

# Effectiveness and safety of sutureless glue-free conjunctival autograft versus sutured conjunctival autograft in primary pterygium surgery: randomized controlled trial

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## ABSTRACT

**Background.** While sutured conjunctival autografting after excision of primary pterygium is associated with low pterygium recurrence rates, patients who undergo the procedure commonly complain of postoperative foreign body sensation and granuloma formation.

**Objective.** To compare the surgery time, effectiveness, and safety of sutureless glue-free conjunctival autograft (SCLA) and sutured conjunctival autograft (SCA) in primary pterygium surgery.

**Design.** Randomized controlled trial.

**Setting.** Department of Ophthalmology, Southern Philippines Medical Center, Davao City, from September 2014 to September 2015.

**Participants.** 84 male and female patients with primary pterygium.

**Interventions.** Random allocation to either SLCA or SCA after pterygium excision.

**Main outcome measures.** Mean surgery time, graft loss and pterygium recurrence rates.

**Main results.** Forty-two (50%) patients received SCA, and the rest received SLCA. The two treatment groups were comparable at baseline in terms of patients' mean age, sex distribution, mean visual acuity, mean degree of astigmatism, and frequencies of chief complaints and grades of pterygium. Mean surgery time was faster in SLCA (16.42 ± 2.97 minutes versus 25.35 ± 3.35 minutes;  $p < 0.0001$ ). Three patients (7.14%) in SLCA versus none in SCA had graft loss, but the difference was not significant ( $p = 0.2410$ ). Postoperatively, the rate of patient-reported foreign body sensation was lower in SLCA (11/42, 26.19% versus 35/42, 83.33%;  $p < 0.0001$ ). On intention-to-treat analysis, graft edema was more common in SCA, and the rates of pterygium recurrence, granuloma formation, subgraft hemorrhage, and graft edge dehiscence were comparable between the two groups, but these inferences were not robust to sensitivity analyses.

**Conclusion.** SCLA had faster surgery time, similar graft loss and pterygium recurrence rates, and lesser postoperative foreign body sensation rate when compared to SCA after primary pterygium surgery.

**Keywords.** autologous blood, graft retention, graft edema, foreign body sensation, subgraft hemorrhage

## INTRODUCTION

Excision followed by autologous conjunctival transplantation is the treatment of choice for pterygium.<sup>1</sup> The approach yields a low 5–10% pterygium recurrence, compared to up to 80% recurrence after the bare sclera technique.<sup>2</sup> In choosing the best technique in pterygium surgery, it is important to take into consideration different factors such as surgery time, postoperative complications, recurrence rate, as well as cosmesis. Sutured conjunctival autografts pose postoperative problems such as foreign body sensation, discomfort, and granuloma formation.<sup>3</sup>

Sutureless grafting has been explored to address the postoperative complications of sutured conjunctival autograft.<sup>4</sup> Instead of sutures, fibrin glue has been used as tissue adhesive for conjunctival autograft, and it has been shown to drastically reduce the

surgical time and recurrence rate of pterygium, and improve postoperative patient

## IN ESSENCE

Conjunctival autografting on the bare sclera after pterygium excision promotes healing and prevents pterygium recurrence.

In this randomized controlled trial, the sutureless glue-free technique of autografting had faster surgery time, similar rate of graft loss, and lesser rate of postoperative foreign body sensation, when compared to the conventional sutured technique of autografting.

By intention-to-treat analysis, pterygium recurrence rates were comparable between sutureless glue-free technique and sutured technique, but the inference was not robust to sensitivity analyses.



comfort and cosmesis.<sup>5</sup> However, since fibrin glue is a blood derivative, it may theoretically transmit blood-borne diseases. On the other hand, the processing of fibrin glue derived from the patient's own blood can take up to 24 hours and is costly. The processing may also produce varying concentrations of clotting factors that provide unpredictable performance.<sup>6</sup> The sutureless, glue-free conjunctival autograft technique, which uses autologous blood coagulum as a graft adhesive, has been suggested as an alternative to using fibrin glue.<sup>7</sup>

We did this study to compare the conventional sutured conjunctival autograft and the sutureless glue-free conjunctival autograft after primary pterygium excision in terms of surgery time, graft loss, and pterygium recurrence.

