

METHODS

Efficacy of autologous blood clot in primary pterygium surgery compared with suture technique in a tertiary hospital of Bangladesh

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Purpose: The aim of this study is to assess the efficacy among patients undergoing pterygium excision and conjunctival autograft utilizing autologous blood or sutures.

Methods: A randomized controlled trial of 1 year and 5 months, with 60 eyes from 60 patients having primary nasal pterygium. As indicated by inclusion criteria, they were chosen and randomized into two arms for conjunctival autograft: treated arm A (30) with autologous blood and arm B (30) with stitches (10-0 monofilament nylon). Preoperative and post-operative results were assessed and analyzed statistically. Follow-up was done at first, seventh, 1 month, 3 months, and half-year post-operative days. Resulting factors were total surgical time, post-operative comfort, graft stability, and recurrence.

Results: 60 patients; mean age of 46.77 ± 7.04 (SD) in arm A (30) and 46.17 ± 7.53 (SD) in arm B (30). In arm A, 22 males (73.3%) and 8 females (26.7%) where arm B had 20 males (66.7%) and 10 females (33.3%). Total surgical time in arm A was 24.73 ± 3.69 (SD) minutes and in arm B was 32.23 ± 4.59 (SD) minutes ($p < 0.001$). Follow-up at the 1st and 7th POD showed significant discomfort in arm B (mean ranks 41.82 and 40.62) compared to arm A (mean ranks 19.18 and 20.38), respectively, ($p < 0.001$). At 1st POD, only 3 (10%) graft retractions in arm A. Within 6 months of follow-up, all grafts were stable; 1 (3.3%) recurrence and 1 (3.3%) granuloma in arm B only.

Conclusion: In primary pterygium surgery, autologous blood showed excellent post-operative results with no recurrence and reduced surgical time. So, it seems to be an effective surgical means to treat primary pterygium.

Keywords: pterygium, conjunctival autograft, autologous blood clot, granuloma, recurrence

1. Introduction

Pterygium a winged-like fibrovascular growth extending from the conjunctiva and limbus toward the corneal surface (1). There is a positive correlation between chronic ultraviolet-B (UV-B) exposure to the ocular surface and pterygium development (2). Migration of abnormal limbal basal epithelial stem cells or pterygium cells in Bowman's layer (BL) leads to the breakdown of this layer, which is covered by conjunctival epithelium.(1) Also, the p53 gene

(chromosome 17) mutation can be a predisposing factor for pterygium.(3).

Pterygium is typically found in the interpalpebral region, most often on the nasal side, and is more common in men than in women (4). According to various population studies, the pre-valence of pterygium ranges from 1% to 30% in different parts of the world (5–7).

Pterygium is usually asymptomatic at an early stage. Later on, the patient may experience foreign body sensations, discomfort, redness, and visual disturbances either due to induced astigmatism or obscuring the visual axis (8).

Pterygium more than 3.5 mm over the cornea is likely to be associated with more than 1 diopter astigmatism (with the rule) (9).

Cosmetic issues, chronic inflammation, visual disturbance, motility restriction, and contact lens fitting difficulty are the main indications of surgery (i.e., pterygium excision) (10). Pterygium excision is the standard treatment. But the failure of pterygium surgery is most often due to post-operative recurrence, which usually happens within the first 6 months post-operatively (11–13). Upregulation of the inflammatory mediators plays a significant role in this process (13).

There are numerous surgical methods available now to treat pterygium (3). These procedures range from a straightforward bare sclera resection to pterygium excision accompanied with conjunctival autografting (14) or amniotic membrane transplantation anchored with either sutures or fibrin glue (15). With the bare sclera, there was a very high recurrence rate (24 to 89%) (9). A number of adjuncts have also been suggested because of their anti-fibrotic and anti-angiogenic effects, including the use of beta radiation and mitomycin C (16). However, using these adjuncts carries some dangers and issues as well (3).

