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Comparing the Efficacy of Autologus Blood Serum vs Fibrin Glue in Conjunctival Autograft for Pterygium Excision

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Abstract: ***Background*: Pterygium is a progressive condition where abnormal conjunctival tissue grows onto the cornea, often caused by UV exposure. It affects populations in tropical regions more frequently. Although early stages are asymptomatic, advanced pterygia can cause visual impairment and cosmetic concerns due to corneal involvement. Surgical removal is typically necessary, with techniques evolving from bare sclera excision (now obsolete due to high recurrence rates) to modern methods like conjunctival-limbal autografts. Recent advancements include using fibrin glue instead of sutures to secure grafts, reducing surgery time and postoperative discomfort. Comparisons between fibrin glue and autologous blood serum, a newer alternative, aim to evaluate operative outcomes, cost-effectiveness, and complication rates in pterygium surgery. Therefore, the purpose of this study is to compare the effectiveness of fibrin glue and autologous blood serum in conjunctival autograft in pterygium surgery. *Material and method*: This prospective experimental study was conducted on Grade II and III pterygium patients who attended Ophthalmology OPD in Rajarajeswari Medical College and Hospital in Bengaluru, India, over a period from August 2022 to February 2024. A total of 100 eligible patients were randomly divided into two groups of 50 participants each. Pre-operative assessments included comprehensive ocular evaluations, and all patients underwent pterygium excision followed by graft placement using either autologous blood serum (Group A) or fibrin glue (Group B). Post-operative follow-ups were conducted at specific intervals to monitor outcomes and complications. Data analysis was performed using IBM SPSS Version 21.0, employing descriptive statistics and appropriate statistical tests to compare results between the two groups. This study contributes valuable insights into optimizing surgical techniques for pterygium management, with implications for improving patient outcomes and reducing recurrence rates. Ethical clearance was obtained, ensuring adherence to ethical standards throughout the study. *Results*: For conjunctival autografts in pterygium surgery, the study contrasted fibrin glue with autologous blood serum. Key findings include a predominant patient age range of 41-60 years, with slightly more males than females in both groups. The left eye was most commonly affected, with all patients experiencing foreign body sensation pre-operatively. Visual impairment and cosmetic concerns were also noted. Operative times were longer with autologous blood serum (Group A) compared to fibrin glue (Group B). Post-operatively, more patients in Group B initially reported pain, though by one month, both groups showed resolution. Foreign body sensation followed a similar trend. Significantly, graft loss occurred more frequently in Group B (fibrin glue) than in Group A (autologous blood serum), with a notable difference in recurrence rates, although not statistically significant. Pre-operative and post-operative visual acuity improvements were observed in both groups, with no significant difference between them. These findings underscore the efficacy and comparative outcomes of using autologous blood serum versus fibrin glue in conjunctival autografts for pterygium surgery. *Conclusion*: Therefore, we draw the conclusion that although though the Autologous Blood Serum group's mean operating time was longer than the Fibrin Glue group's, there were less post-surgical complications in the group receiving autologous blood serum, with a statistically significant difference in the complication of graft loss. Therefore, conjunctival autograft combined with pterygium removal produces better outcomes. Conjunctival autograft fixation with autologous serum is a feasible and safe substitute for the fibrin glue method.***

Keywords: pterygium surgery, autologous blood serum, fibrin glue, conjunctival autograft, ophthalmic surgery

1. Introduction

Pterygium is a degenerative disease of the subconjunctival tissue that invades the cornea and destroys it by multiplying as vascularized granulation tissue. Superficial layers of Bowman's membrane and stroma, are covered by conjunctival epithelium[1]. In the palpebral fissure area, vascularized conjunctival tissue encroaches on the cornea in the form of a wing-shaped triangular intrusion[2]. Because of exposure to ultraviolet (UV-B) sunshine, it is more common in tropical and subtropical regions.