## METHODS

### Study design and setting

We did an open-label randomized controlled trial from September 2014 to September 2015 among patients diagnosed with primary pterygium at the Ophthalmology Outpatient Clinic in Southern Philippines Medical Center, a tertiary hospital in Davao City. The clinic caters to about 23,000 clinic visits, including an average of 200 pterygium surgeries, annually.

### Participants

Patients 25 to 70 years old with Grade 2 to 4 pterygium<sup>8</sup> complaining of foreign body sensation, redness, tearing and blurring of vision were chosen for the study. Excluded were patients regularly taking aspirin or other anticoagulants, those with coagulation factor deficiencies, uncontrolled systemic illnesses, eye infections and other eye pathologies.

To determine the minimum sample size for this study, we assumed that sutured autografts would have a 5% graft loss rate. Calculation was done in order for the study to detect a 25% difference in graft loss rates between the two intervention groups as statistically significant. In a statistical test for comparison of two proportions carried out at a <5% level of significance, a minimum sample size of 36 per group will have 80% power of rejecting the null hypothesis if the alternative holds. For this study, we screened 102 eligible patients, but we had to exclude 18 patients because they either refused to participate, or had one or more exclusion criteria (Figure 1). We recruited a total of 84

patients into this study.

### Interventions and randomization

We randomly assigned patients undergoing pterygium excision to receive either sutured conjunctival autograft (SCA) or sutureless glue-free conjunctival autograft (SLCA). All the surgeries were performed by a single surgeon to maintain uniformity of surgical technique across all patients.

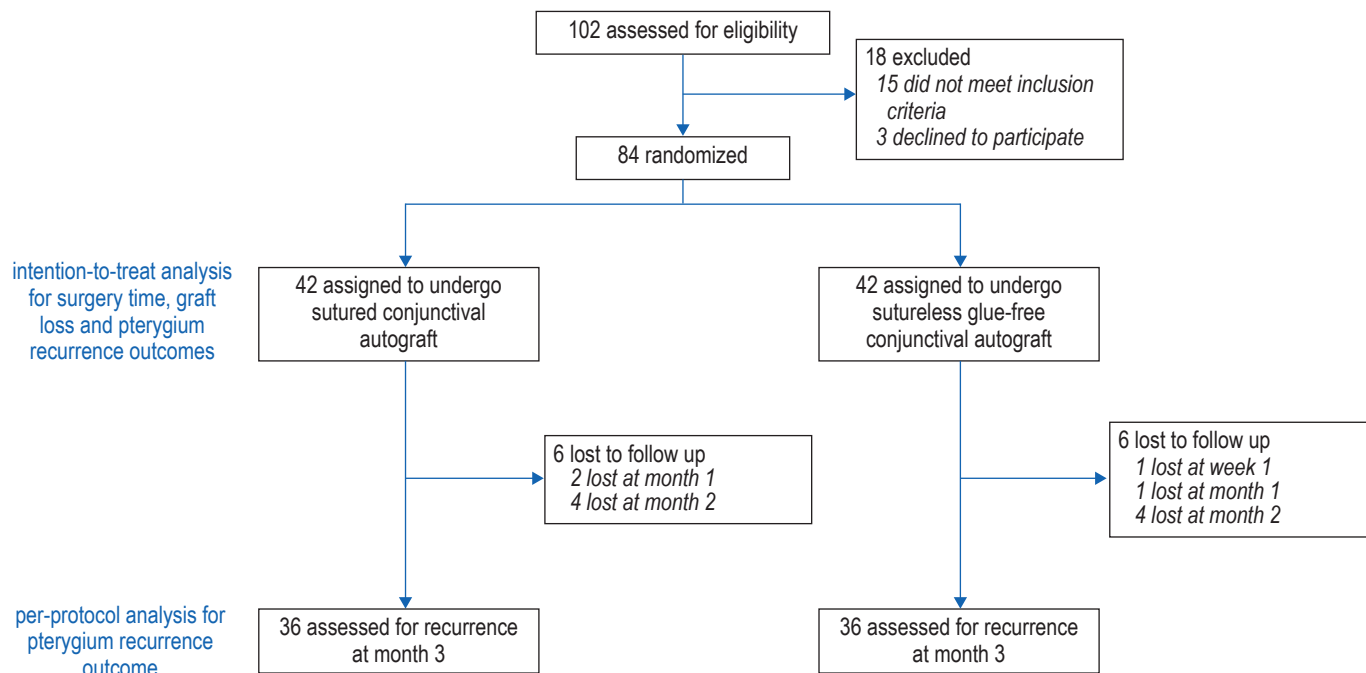
For each autograft procedure, the donor inferior bulbar conjunctival graft was taken from the same eye with the pterygium. After surgery, the operated eye was covered with a gauze patch. The patients were instructed not to take off the patch and to avoid rubbing their affected eyes. We prescribed oral mefenamic acid 500 mg every 8 hours as needed for pain. Removal of gauze patches was done by the surgeon the next day on follow up. We prescribed tobramycin + dexamethasone eye drops, one drop on the affected eye, four times a day for two weeks. For patients who received SCA, sutures were removed 1 week postoperatively.