Currently, pterygium excision with limbal conjunctival autograft is regarded as the gold standard in surgical treatment. Conjunctival autografts using sutures enable graft stability here. But this technique increases the duration of the operation and post-operative discomfort and is sometimes associated with chronic inflammation and granuloma formation (17).

Conjunctival autograft surgeries now take less time and thanks to the recent usage of fibrin adhesive, which also results in reduced pain and suffering after surgery. However, the adhesive is generally more expensive than sutures, which raises the overall cost of the operation. Additionally, there is a chance that viral diseases will be transmitted and that allergic reactions could occur (18–20).

Autologous blood is natural, has no extra cost or associated risks, and can reduce post-operative irritations to a great extent. This study was designed to assess the long-term result of the autologous blood clot and suture techniques in primary pterygium excision.

2. Method

This prospective, randomized clinical trial of 1 year and 5 months included 60 eyes of 60 patients with primary nasal pterygium who underwent pterygium excision with conjunctival autografting. The study followed the Declaration of Helsinki and was approved by the Ethics Committee of the Chittagong Medical College, Chattogram, Bangladesh (ERB memo: CMC/PG/2017/334). It was registered at www.clinicaltrials.in.th (No. TCTR20180527002). After proper explanations of the

detailed procedure, written informed consent was obtained from all subjects.

2.1. Inclusion and exclusion criteria

Patients who had grade 1, 2, or 3 primary nasal pterygia requiring pterygium excision with conjunctival autograft were included. The exclusion criteria were age younger than 33 years or older than 58 years (as they might not cooperate during surgery, or follow the post-operative instructions, especially with autologous blood clot technique), temporal pterygium, double-headed pterygium, recurrent pterygium, pseudopterygium, atrophic, cystic or inflamed pterygium, patients on antiplatelet or anticoagulant drugs, patients with known bleeding or clotting disorder, patients with associated ocular surface disorders (e.g., dry eye disease and blepharitis), and patients with the previous history of any ocular trauma or surgery in the same eye.

2.2. Surgical procedure

All procedures were performed by a competent surgeon. For arm A, conjunctival autograft was fixed with the autologous blood clot, and for arm B, conjunctival autograft was fixed with suture (10-0 monofilament nylon). The procedures were as follows: meticulous dissection of a pterygium from apex to periphery, followed by tenon-free conjunctival autograft from the superotemporal area, approximately 0.5–1 mm larger than the bare sclera. Secure the conjunctival autograft either by the autologous blood clot or 10-0 monofilament nylon sutures.

With autologous blood clots, spontaneous hemostasis was allowed to form fibrin to attach the conjunctival autograft to the bare sclera. Residual bleeding was carefully removed so as not to lift the graft. Gentle pressure over the graft with fine non-toothed forceps for around 5 min ensured the graft held its position (**Figure 1**).

With 10-0 monofilament nylon sutures, autograft was sutured. Two limbal corners were sutured into the episclera initially, then the posterior corners of the graft were sutured to the bulbar conjunctiva (**Figure 2**).

2.3. Post-operative regimen

The application of topical eye drops moxifloxacin (0.5%) 4 times daily for a week and fluorometholone (0.1%) 6 times daily, gradually tapered over 6–8 weeks according to the degree of inflammation, and topical eye drop carboxymethylcellulose (10 mg) 6 times daily for 4–6 months.

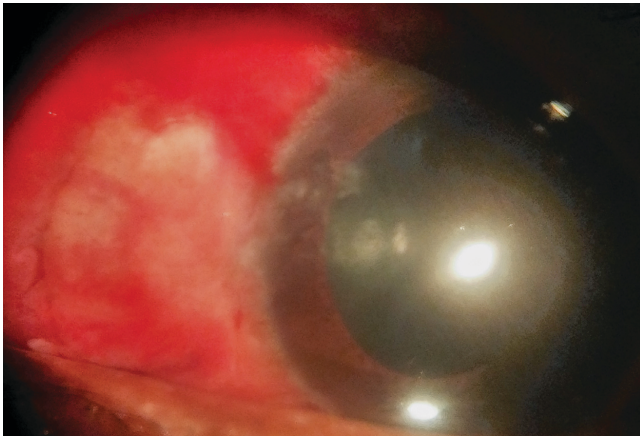


FIGURE 1 | Conjunctival autograft secured with autologous blood clot.