Pterygia that extends over the cornea results in cosmetic deformity, induced astigmatism, and obstruction of the visual axis, which impair vision.[3'4] It requires surgical removal because the medicinal treatment for this problem is inadequate. The bare sclera procedure, conjunctival graft autorotation, amniotic membrane graft, and conjunctivo-limbal autograft are examples of surgical techniques that have changed throughout time[5–7]. Surgery is recommended for the following reasons: (1) cosmetic; (2) visual axis involvement; and (3) induced astigmatism.[12]

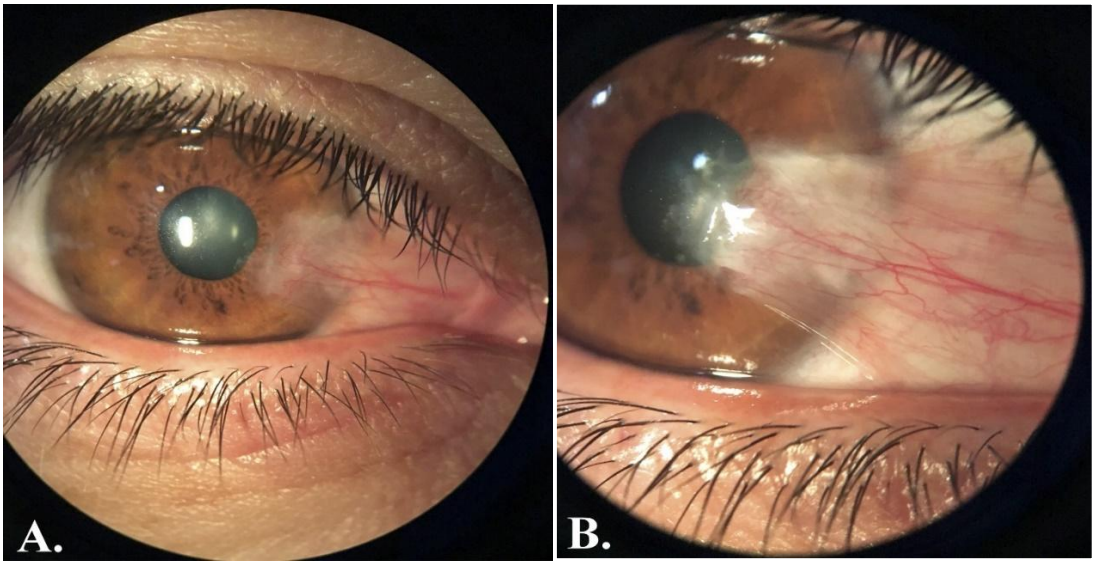

Figure 1: (A) Nasal Pterygium of the Right Eye (B) Higher magnification.

Adjunctive therapy, which drastically lower the recurrence rate, are taken into consideration to prevent recurrence. These consist of amniotic membrane grafting, conjunctival or limbal conjunctival autograft (CAG), radiation therapy, and the administration of Mitomycin C. Since surgical techniques have a high probability of recurrence, no single technique has been widely acknowledged as ideal.

Adhesives were used to replace the sutures, which shortened the operating time and increased post-operative comfort. However, the price and possible risk of infection transmission are fibrin glue's main issues[8]. Being a substance derived from blood, fibrin biodegradable, user-friendly biologic glue. You can keep it at room temperature. It imitates the final stage of the cascade of coagulation. Nonetheless, the price of five sutures is roughly equivalent to the cost of fibrin glue[10]. By using the patient's own blood, the risk of disease transmission, autoimmune reactions, and allergic accidents are eliminated. This way, adhesive costs are avoided, along with the hassle of preparation and any doubts about its sterilization status. All of these problems brought on by sutures were lessened by fibrin glue and autologous blood. Autologous blood and fibrin glue helped to alleviate all of these suture-related problems. A significant advancement in pterygium surgery was the use of fibrin glue to secure autograft[11]. In light of this, the current study aimed to examine the outcomes of fibrin glue and autologous blood serum in pterygium surgery, as well as the cost and duration of the procedure and the complications that arose from the aforementioned surgical technique.

Purpose of Study

This study aims to compare the efficacy of autologous blood serum and fibrin glue for conjunctival autograft fixation in pterygium excision, focusing on operative outcomes, post-operative complications and recurrence rates.

2. Methodology

This prospective experimental study is conducted among 100 Pterygium patients attending the OPD at Rajarajeswari medical college Hospital, Bangalore from August 2022-February 2024. After informed consent from the patients who are willing to participate in the study.