### Data collection

We gathered baseline demographic and clinical data of the patients including age, sex, visual acuity, degree of astigmatism, chief complaint and grade of pterygium.<sup>9</sup> We also recorded the surgery time for each procedure by measuring the duration from the initial cutting of the pterygium to the removal of lid retractor at the end of the surgical procedure.

We instructed the patients to return to our clinic for follow up and reassessment on day 1, week 1, month 1, month 2 and month 3 postoperatively. Every follow up visit, we repeated the measurements of visual acuity and degree of astigmatism, and we evaluated the graft area under a slit-lamp. Patients who did not come for two consecutive times during the scheduled follow up visits were considered lost to follow up.

The main outcome measures for this study were surgery time, graft loss rates and pterygium recurrence rates. We determined the presence or loss of the autograft during follow up one day after surgery. Pterygium recurrence was considered when a new pterygium developed in the surgical site within three months after excision of the primary pterygium. For secondary outcomes, we measured the postoperative visual acuity and percentage of astigmatic reduction from



**Figure 1** Screening, randomization, follow up, and analysis of patients in the study.

baseline, and compared their respective means between the two groups. We also determined the presence of graft edema, granuloma formation, subgraft hemorrhage, graft edge dehiscence, and patient-reported foreign body sensation, and compared their respective rates between the groups. Study outcomes were separately assessed by three ophthalmologists.

#### Statistical analysis

The primary analysis for this study was done using the intention-to-treat (ITT) approach. For all outcomes, the ITT population included all patients who were randomized to either of the two interventions. Missing continuous data were filled in by last-observation-carried-forward method. To evaluate the robustness of the ITT inferences, we also performed per-protocol analyses that only included data of patients who were assessed for specific outcomes according to the protocol, even if the patients were subsequently lost to follow up. Additional sensitivity analyses for binary outcomes were done by making several sets of assumptions (best and worst case scenarios) about the outcomes in patients who did not have the outcome before they were lost to follow up and repeating the analyses per set of assumptions. Continuous

data were summarized as means  $\pm$  standard deviations and compared using t-test. Categorical data were summarized using frequencies and percentages and compared using chi-square test or Fisher's exact test. A two-tailed p-value of  $<0.05$  was considered significant. All statistical tests were done using Epi Info 7.1.4.0.

## RESULTS

### Patients' characteristics

Of the 84 patients recruited into this study, 42 (50%) were randomized to SCA, while the rest were randomized to SLCA. Table 1 shows the baseline demographic and clinical characteristics of the patients and mean surgery times for the two intervention groups. Both groups were comparable at baseline in terms of mean age, sex distribution, mean visual acuity, mean degree of astigmatism, frequencies of chief complaints, and frequencies of the different grades of pterygium.

