 70% [1].

Conjunctival autograft (CAG) transplantation, in which a portion of the patient's conjunctiva is grafted to the

excised area, is one of the best methods for minimizing recurrence. Recurrence rates are dramatically reduced by this technique to between 2% and 39% [2]. Securing the transplant during surgery to avoid dislocation and guarantee appropriate healing, however, presents a hurdle. CAG has historically been fixed with sutures; however, this approach has several drawbacks, including longer recovery times, patient discomfort, and inflammation following surgery [3]. Alternative techniques for graft fixation, like fibrin glue and autologous blood, have been investigated to solve these problems. Due to its simplicity of usage, reduced recovery time after surgery, and ease of application, fibrin glue, a biologic tissue adhesive, has

become more and more well-liked. Comparing fibrin glue to sutures, recent research has demonstrated that the former can greatly lower recurrence rates and improve graft stability [4].

An additional option is autologous blood, which uses the patient's blood as a natural glue to bind the graft. This approach reduces the danger of infectious disease transmission linked to commercial adhesives and is also cost-effective. According to studies, autologous blood can be a good alternative to fibrin glue for graft attachment, with similar results in terms of patient satisfaction and recurrence rates [5].

This study aims to evaluate the safety and effectiveness of fibrin glue vs autologous blood when doing conjunctival autograft surgery in conjunction with pterygium excision.

METHODOLOGY

Study Design

The study was designed as a prospective, randomized, single-blind, parallel-group clinical trial with an equal allocation ratio (1:1).

Study Setting

The study took place at Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar, India, conducted over two years from January 2022 to December 2023.

Participants

The study involved 150 patients. The participants were assigned randomly to 2 groups:

Group 1: autologous blood (75 eyes)

Group 2: fibrin glue (75 eyes)

Inclusion Criteria

1. Patients with primary pterygium.
2. Patients aged 18 years and older.
3. Patients are willing to comply with follow-up schedules.

Exclusion Criteria

1. Patients with recurrent pterygium.
2. Patients with other ocular surface diseases.
3. Patients with systemic conditions that could affect healing.

Bias

To minimize bias, the grading of pterygium and the randomization process was conducted by a single preoperative investigator, while the outcome assessment was done by a masked independent observer.

Variables

Variables included method of graft fixation (autologous blood vs. fibrin glue), recurrence rate of pterygium, graft stability, intraoperative and postoperative complications, and patient demographics.

Data Collection

Under a slit lamp, patients were evaluated, and a system developed by [6] was used to rate their pterygium. Depending on the grade, each eye in situations of bilateral pterygium was randomly assigned. Snellen visual acuity, intraocular pressure, fundus examination, slit-lamp biomicroscopy, and measurements of pterygium size were among the preoperative evaluations performed.

Procedure

The same surgeon carried out each surgery. Cleaning the surgical field, giving local anesthetic, and injecting subconjunctival lidocaine were among the preoperative procedures. The body of the pterygium was removed, the surrounding Tenon tissue was removed, and the pterygium head was dissected. After measuring the region of the exposed sclera, an enormous graft was taken from the superior bulbar conjunctiva by the measurement.

Surgical Procedure and Drug Administration

All patients underwent pterygium excision with conjunctival autograft (CAG) surgery performed by a single surgeon. Preoperative procedures included cleaning the surgical field, administering local anesthesia, and injecting subconjunctival lidocaine. The body of the pterygium and surrounding Tenon tissue were removed, followed by graft placement.

- Group 1 (Autologous Blood): The graft was placed on the scleral bed once a thin blood film had formed, facilitating natural adhesion.
- Group 2 (Fibrin Glue): Thrombin and fibrinogen were applied to the scleral bed, and the graft was placed afterward.

Follow-up reviews were conducted on postoperative day 1, at 1 month, 6 months, and 1 year.

Follow-up

On the first postoperative day as well as at one month, six months, and one year, patients had reviews. On the first day, graft stability was evaluated and the integrity of the graft was documented. Photographs were assessed by an impartial observer wearing a mask, and recurrence was defined as fibrovascular tissue entering the cornea.