Study Design: Prospective Experimental Study

Inclusion Criteria

- Patients age 18 years and above, consenting for the study
- Patients diagnosed with Grade II and Grade III Pterygium

Exclusion Criteria

- Patients diagnosed with Grade 1 Pterygium
- Pseudo-pterygium, Recurrent pterygium
- Any other Ocular Surface Pathology
- Patients not consenting for the study

3. Methodology of Study

Pterygium patients who attended the outpatient and inpatient department, fulfilling inclusion and exclusion criteria were enrolled in the present study.

Estimation of Sample Size:

For the study population fitting the inclusion criteria with study duration of 18 months, the Yamane formula was used to determine the sample size.

$$n = N/1+Ne2$$

n=sample size N=population size

e= margin of error (for 95% of confidence level, margin error =0.05)

$$n=100$$

Therefore, the sample size of the study participants was fixed at 100.

A total 100 Pterygium Patients with grade Grade II and III were randomly selected and divided into two groups of 50 patients each. Routine pre-operative evaluation done as per standards which includes Relevant ocular history, Uncorrected and best corrected visual acuity, Slit lamp examination of type and extent of pterygium, Pre operative

refraction, Fundus examination, IOP using Applanation Tonometry, Keratometry and Lacrimal Syringing.

Both groups underwent pterygium excision and replacement with conjunctival autograft following **Group A** using Autologous Blood Serum and **Group B** using Fibrin Glue. The surgical procedure was explained to the patient. Patients in groups A and B are having pterygium excision and conjunctival limb autografts utilizing autologous blood serum and fibrin glue, respectively. Post operated patients were reviewed on Post-Operative Day1, followed up after 1 week and then after 1 month. Results were judged, based on the observations, clinical examinations, investigation and outcome interpretation as per proforma.

Figure 2: Fibrin Glue kit comprising of A) Human Fibrinogen B) Synthetic Aprotinin C) Calcium Chloride D) Human Thrombin E) Duploject Injection

Ethical committee approval: ***The Institutional Ethics Committee granted ethical permission for the study (D.No.RRMCH-IEC/119/2022). Prior to their participation in the study, the individuals gave their informed consent.***

Statistical Analysis:

Data analysis was done using SPSS (Version 26.0). The threshold for significance was set at 5% ($\alpha = 0.05$). The ANOVA test was used to compare the mean values between variables, and the chi-square test was used to analyze the proportions between variables. Frequencies and percentages are used to convey qualitative variables, while means and standard deviations are used to communicate quantitative variables.

4. Results

Most patients in this study were aged 51-60 years, followed by those aged 41-50 years.

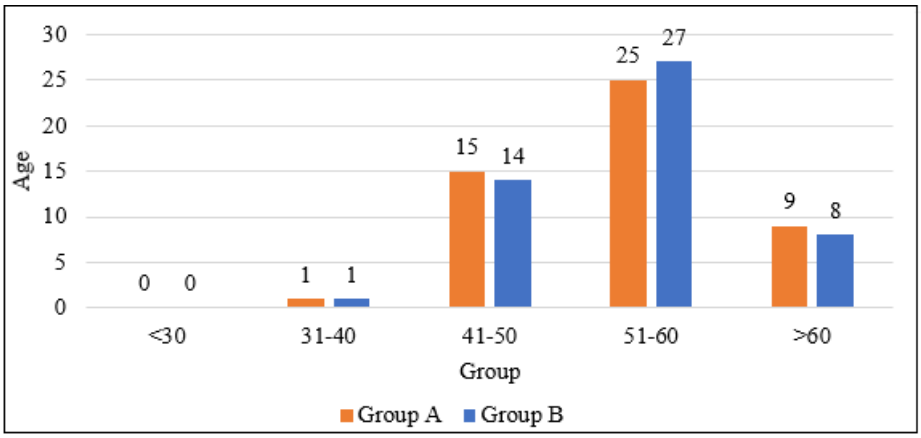

Figure 3: Distribution of patients according to age

It was seen that in group A, 58% were male patients and 42% were female. While in group B, 56% patient were male and 44% were female.