### Postoperative follow up

Figure 1 shows the details of patient follow up after the interventions. Follow up was complete on the first postoperative day. On postoperative week 1, one patient from SLCA was lost to follow up. By the third postoperative month, a total of six patients

**Table 1** Baseline patients' characteristics

Characteristics	SCA n=42	SLCA n=42	p-value
Mean age $\pm$ SD, years	54.79 $\pm$ 13.40	51.17 $\pm$ 14.03	0.2303
Sex, frequency (%)			0.2740
Male	22 (52.38)	17 (40.48)	
Female	20 (47.62)	25 (59.50)	
Mean visual acuity $\pm$ SD*	0.66 $\pm$ 0.31	0.75 $\pm$ 0.24	0.1382
Mean degree of astigmatism $\pm$ SD, diopters	0.98 $\pm$ 1.07	0.72 $\pm$ 0.67	0.1899
Chief complaint, frequency (%)			0.2441
Blurring of vision	5 (11.90)	8 (19.05)	
Foreign body sensation	13 (30.95)	18 (42.86)	
Tearing	16 (38.10)	8 (19.05)	
Eye redness	8 (19.05)	8 (19.05)	
Grading of pterygium, frequency (%)			0.6895
II	25 (59.52)	27 (64.29)	
III	13 (30.95)	13 (30.95)	
IV	4 (9.52)	2 (4.76)	

\* Converted to decimal.

from the SLCA group and a total of six patients from the SCA group were lost to follow up. Hence, per-protocol analysis of the pterygium recurrence outcome only included 36 patients from the SLCA group and 36 patients from the SCA group. Some patients from both groups were assessed to have postoperative graft edema, granuloma formation, subgraft hemorrhage, graft edge dehiscence or patient-reported foreign body sensation before they were lost to follow up, so their respective data were accounted for in all the analyses performed in this study.

#### Intention-to-treat analysis

Intention-to-treat analysis of postoperative outcomes between the two intervention arms are shown in Table 2. The mean surgical time was significantly longer in the SCA group than in the SLCA group (25.35  $\pm$  3.35 minutes versus 16.42  $\pm$  2.97 minutes;  $p < 0.0001$ ). None in the SCA group and 3/42 (7.14%) patients in the SLCA group had graft loss on the first postoperative day, but the difference was not statistically significant ( $p = 0.2410$ ). Similarly, none in the SCA group and 3/42 (7.14%) patients in the SLCA group—the same three patients who had graft loss—had pterygium recurrence within three months postoperatively, but the difference was not statistically significant ( $p = 0.2410$ ). On postoperative day 1, percentage of astigmatic reduction was significantly higher in the SLCA group than

in the SCA group (19.04  $\pm$  33.00 versus 7.74  $\pm$  14.01;  $p = 0.0444$ ). During the 3-month postoperative follow up, graft edema was significantly more common in the SCA group (32/42, 76.19%) than in the SLCA group (23/42, 54.76%;  $p = 0.0389$ ). Likewise, foreign body sensation was significantly more common in the SCA group (35/42, 83.33%) than in the SLCA group (11/42, 26.19%;  $p < 0.0001$ ) during the follow up period. Other clinical outcomes such as granuloma formation, subgraft hemorrhage, and graft edge dehiscence were comparable between groups. The two patients with granuloma formation in the SLCA group subsequently underwent granuloma excision. All patients with graft edema, subgraft hemorrhage or graft edge dehiscence were observed for progression of their conditions, but none required further intervention.

#### Per-protocol analysis

Table 2 also shows the per-protocol analysis of the postoperative outcomes between the two interventions. Since patient follow up was complete during the assessment of mean surgical time (end of surgery), graft loss (day 1), day 1 postoperative mean visual acuity, and day 1 postoperative percentage of astigmatic reduction, no per-protocol analyses on the respective outcomes were done. Per-protocol analysis for the outcome on graft edema showed that the rates did not significantly differ between the two groups (32/42, 76.19% in SCA versus 23/41, 56.10% in SLCA;  $p = 0.0529$ ). Results of the per-protocol analysis of the rest of the outcomes—pterygium recurrence, foreign body sensation, granuloma formation, subgraft hemorrhage, graft edge dehiscence, postoperative mean visual acuity, and postoperative percentage of astigmatic reduction—did not differ from the respective intention-to-treat analysis results.