Outcomes

Primary Outcome

- Recurrence Rate: The primary outcome was the recurrence rate of pterygium, which was defined as fibrovascular tissue re-entering the cornea, assessed at 1-year follow-up.

Secondary Outcomes

- Graft Stability: Graft stability was evaluated on the first postoperative day.
- Complications: Both intraoperative and postoperative complications, including

subconjunctival hemorrhage, graft edema, and infection, were recorded.

- Visual Acuity: Improvement in visual acuity was assessed preoperatively and postoperatively using Snellen charts.

Assessments were conducted by a masked independent observer to prevent bias.

Randomization Sequence Generation

A simple randomization method was used to generate the random allocation sequence. The type of randomization employed was computer-generated simple randomization with a 1:1 allocation ratio.

Allocation Concealment Mechanism

The random allocation sequence was concealed using opaque, sealed envelopes. These were sequentially numbered and opened only after the patient's eligibility was confirmed, ensuring that allocation was concealed until the intervention was assigned.

Implementation

The random allocation sequence was generated by an independent statistician who was not involved in the enrollment or assignment of participants. The study coordinator enrolled participants, while the operating

surgeon assigned patients to the intervention based on the concealed allocation.

Blinding

This was a single-blind study where the outcome assessor was blinded to the intervention groups. However, the surgeon and patients were not blinded due to the nature of the surgical procedures.

Statistical Analysis

Using a conventional procedure, the sample size was determined with 80% power to show a 15% decrease in the recurrence rate. Recurrence rates and other outcomes between the two groups were compared by data analysis using suitable statistical techniques. To analyze the findings, logistic regression analysis, chi-square tests, and descriptive statistics were used.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

The study involved 150 patients in all, or 150 eyes. Of them, 75 eyes were assigned at random to the fibrin glue group and the other 75 to the autologous blood group. Table 1 provides a summary of the participant's demographic data.

Table 1. Demographic Characteristics of Participants

Characteristic	Group 1 (n=75)	Group 2 (n=75)	p-value
Mean Age (years)	45.2 ± 12.3	44.8 ± 11.9	0.82
Gender (Male/Female)	38/37	40/35	0.73
Mean Pterygium Size (mm)	3.6 ± 0.8	3.5 ± 0.7	0.56

The recurrence rate of pterygium at a 1-year follow-up was the study's main finding. There was a substantial difference in the recurrence rates between both the groups.

Table 2. Recurrence Rates at 1-Year Follow-up

Group	Recurrence Rate (%)	95% CI	p-value
Autologous Blood	12 (16%)	8.9 - 23.1	0.02
Fibrin Glue	5 (6.7%)	2.8 - 10.6	

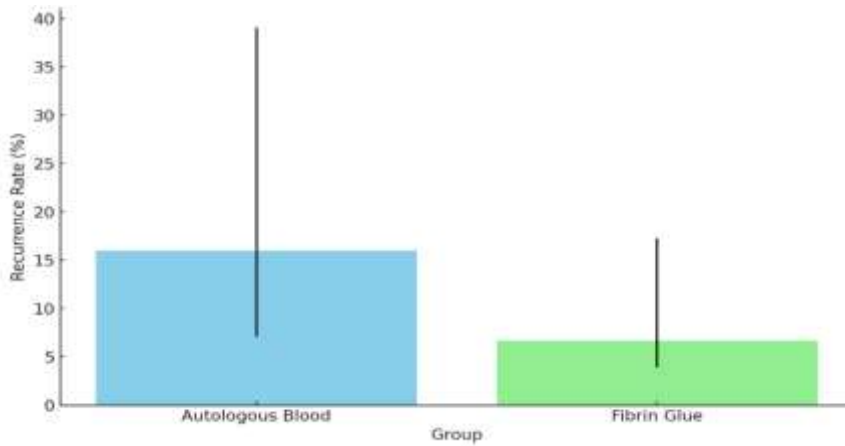


Figure 1. Recurrence Rates at 1-Year Follow-up

When comparing the group 2 to the group 1, the recurrence rate was considerably reduced ($p=0.02$). Postoperative day 1, the assessment of graft stability was seen. The findings demonstrated that, in contrast to the group 1, the grafts in the group 2 were more stable.