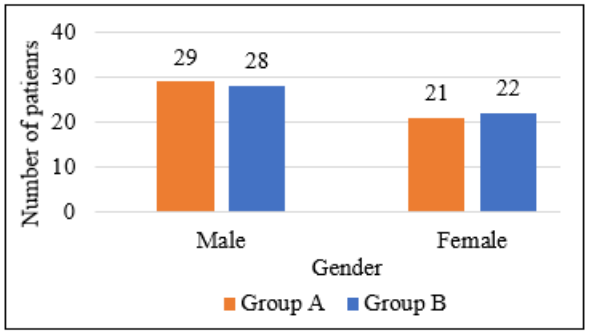

Figure 4: Distribution of patients according to gender

It was observed that in the present study all the patients (100%) presented with foreign body sensation. Whereas visual empowerment was the second most common presenting complaint. And 24% patients in group a and 18% patients in group B complaint of cosmetic disfigurement.

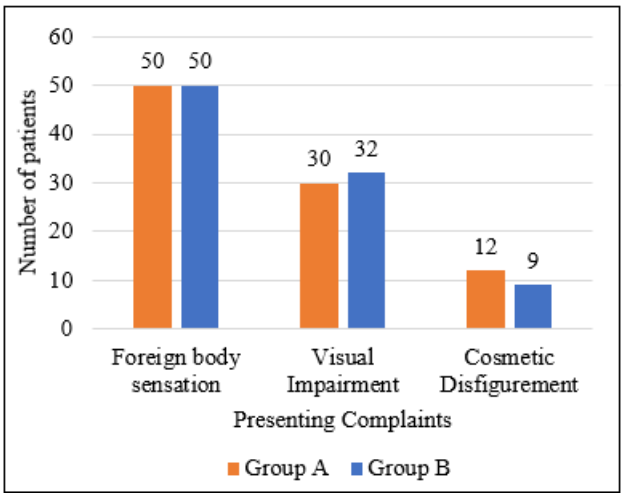

Figure 5: Distribution of patients according to presenting complaints

The mean operative time in group a patient was 35.80 minutes with standard deviation of 3.96 minute where has in group B the main operative time was 30.90 minutes with standard deviation of 4.92 minutes does the operative time was more in Group A (Autologous blood serum) as compared to the Group B (fibrin glue).

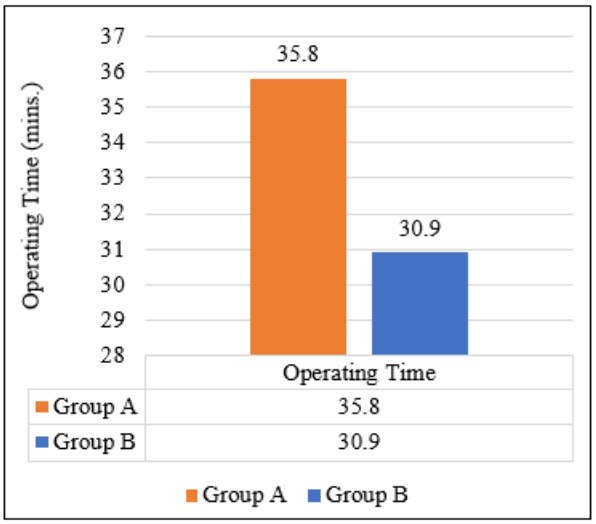

Figure 6: Distribution of patients according to Operating Time for both study groups

It was observed that on post-operative day one, 36 patients from group A complain of pain whereas 39 patients from group B complain of pain.

After one week of operative procedure, it was observed that 8 patients from group A and 12 patients from group B were complaining of pain.

After 1 month no patient from both the group complain of post-operative pain.

The difference observed in post-operative pain in group A and group B was not statistically significant.