#### Sensitivity analysis

Sensitivity analyses using best and worst case scenarios for the outcome results of patients who did not have the outcome before they were lost to follow up are shown in Table 3. The results of the pterygium recurrence, graft edema, granuloma formation, subgraft hemorrhage, and graft edge dehiscence outcomes were inconsistent across the scenarios in their respective sensitivity analyses. Only the results of the foreign body sensation outcome were consistent across all

Table 2 Clinical outcomes

Characteristics	Intention-to-treat analysis			Per-protocol analysis				
	SCA (n=42)	SLCA (n=42)	p-value	n	SCA	n	SLCA	p-value
Mean surgery time $\pm$ SD, minutes	25.35 $\pm$ 3.35	16.42 $\pm$ 2.97	<0.0001					
Graft loss, frequency (%)	0 (0.00)	3 (7.14)	0.2410†					
Pterygium recurrence, frequency (%)	0 (0.00)	3 (7.14)	0.2410†	36	0 (0.00)	36	3 (8.33)	0.2394†
Postoperative mean visual acuity $\pm$ SD								
Day 1	0.66 $\pm$ 0.31	0.75 $\pm$ 0.24	0.1204					
Week 1	0.66 $\pm$ 0.31	0.75 $\pm$ 0.24	0.1204	42	0.66 $\pm$ 0.31	41	0.75 $\pm$ 0.24	0.1486
Month 1	0.66 $\pm$ 0.31	0.75 $\pm$ 0.24	0.1204	40	0.66 $\pm$ 0.31	40	0.75 $\pm$ 0.24	0.1208
Month 2	0.66 $\pm$ 0.30	0.75 $\pm$ 0.24	0.1264	36	0.66 $\pm$ 0.30	36	0.76 $\pm$ 0.24	0.1022
Month 3	0.66 $\pm$ 0.30	0.75 $\pm$ 0.24	0.1264	36	0.66 $\pm$ 0.30	36	0.76 $\pm$ 0.24	0.1022
Postoperative mean astigmatism % reduction $\pm$ SD								
Day 1	7.74 $\pm$ 14.01	19.04 $\pm$ 33.00	0.0444*					
Week 1	10.18 $\pm$ 20.37	19.38 $\pm$ 28.30	0.0910	42	10.18 $\pm$ 20.37	41	19.85 $\pm$ 28.48	0.0783
Month 1	15.50 $\pm$ 40.88	19.10 $\pm$ 24.58	0.6692	40	15.79 $\pm$ 41.89	40	19.10 $\pm$ 24.90	0.6683
Month 2	11.42 $\pm$ 29.19	20.04 $\pm$ 25.00	0.1499	36	12.21 $\pm$ 31.36	36	22.34 $\pm$ 26.15	0.1412
Month 3	10.91 $\pm$ 19.79	17.58 $\pm$ 26.24	0.1925	36	11.96 $\pm$ 20.99	36	19.86 $\pm$ 27.58	0.1757
Graft edema, frequency (%)	32 (76.19)	23 (54.76)	0.0389*	42	32 (76.19)	41	23 (56.10)	0.0529
Foreign body sensation, frequency (%)	35 (83.33)	11 (26.19)	<0.0001*	40	35 (87.50)	37	11 (29.73)	<0.0001*
Granuloma formation, frequency (%)	0 (0.00)	2 (4.76)	0.4940†	36	0 (0.00)	36	2 (5.56)	0.4930†
Subgraft hemorrhage, frequency (%)	0 (0.00)	1 (2.38)	1.0000†	36	0 (0.00)	36	1 (2.78)	1.0000†
Graft edge dehiscence, frequency (%)	0 (0.00)	3 (7.14)	0.2410†	36	0 (0.00)	36	3 (8.33)	0.2394†

\* Significant at  $p < 0.05$ .