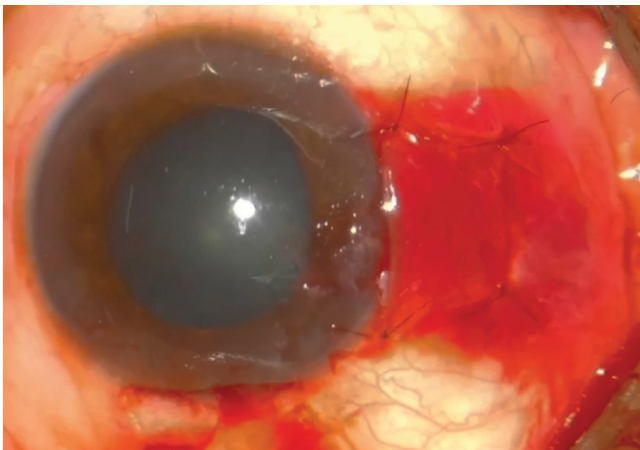


FIGURE 2 | Conjunctival autograft secured with 10-0 monofilament nylon.

2.4. Post-operative counselling

Patching time for both arms was almost the same (around 12 h).

All post-operative patients were advised not to rub or blink too frequently as this might displace the graft.

2.5. Post-operative follow-up

Post-operative follow-up visits were scheduled on days 1 and 7 and on months 1, 3, and 6 after the operation. With 10-0 monofilament nylon, sutures were removed at month post-operatively.

2.6. Data analysis

The clinical data collected were age, sex, occupation, and grade of pterygium. The primary outcome variables were total surgical time (the time required from first cut of

TABLE 1 | Demographic patterns of the study population.

| Parameter | Arm-A | Arm-B | <i>p</i> -value |
|--------------------------|------------------|------------------|-------------------|
| Age (yrs), mean \pm SD | 46.77 \pm 7.04 | 46.17 \pm 7.53 | 0.75* |
| Sex (%) | | | |
| Male | 22 (73.3) | 20 (66.7) | |
| Female | 8 (26.7) | 10 (33.3) | |
| Grading of pterygium (%) | | | 0.13 [†] |
| Grade 1 | 2 (6.7) | 4 (13.3) | |
| Grade 2 | 28 (93.3) | 23 (76.7) | |
| Grade 3 | 0 (0.0) | 3 (10.0) | |

SD, standard deviation.

Arm A comprises conjunctival autograft with the autologous blood clot.

Arm B comprises conjunctival autograft with sutures.

**t*-test.

[†] Chi-square test.

the conjunctiva to the removal of the lid speculum), post-operative patient comfort as measured by the patient comfort scale (scale 0: no complaints, scale 1: mild lacrimation and irritation, scale 2: severe lacrimation, redness, and foreign body sensation, and scale 3: inability to open the eyes), graft stability (graft in place at day 1 and 1 week post-operatively), and recurrence (any post-operative regrowth of fibrovascular tissue crossing the limbus within 6 months). Other outcome measures included graft retraction (at least 1 mm graft retraction from either the conjunctival or limbal side) and granuloma formation.

The mean, standard deviation, and frequency (percentage) values were used as data representation. The *t*-test, the Mann-Whitney *U* test, the chi-square test, and the Fisher exact test were used to compare the differences between the study groups.

IBM[†] SPSS[†] Statistics version 25 for Windows (International Business Machines Corp., Armonk, NY, USA) was used for statistical analysis *p*-values of less than 0.05 were considered to be statistically significant.

3. Results

This trial included 60 eyes of 60 patients; an equal number of eyes (30) were assigned randomly to study arms A and B with a mean age of 46.77 \pm 7.04 years and 46.17 \pm 7.53 years, respectively, ($P = 0.751$). Follow-ups were done on days 1 and 7 and on months 1, 3, and 6 after the surgery. **Table 1** visualizes the demographic patterns of the two study arms, and there were no significant differences observed between them.