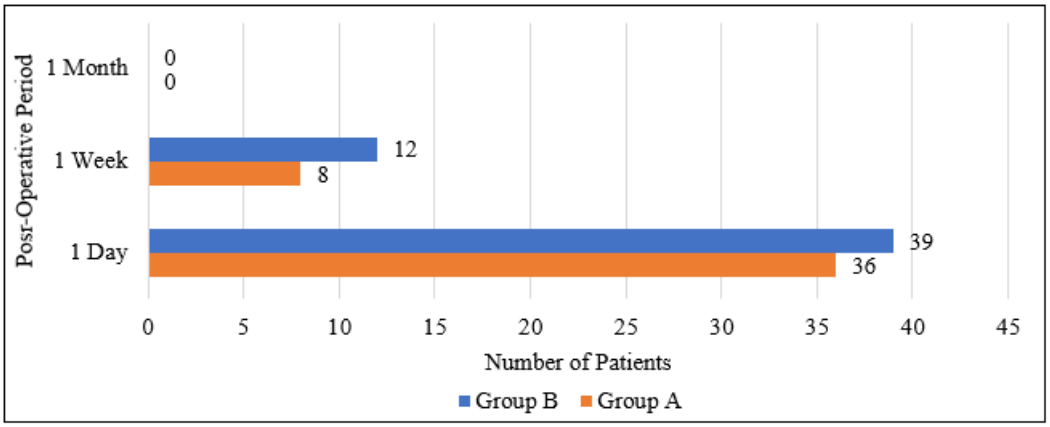

Figure 7: Distribution of patients according to Assessment of post-operative pain

It was observed that on post-operative day one, 31 patients from group A complaining of foreign body sensation whereas 35 patients from group B complain of foreign body sensation.

After one week of operative procedure, it was observed that 8 patients from group A and 12 patients from group B were complaining of foreign body sensation.

After 1 month no patient from both the group complain of post-operative foreign body sensation.

The difference observed in post-operative foreign body sensation in group A and group B was not statistically significant.

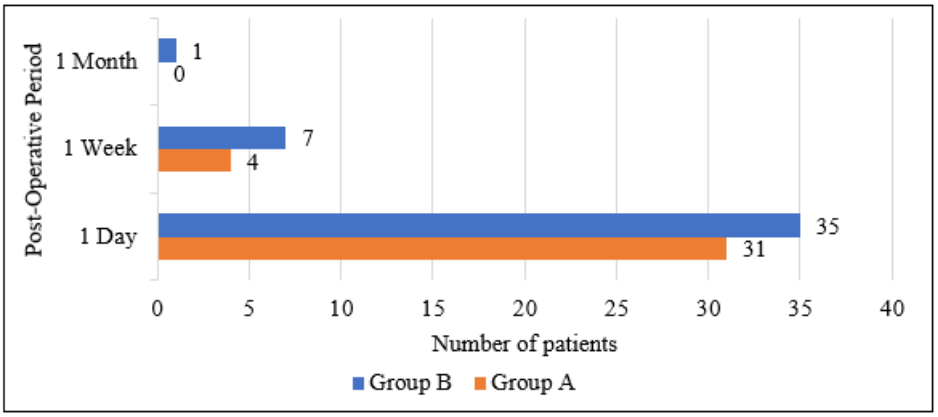

Figure 8: Distribution of patients according to post-operative foreign body sensation

In the course of examining the problems, it was found that 15 patients in group B experienced graft loss, compared to just two patients in group A. This difference was statistically significant (p=0.001). Although three patients from group B and one patient from group A reported pterygium recurrence, the difference was not statistically significant (p=0.610).

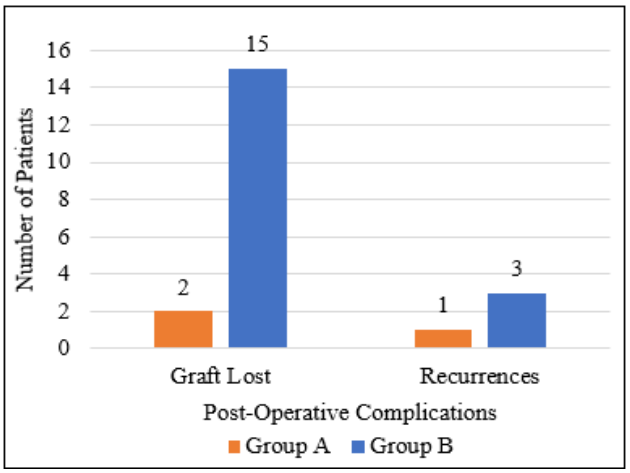

Figure 9: Distribution of patients according to Complications

Table no.1: Comparison of pre-operative and post-operative log MAR visual acuity (uncorrected) between Both the study groups