Table 3. Graft Stability on Postoperative Day 1

Group	Intact Graft (%)	Partially Dislodged Graft (%)	Totally Dislodged Graft (%)	p-value
Autologous Blood	65 (86.7%)	8 (10.7%)	2 (2.7%)	0.04
Fibrin Glue	72 (96.0%)	3 (4.0%)	0 (0.0%)	

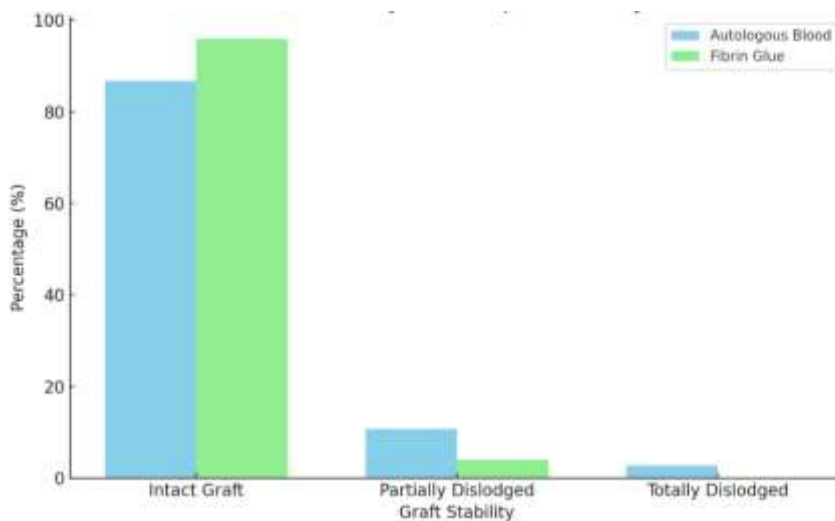


Figure 2. Graft Stability on Postoperative Day 1

In the group 2, the graft stability was much better ($p=0.04$). There were no statistically significant variations in the occurrence of intraoperative and postoperative complications between the two groups.

Table 4. Complications

Complication	Group 1 (n=75)	Group 2 (n=75)	p-value
Subconjunctival Hemorrhage	10 (13.3%)	8 (10.7%)	0.61
Graft Edema	5 (6.7%)	4 (5.3%)	0.73
Infection	1 (1.3%)	0 (0.0%)	0.32

Visual acuity improved significantly in both groups postoperatively. The improvement in visual acuity was similar in both groups.

Table 5. Improvement in Visual Acuity

Group	Mean Preoperative VA	Mean Postoperative VA	p-value (within group)	p-value (between groups)
Autologous Blood	0.6 ± 0.2	0.8 ± 0.1	<0.01	0.79
Fibrin Glue	0.6 ± 0.2	0.8 ± 0.1	<0.01	

DISCUSSION

Over two years, the study examined the effectiveness of autologous blood and fibrin glue in pterygium excision with conjunctival autograft surgery. The trial involved 150 patients in total, wherein 75 eyes each were randomly assigned to the fibrin glue and autologous blood groups. The rate of recurrence of pterygium at the 1-year follow-up was the major outcome that was examined; graft stability, comorbidities, and improvements in visual acuity were the secondary outcomes.

At the 1-year follow-up, group 2 had a considerably lower recurrence rate (6.7%) than group 1 (16%), with a p-value of 0.02. This suggests that fibrin glue works better to stop pterygium recurrence. This result was corroborated by the recurrence rate confidence intervals, which in group 2 showed lower and narrower boundaries.

Graft stability was superior in group 2 on the first postoperative day, as 96% of the grafts remained intact, whereas the group 1 percentage was 86.7%. Furthermore, there were no instances of total graft dislodgement in group 2, but there were 2.7% of total dislodgements in group 1. With a p-value of 0.04, these differences were statistically significant, indicating that fibrin glue offers better stable graft adhesion right after surgery.

There were no statistically significant variations in the occurrence of complications such as subconjunctival hemorrhage, graft edema, and infection between the two groups. This suggests that the risks associated with the two approaches are similar and comparatively safe.