Table 2 summarizes the outcome measures of the study arms. Arm A required significantly less surgical time than arm B ($P \leq 0.001$). Arm A showed consistently and significantly higher post-operative patient comfort at all follow-up intervals, except from 1 month and thereafter up to 6 months follow-up, where both arms showed no discomfort

($P \leq 0.001$; **Tables 2, 3** and **Figure 3**). There was 1 (3.3) recurrence in arm B, which was not significant ($P = 0.999$). There were 3 (10.0) graft retractions in arm A ($P = 0.237$) and 1 (3.3) granuloma formation in arm B ($P = 0.999$) (**Figure 4**), which were not significant as well.

Table 3 shows the distribution of study patients by post-operative comfort scale at 1st and 7th POD. At 1st POD, the mean rank was statistically significant, where Arm A was 20.38 and Arm B was 40.62 ($P < 0.001$). The mean rank at 7th

TABLE 2 | Summary of surgical outcomes.

| Parameter | Arm A | Arm B | P-value |
|---|------------------|------------------|-------------------|
| Surgical time (minute), mean \pm SD | 24.73 \pm 3.69 | 32.23 \pm 4.59 | <0.0* |
| Post-operative comfort (at 1st POD) | | | <0.0 [‡] |
| Mean \pm SD | 0.57 \pm 0.5 | 1.6 \pm 0.56 | |
| Mean rank | 19.18 | 41.82 | |
| Post-operative comfort (at 7th POD) | | | <0.0 [‡] |
| Mean \pm SD | 0.1 \pm 0.4 | 0.77 \pm 0.43 | |
| Mean rank | 20.38 | 40.62 | |
| Recurrence (%) | 0 (0.0) | 1 (3.3) | 1.0 [§] |
| Graft retraction (%) | 3 (10.0) | 0 (0.0) | 0.24 [§] |
| Granuloma formation (%) | 0 (0.0) | 1 (3.3) | 1.0 [§] |

SD, standard deviation.

Arm A comprises conjunctival autograft with the autologous blood clot.

Arm B comprises conjunctival autograft with sutures.

*t-test

[‡]Mann-Whitney U test

[§]Fisher's Exact test

TABLE 3 | Distribution of study population by post-operative comfort scale.

| Post-operative comfort Scale | Arms | | p-value* |
|------------------------------|----------------|-----------------|-------------------|
| | Arm-A | Arm-B | |
| 1st POD | | | |
| 0 | 13 (43.3) | 0 (0.0) | |
| 1 | 17 (56.7) | 13 (43.3) | |
| 2 | 0 (0.0) | 16 (53.3) | |
| 3 | 0 (0.0) | 1 (3.3) | |
| Total | 30 (100.0) | 30 (100.0) | |
| Mean \pm SD | 0.57 \pm 0.5 | 1.6 \pm 0.56 | |
| Mean Rank | 19.18 | 41.82 | <0.0 ^s |
| 7th POD | | | |
| 0 | 28 (93.3) | 7 (23.3) | |
| 1 | 1 (3.3) | 23 (76.7) | |
| 2 | 1 (3.3) | 0 (0.0) | |
| Total | 30 (100.0) | 30 (100.0) | |
| Mean \pm SD | 0.1 \pm 0.4 | 0.77 \pm 0.43 | |
| Mean Rank | 20.38 | 40.62 | <0.0 ^s |

s = significant.

Figure within parentheses indicates in percentage.

*Mann-Whitney U test

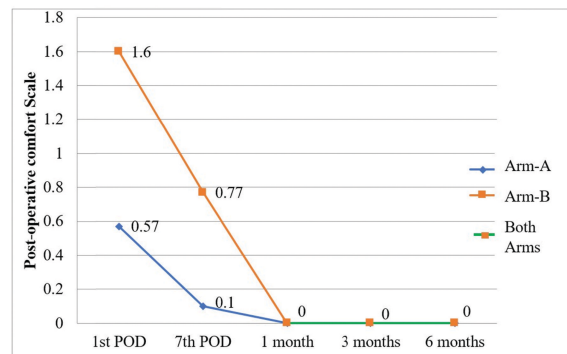


FIGURE 3 | Line chart of post-operative comfort scale during the different follow-up period of both arms.