† Fisher's exact test.

scenarios in the sensitivity analysis and per-protocol analysis, and had the same inference as in the intention-to-treat analysis.

## DISCUSSION

### Key results

We did this study in order to find out whether SLCA is comparable to SCA after primary pterygium excision. Surgery was significantly faster in the SLCA group. The two autograft approaches did not significantly differ in terms of graft loss rates. The SLCA group had a lesser rate of foreign body sensation postoperatively. There was also greater astigmatic reduction in the SLCA group a day after the surgery, but astigmatic reductions became comparable between the two groups after day 1. Visual acuity were comparable between the two groups throughout the whole postoperative follow up period. By intention-to-treat analyses, SCA had higher rates of graft edema compared to SLCA, and both groups did not significantly differ with each other in terms of pterygium recurrence, granuloma formation, subgraft hemorrhage, and graft

edge dehiscence, but all these results were not robust to sensitivity analyses.

### Strengths and limitations

We were able to demonstrate that sutureless glue-free conjunctival autograft can be used as an alternative technique to sutured conjunctival autograft in pterygium surgery. Some advantages were evident in favor of SLCA, including significantly less foreign body sensation and faster surgery time.

Shortened surgery time greatly helps surgeons cater to more patients, especially during surgical missions. The sutureless technique also eliminates the need for an additional follow up for suture removal and decreases the possibility of complications brought about by the introduction of sutures into the graft.

There were some limitations in this study. We did not monitor some factors that could possibly affect the outcomes that we measured, such as rubbing of the eyes postoperatively and other practices that may dislodge the autograft. The inferences on pterygium recurrence rate, graft edema,

**Table 3** Sensitivity analyses using best and worst case scenarios

Characteristics	Scenario 1*			Scenario 2†			Scenario 3‡		
	SCA (n=42)	SLCA (n=42)	p-value	SCA (n=42)	SLCA (n=42)	p-value	SCA (n=42)	SLCA (n=42)	p-value
Pterygium recurrence, frequency (%)	6 (14.29)	9 (21.43)	0.3927	6 (14.29)	3 (7.14)	0.2899	0 (0.00)	9 (21.43)	0.0024§
Graft edema, frequency (%)	32 (76.19)	24 (57.14)	0.0641	32 (76.19)	23 (54.76)	0.0389§	32 (76.19)	24 (57.14)	0.0641
Foreign body sensation, frequency (%)	37 (88.10)	16 (38.10)	<0.0001§	37 (88.10)	11 (26.19)	<0.0001§	35 (83.33)	16 (38.10)	<0.0001§
Granuloma formation, frequency (%)	6 (14.29)	8 (19.05)	0.5582	6 (14.29)	2 (4.76)	0.2646	0 (0.00)	8 (19.05)	0.0054§
Subgraft hemorrhage, frequency (%)	6 (14.29)	7 (16.67)	0.7629	6 (14.29)	1 (2.38)	0.1092	0 (0.00)	7 (16.67)	0.0119§
Graft edge dehiscence, frequency (%)	6 (14.29)	9 (21.43)	0.3927	6 (14.29)	3 (7.14)	0.4827	0 (0.00)	9 (21.43)	0.0024§

\* Scenario 1 - All patients who did not have the outcome before they were lost to follow up were assumed to have the outcome.

† Scenario 2 - All patients in SCA group who did not have the outcome before they were lost to follow up were assumed to have the outcome. All patients in the SLCA group who did not have the outcome before they were lost to follow up were assumed not to have the outcome.

‡ Scenario 3 - All patients in the SCA group who did not have the outcome before they were lost to follow up were assumed not to have the outcome. All patients in SLCA group who did not have the outcome before they were lost to follow up were assumed to have the outcome.

§ Significant at  $p < 0.05$ .

|| Fisher's exact test.

granuloma formation, subgraft hemorrhage, and graft edge dehiscence were not robust. This is probably related to the limited power of the study to generate inferences from only those patients who were able to return for follow up assessment.