		Mean	SD	t Value	P value
Pre Op	Group A	.380	.146	0.552	0.5824 (NS)
	Group B	.396	.144		
Post Op	Group A	.188	.109	0.409	0.6834 (NS)
	Group B	.197	.111		

While studying the visual acuity it was observed that among group A (0.380±0.146) and group B (0.396±0.144) preoperative visual acuity was not statistically significant whereas post operatively the visual equity was improved (0.188±0.197 and 0.197±0.111 in Group A and Group B respectively) but the difference observed in both the group was not statistically significant.

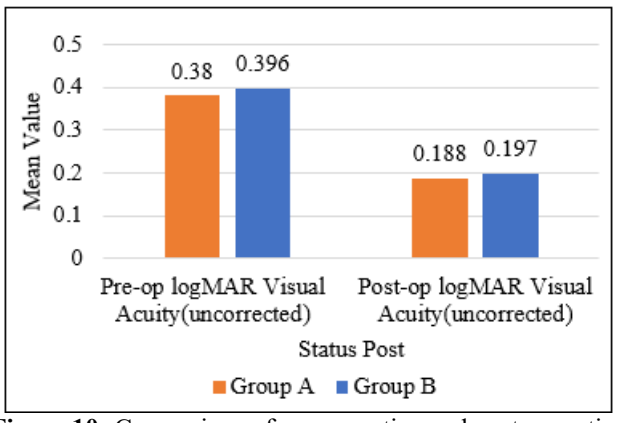

Figure 10: Comparison of pre-operative and post-operative log MAR visual acuity (uncorrected) between Both the study groups

5. Discussion

Pterygia can be managed with a variety of surgical procedures, but there isn't a single, accepted method. The purpose of pterygium surgery is to remove the pterygium and stop it from coming back. In pterygium surgery, there are several ways to reduce postoperative recurrence, but the conjunctival autograft technique has proven to be the most successful, with low rates of recurrence. The purpose of the current study was to compare the effectiveness of fibrin glue and autologous blood serum in conjunctival autograft in pterygium surgery.

It was observed that majority if the patients in the present study were in the age group of 51-60 years and was followed by 41-50 years of age. Similar findings were also observed by B. Asritha [162] Boucher et al[166] and Nadarajah et al[167] in their studies. It was seen that in group A, 58% were male patients and 42% were female. While in group B, 56% patient were male and 44% were female. Thus, male predominance was observed. Similarly male predominance was also reported by Boucher et al [166] and Nadarajah et al[167] in their studies. It was seen that among the majority of patients left eye was affected most commonly. In the study by Rafe A, et al[161] , 10 (50%) left and 10 (50%) right eyes were present in Group B, whereas 14 (70%) left and 6 (30%) right eyes were present in Group A.

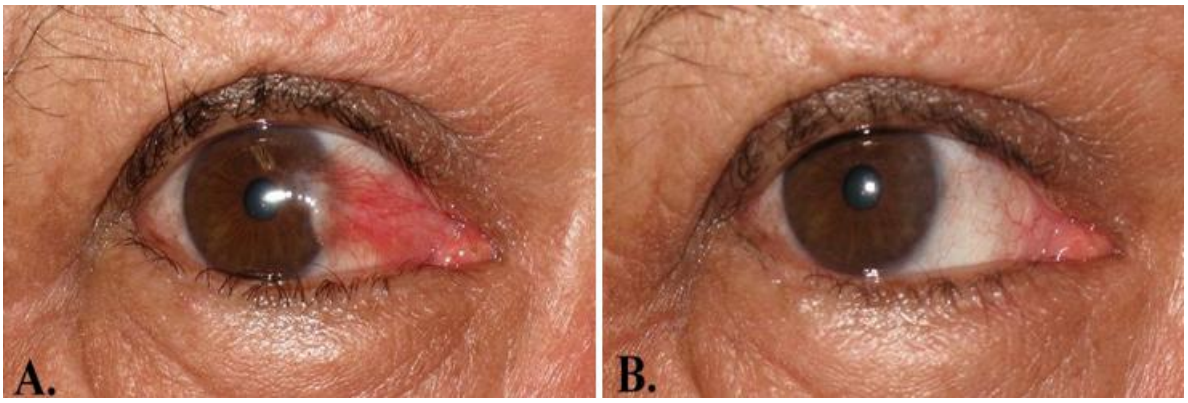

Figure 11: A) Pre-operative and B) Post-operative (1 month) photo following Pterygium Excision with CLAG using Fibrin Glue