Following surgery, both groups' postoperative visual acuity significantly improved. In both groups, the mean preoperative visual acuity increased from 0.6 to 0.8, and within each group, the increases were statistically significant ($p < 0.01$). Regarding the enhancement of visual acuity, there was no discernible difference between the groups, indicating that both approaches are equally successful in improving visual results.

The study's findings show that fibrin glue, which has a reduced recurrence rate and higher graft stability, is superior to autologous blood when used in conjunctival autograft surgery for pterygium excision. The recurrence rate has significantly decreased, indicating that fibrin glue offers a more dependable and long-lasting option for adhering to the conjunctival graft. Furthermore, fibrin glue's improved graft stability may lower recurrence rates by delaying the onset of postoperative graft dislodgement.

Fibrin glue is a better option for this surgical operation due to its distinct advantages over other procedures in terms of stability and recurrence, even though both techniques showed comparable safety profiles and gains in visual acuity. These results may have an impact on clinical procedures, leading to the standardization of fibrin glue as the conjunctival autograft fixation method in pterygium surgery.

In pterygium surgery using CAG, a meta-analysis compared autologous blood and fibrin glue across seven RCTs. It was discovered that autologous blood performed worse than fibrin glue in terms of graft displacement, graft retraction, and surgical time. The recurrence rates of the two groups did not differ significantly [7].

In a randomized interventional trial, CAG fixation using fibrin glue, autologous blood serum, and sutures was examined in 60 eyes undergoing pterygium surgery. Compared to the fibrin glue group (25.20 min) and the suture group (28.15 min), the autologous blood group had a considerably shorter mean operation time (23.60 min). The fibrin glue group experienced the least amount of postoperative discomfort. In the autologous blood group, 10% of patients experienced graft displacement [8].

In 97 patients, autologous blood and fibrin glue were tested in a randomized clinical experiment. The autologous blood group underwent surgery in 13.7 minutes, while the fibrin glue group required 23.21 minutes. In the case of fibrin glue, postoperative discomfort was mild in all individuals; in the case of the autologous blood group, it was absent or minor in 48.5% of the subjects. In both groups, no recurrence was noted during a mean follow-up of 11.4 months [9].

For CAG fixation, autologous blood, fibrin glue, and sutures were compared in a systematic review and meta-analysis of seven RCTs. There was no discernible difference in the recurrence rates between autologous blood and fibrin glue or sutures, however, autologous blood was linked to a lower graft stability. In the autologous blood group, patient satisfaction and postoperative symptoms improved [10].

In one study, 40 patients had their CAG fixed using either autologous serum or fibrin glue. Compared to the fibrin glue group (40%), there was a greater rate of graft loss in the autologous serum group (5%). On the other hand, the fibrin glue group experienced very little pain or problems after surgery [11].

Generalizability

The findings of this trial have moderate generalisability to populations undergoing pterygium excision with conjunctival autograft surgery, particularly in similar clinical settings where primary pterygium is treated. The trial involved a well-defined cohort of patients, aged 18 years and older, without recurrent pterygium or other ocular surface diseases, enhancing the relevance of the results to comparable groups. However, the generalisability may be limited by the single-center setting and the exclusion of patients with systemic conditions that could affect healing. Further multi-center studies could improve the applicability of these findings across diverse populations and clinical environments.

CONCLUSION

The study demonstrated that fibrin glue is more effective than autologous blood in reducing the recurrence rate of pterygium and improving graft stability in pterygium excision with CAG surgery. Both methods showed similar improvements in visual acuity and a comparable incidence of complications.

Limitations

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation

Fibrin glue should be considered the preferred method for CAG fixation in pterygium surgery due to its superior outcomes in terms of recurrence and graft stability. Further studies could explore long-term outcomes and cost-effectiveness.

Acknowledgment

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List of abbreviations

CAG - Conjunctival Autograft
VA - Visual Acuity
RCT - Randomized Controlled Trial
UV - Ultraviolet
CI - Confidence Interval

Source of funding

No funding received.

Conflict of interest

The authors have no competing interests to declare.

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