POD was also statistically significant with 20.38 and 40.62 in Arm A and Arm B, respectively, ($P < 0.001$).

4. Discussions

This study primarily evaluated the total surgical time, graft stability, post-operative comfort, and recurrence in conjunctival autografting following primary pterygium excision using an autologous blood clot and suture techniques.

This study showed the mean age of the patient was 46.77 ± 7.04 years for Arm A and 46.17 ± 7.53 years for Arm B (**Table 1**). Rathi G et al. (8), Malik K et al. (17), Javadekar S et al. (21), and Nadarajah G et al. (22) showed a mean age of 42.5 ± 4 (range 30–55 years), 42.8 (range 23–61 years), 53.61 ± 14.269 years (range 26–76 years), and 53.6 ± 1.8 years, respectively. The variation in mean age may be due to exposure to outdoor activity patterns of different age groups. With aging, there are some degenerative changes in the conjunctiva as well, which will ultimately predispose to pterygium formation.

Here, out of 60 patients, 42 were men and 18 were women (**Table 1**). Nishant et al. studied 60 patients where 40 were men and 20 were women (23) Kumar P et al. (19) studied 64 patients, showing 24 men and 40 women, while Dasgupta S et al. (13) showed 44 women and 16 men in a total of 60 patients in their studies. Pterygium is usually seen more often in men than women (4) but nowadays, there are more outdoor activities for women, which makes them more likely to develop pterygium.

Most of the pterygium was grade 2 in both arms in this study: 28 (93.3%) in arm A and 23 (76.7%) in arm B (**Table 1** and **Figure 5**). Nadarajah G et al studied 111 patients and showed grade 1 pterygium at 14 (11.7%) in the autologous blood group and 13 (10.8%) in the fibrin group, grade 2 pterygium at 30 (25%) in the autologous blood group, and 31 (25.8%) in fibrin group and grade 3 pterygium 18 (15%) in autologous blood group and 14 (11.7%) in fibrin group. (22) Grade 2 pterygium is commonly encountered, most

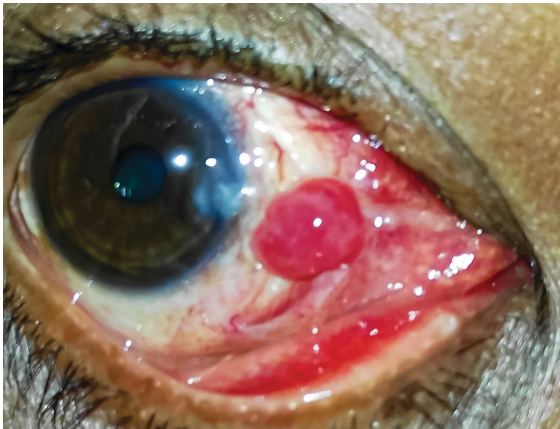


FIGURE 4 | Granuloma formation.

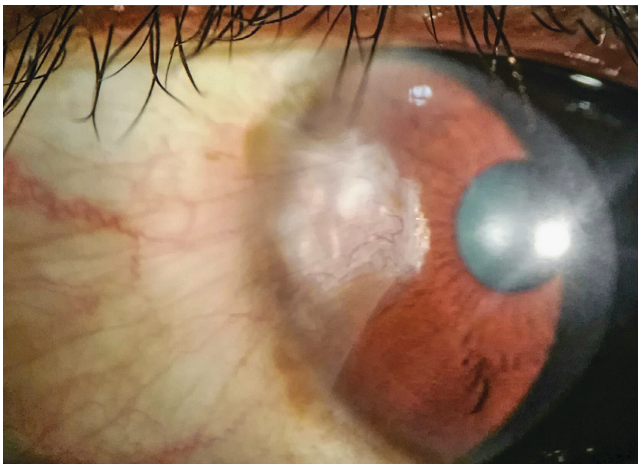


FIGURE 5 | Grade 2 nasal pterygium.

probably due to its visibility within the interpalpebral fissure, by patients as well as by others, and at that time, patients come to seek medical attention.