It was noted that every patient in the current study (100%) had a foreign body experience when they first arrived. On the other hand, the second most frequent presenting issue was visual empowerment. Additionally, 18% of group B patients and 24% of group A patients complained of cosmetic deformity. The B. Asritha[162] study found that foreign body sensation was the most frequent reason for surgery, followed by cosmetic disfigurement and vision impairment. As a result, the results were similar to the current investigation.

The mean operative time in group a patient was 35.80 minutes with standard deviation of 3.96 minute where has in group B the main operative time was 30.90 minutes with standard deviation of 4.92 minutes does the operative time was more in Group A (Autologous blood serum) as compared to the Group B (fibrin glue). Similarly in the Dhairya Parikh et al.[168] study, the mean operating time in fibrin group was 30.95 minutes (SD= 2.946), whereas in Conjunctival autograft with suture group, the mean operating time was 43.40 minutes (SD = 2.703). In a similar vein, the fibrin group's mean operating time in the Dhairya Parikh et al.18 study was 30.95 minutes (SD = 2.946), while the conjunctival autograft with suture group's mean operating time was 43.40 minutes (SD = 2.703). Thus, it was discovered that the fibrin group's mean surgery time was substantially shorter than the suture group conjunctival autograft. Reducing operating time has significant ramifications because longer operating times are thought to be directly linked to improved postoperative response and an elevated risk of infection. Another study by Bisen Rk19 found that the fibrin glue group had a considerably lower mean surgery time than the suture group (22.72 ± 3.69 minutes vs. 41.0 ± 3.53 minutes).

It was observed that on post-operative day one, 36 patients from group A complain of pain whereas 39 patients from group B complain of pain. After one week of operative procedure, it was observed that 8 patients from group A and 12 patients from group B were complaining of pain. After 1 month no patient from both the group complain of post-operative pain. The difference observed in post-operative pain in group A and group B was not statistically significant. Similar findings were also reported by B. Asritha[162] and Dhairya Parikh et al.[168] in their study.

It was observed that on post-operative day one, 31 patients from group A complaining of foreign body sensation whereas 35 patients from group B complain of foreign body sensation. After one week of operative procedure, it was observed that 8 patients from group A and 12 patients from group B were complaining of foreign body sensation. After 1 month no patient from both the group complain of post-operative foreign body sensation. The difference observed in post-operative foreign body sensation in group A and group B was not statistically significant. Similar findings were also reported by B. Asritha[162] and Dhairya Parikh et al.[168] in their study.

A number of problems, including pain, increased lacrimation, and occasionally suture-related granuloma or abscess, are linked to the presence of sutures. With the development of more recent substitutes like autologous blood and fibrin glue, Complications from sutures have stopped. Cohen and McDonald 20 initially reported the use of fibrin glue in pterygium surgery in 1993. Numerous research on the effectiveness and safety of fibrin glue in ocular surgery have since been published. The usage of fibrin glue carries a danger of spreading blood-related illnesses because it is a product generated from blood. Autologous blood is a good substitute in these situations since it is readily available; the only exceptions are people who frequently take aspirin or other blood thinners or individuals who are deficient in a coagulation factor.[21–22]

While examining the complications, it was found that only two patients from group A complained of graph loss, while 15 patients from group B experienced graft loss. This difference was statistically significant (p=0.001). The lost graft was the most frequent issue observed by Rafe A. et al.[17] in both groups. It was observed in one eye (5%) in group B (autologous serum) and eight eyes (40%) in group A (fibrin glue). There was a statistically significant difference (p = 0.008). As a result, the results were equivalent to the current investigation.