In this study, the mean surgical time for arm A was 24.73 ± 3.69 min and for arm B was 32.23 ± 4.59 min, which was statistically significant ($P < 0.001$) (Table 2). Javadekar et al showed a mean surgical time of 13.96 ± 3.2 min in autologous blood technique. (21) Kumar et al showed a mean surgical time of 23.83 ± 1.05 min (range 22–28 min) in autologous blood clot technique and 24.41 ± 2.62 min (range 21–31 min) in suture technique. (19) Sangole AM and Kose DA showed a mean surgical time of 31.48 ± 6.15 min in the suture technique and 19.71 ± 5.13 min in own blood technique. (5) The duration of the procedure varies widely with the skill of the surgeon, the procedure chosen, availability of the proper instruments, and an expert assistant and OT supplies, and patient cooperation.

In the current study, at 1st POD, 13 (43.3%) patients showed scale 0 response in arm A, whereas arm B showed scale 2 response in 16 (53.3%) patients. There was no scale 2 response for arm A, and 1 (3.3%) patient had a scale 3 response in arm B only. The mean rank was statistically

significant where arm A was 20.38 and arm B was 40.62 ($P < 0.001$). At 7th POD, 28 (93.3%) patients showed a scale 0 response in arm A, but 23 (76.7%) in arm B showed a scale 1 response. One (3.3%) patient in arm A showed a scale 2 response in arm A, but none was in arm B with a scale 2. Mean rank at 7th POD was also statistically significant with 20.38 and 40.62 in arm A and arm B, respectively, ($P < 0.001$). From 1 month and thereafter up to 6 months follow-up, there was a scale 0 response in both arms (Table 2 and Figure 1). Javadekar S et al. reported post-operative discomfort was significantly higher in the suture group ($P < 0.001$) than in the autologous blood group on 1st and 7th POD and on the last 6 week post-operative follow-up discomfort was absent in all cases (21). Kumar P et al reported greater post-operative discomfort at 1st POD in the suture group (moderate 50% and severe 23.52%) in relative to autologous blood (moderate 13.33% and severe 10%) (19). Sangole AM and Kose DA mentioned post-operative discomfort and pain in the suture group significantly high than in their own blood group ($P = 0.0058$) (5). In the case of the suture technique, the free ends of the knots will irritate the palpebral conjunctiva and will cause discomfort with the eyes closed as well as with each blink. But in the case of the autologous blood clot technique, there will be no such problems. With time, the conjunctival epithelium may cover the free ends of the knots, which will ultimately reduce the discomfort.

In this study, there was 1 (3.3%) recurrence in arm B only and no recurrence in arm A within 6 months of follow-up post-operatively ($P = 0.999$) (Table 2 and Figures 6, 7). Wit D et al. reported no recurrence and complication with the autologous blood technique (24). Kurian A et al. (2) mentioned that the recurrence rate was 6.25% in the autologous blood group ($P > 0.05$), whereas Nishant K et al. (23) mentioned the recurrence rate in the suture group was 20%. Dasgupta S et al studied the recurrence rate

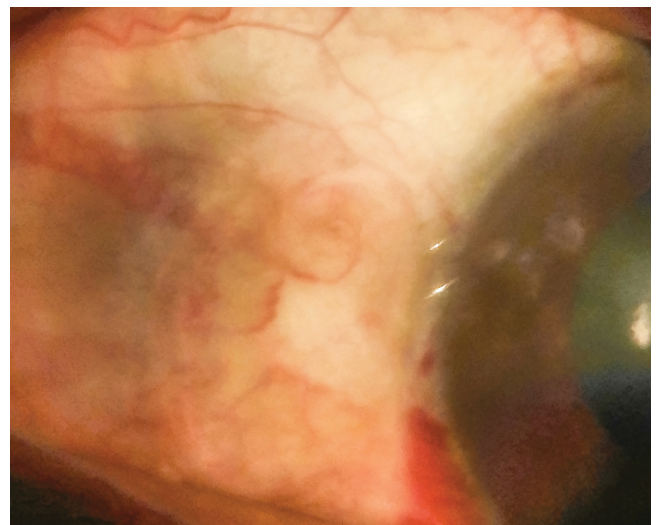


FIGURE 6 | Conjunctival autograft with autologous blood clot at 6 months post-operatively.

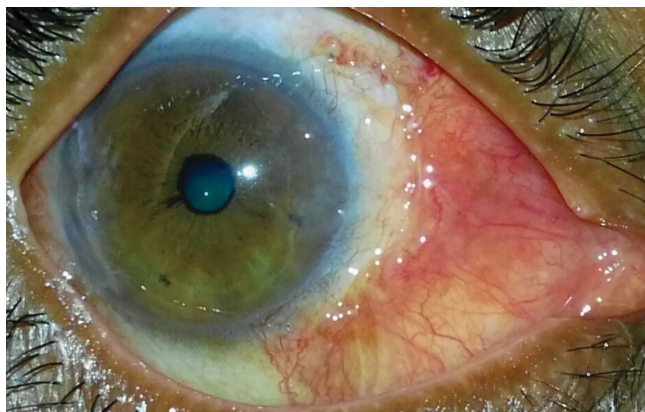


FIGURE 7 | Conjunctival autograft with 10-0 monofilament nylon at 6 months post-operatively.

with the autologous blood clot was 1.67% up to 6 months post-operative follow-up (13). Nadarajah G et al mentioned a 10.6% recurrence rate following autologous blood clots ($P = 0.238$) (22). Autologous blood clot technique shows less recurrence probably due to less handling and less surgical time and ultimately less inflammatory reaction to the operative site. But in the case of suture technique, it will take more time to perform as well as more injury to the operative site, and ultimately, more aggressive inflammation may lead to recurrence.

This study showed 3 (10%) graft retraction in arm A only within 6 months of follow-up post-operatively ($P = 0.237$) (Table 2). Malik K et al. showed 7.5% graft retraction after pterygium excision. (17) Kurian A et al showed 8.16% graft retraction with autologous blood (2). Graft retraction can occur if a smaller graft than the bare sclera is used, and careful dissection of the subepithelial graft tissue is not performed.

Graft stability is a major concern after pterygium excision and can usually be determined within the first 24 h. In this study, there was no graft displacement. Rathi G et al. reported 1% graft loss following the autologous blood clot technique (8). 3.33% graft displacement following an autologous blood clot was reported by Kumar P et al. (19). Improper excision of pterygium or too much Tenon tissue on the graft may lead to graft displacement. Proper dissection of Tenon's capsule and slight pressure over the graft with an iris repositor for a few minutes to adhere with bare sclera can ensure the graft's stability in the autologous blood clot technique, and these were followed in this study.

In this study, there was 1 (3.3%) granuloma formed in arm B only within 6 months of post-operative follow-up (Table 2). Kumar P et al. showed 1 (2.94%) suture-related granuloma following pterygium excision (19). Suture materials as well as residual exposed tenons can initiate an aggressive local inflammatory response in some patients due to a host-immune response and ultimately present with granulomas.

After careful analysis, it is clear that autologous blood is a better option following primary pterygium excision with

significantly less surgical time, greater post-operative patient comfort, and no recurrence or complications.

5. Conclusion

The autologous blood clot technique resulted in significantly less post-operative discomfort and shorter surgery times than using sutures with no recurrence. So, the autologous blood technique is safe and effective for conjunctival autografting and can be performed as the first method of choice for primary pterygium surgery in developing countries like Bangladesh, where tissue glue is not readily available and patients are not that compliant with regular follow-up so that the suture-related complications can be avoided.

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