Although three patients from group B and one patient from group A reported a pterygium recurrence, the difference was not statistically significant (p=0.610). In a 2009 study, Farid et al.[23] similarly found that the fibrin glue group had a greater recurrence rate. Nineteen patients in the Mitra et al.[4] trial had autologous blood used for graft fixation; none of them experienced any losses or recurrences. In a study comparing

the use of fibrin glue and autologous blood in pterygium surgery, Nadarajah et al.16 found that two (3.4%) recurrences occurred in the fibrin adhesive approach, while five (10.6%) recurrences happened with the autologous blood approach. This was not statistically significant in their study, though, therefore autologous blood as a sealant was not ruled out as a potential treatment for recurrent pterygia.

Recurrence rates in the Elwan SA study were 8% in the sutured group and 6% in the non-sutured group[24]. Rafe A. et al.[17] found that the group treated with fibrin glue had a greater recurrence rate (n = 5; 25%) than the group treated with fibrin glue with n = 3 (15%) while the difference was not statistically significant (p = 0.429) in those receiving autologous serum treatment.

According to a study by Koranyi et al.[25], the fibrin glue approach was found to be a good substitute for suturing, which was linked to shorter recovery times and less postoperative problems and discomfort. But it does have certain negative effects, such as infection transmission, according to Foroutan et al. [26]. According to research by De Wit et al.[7], using fibrin glue may result in allergic reactions. We did not find any instances of infection or anaphylactic reaction during our investigation. In their study, Ayala et al.[27] found that the fibrin glue group experienced a greater recurrence rate than the autologous serum group. This result is consistent with our research. They discovered that additional issues were also higher in the process of fibrin glue. Similar to our findings, a 2009 study by Farid et al. [23] found that although the recurrence rate was greater in the fibrin glue group, there were no instances of anaphylactic reaction.

While studying the visual acuity it was observed that among group A (0.380±0.146) and group B (0.396±0.144) preoperative visual acuity was not statistically significant whereas post operatively the visual equity was improved (0.188±0.197 and 0.197±0.111 in Group A and Group B respectively) but the difference observed in both the group was not statistically significant.

According to Dhairya Parikh et al.[18], the fibrin group's mean preoperative uncorrected log MAR values dropped from 0.390 (SD=0.161) to 0.190 (SD=0.085). Within the Conjunctiva. The mean pre-operative uncorrected log MAR values for the autograft with suture group were 0.366 (SD=0.170), which dropped to 0.196 (SD=0.088). The removal of pterygium from the visual axis and a decrease in astigmatism could be the cause of the improved vision. Similarly, in B. Asritha's study, on the 45th POD, distant visual acuity improved in 14 out of 44 individuals.

Pterygium is a prevalent ailment in our nation because to the abundance of sunlight, dust, smoking, and hot, dry weather. The preferred course of treatment is surgical excision combined with conjunctival autograft[28]. Kenyon et al. were the first to describe this method. In 1985[29] Since then, this process has been continuously modified to enhance cosmetic outcomes and lower recurrence rates. The first procedure was to suture the transplant. Prabhaswat et al.[31] demonstrated this as well, stating that conjunctival autograft was linked to fewer adverse effects and improved results. Its minor disadvantages include a longer recovery period, post-operative discomfort, and a higher risk of granuloma formation, which is brought on by the use of sutures.

This study is significant as it evaluates an alternative fixation method in pterygium surgery that may reduce costs, improve patient comfort, and minimize complications. Given the global prevalence of pterygium, optimizing surgical techniques can have widespread benefits in ophthalmology.

6. Conclusion

This study concludes that while autologous blood serum results in longer operative time compared to fibrin glue, it significantly reduces post- surgical complications, particularly graft loss. Therefore, autologous blood serum is a safe and effective alternative for conjunctival autograft fixation in pterygium excision.

7. Limitations

1) The fact that the study was limited to a single institution may have limited the findings' applicability to other contexts with distinct patient demographics and surgical techniques.
2) Pterygium prevalence and patient demographics can vary significantly across different geographic regions and ethnicities, which could influence surgical outcomes and complication rates.
3) The post-operative follow-up long-term outcomes such as recurrence rates beyond the immediate post-operative period was not measured in the present study.

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