### Interpretation

The sutureless glue-free technique omits the time-consuming step that involves suturing of the autologous conjunctival graft to the adjacent conjunctiva over the recipient bed.<sup>7</sup> Thus, in our study, the mean surgery time for performing the sutureless technique was significantly faster.

Graft retention is of utmost importance in pterygium surgery, since the conjunctival graft helps prevent pterygium recurrence.<sup>2</sup> The main disadvantage of SLCA group is graft loss in the immediate postoperative period. However, once a sutureless autograft is retained in the first postoperative day, it will stick throughout healing period.<sup>10</sup>

Postoperative foreign body sensation was more common among patients in our study who received SCA. Sutures used in the procedure contribute to this symptom and can also cause eye irritation.<sup>10</sup> Sutureless grafts provide patients with a more comfortable postoperative experience.

Astigmatism may occur in pterygium because, as the lesion encroaches the cornea, the normal corneal curvature may be distorted. Removal of the pterygium is expected to reduce or correct the astigmatism.<sup>11</sup> The use of sutures to hold conjunctival autografts in place can cause

tension in the cornea and can result in or maintain astigmatism. In our study, we did not find any postoperative visual deterioration, increase in astigmatism or development of any sight-threatening complications among our patients. On the first postoperative day, we found out that the decrease in astigmatism was significantly greater among patients in the SLCA group. From week 1 onwards, however, the two groups were comparable in terms of percentage of astigmatic reduction. Among patients who received SCA, the additional percentage of astigmatic reduction could be the effect of removal of sutures from the autograft on week 1. Pterygium excision may also improve visual acuity due to the clearance of visual axis afforded by the procedure,<sup>12</sup> but we were not able to demonstrate this in our study.

In our study, complications from pterygium excision and conjunctival autografting were very minimal. Two participants had granuloma formation and subsequently underwent granuloma excision. Graft edema, subgraft hemorrhage and graft edge dehiscence all resolved spontaneously without needing further management. These complications are self-limited and usually do not require further intervention.<sup>10</sup>

Based on varying results from the different analyses performed in this study, we do not have conclusive inference on the comparative recurrence rates of SCA and SLCA. What we do know is that the three patients who had pterygium recurrence were the same patients who had graft loss at day 1.

A successful graft helps prevent pterygium recurrence. The presence of a conjunctival epithelial defect, such as an exposed sclera, induces vigorous fibrovascular proliferation that leads to pterygium recurrence.<sup>13</sup> Apart from graft loss, are other factors that may increase the risk for pterygium recurrence. A study identified age <40 years and the presence of postoperative complications, such as graft edge dehiscence, graft failure, or graft damage, to be significant risk factors.<sup>13</sup>

### Generalizability

We did this study among patients with varied demographic characteristics and clinical profile. The signs and symptoms presented by the patients at baseline were typical of pterygium. Hence, the results of this study can be applicable to most patients diagnosed with pterygium. Our findings support the use of the sutureless glue-free technique in performing conjunctival autograft, as it is comparable with the sutured technique, with the added advantages of shorter surgery time and lesser chances of having postoperative foreign body sensation. In the future, studies with better statistical power can be conducted in order to build conclusive evidence on the rates of pterygium recurrence, graft edema, granuloma formation, subgraft hemorrhage, and graft edge dehiscence among patients receiving conjunctival autografts using the sutureless glue-free technique. Inferences around the use of this technique can also be improved by investigating the role of postoperative factors, such as eye rubbing and other practices that may cause autograft displacement, on foreign body sensation, graft loss, and pterygium recurrence, foreign body sensation, and other postoperative complications.

### CONCLUSION

In this randomized controlled trial, surgery time was faster among patients who received SLCA than among those who received SCA. The two groups did not significantly differ in terms of graft loss rates and postoperative visual acuity. The SLCA group had a lesser rate of postoperative foreign body sensation and greater astigmatic reduction on postoperative day 1. Astigmatic reductions from week 1 onwards were comparable between the two groups. Graft edema was more frequent in the SCA group, and the rates of pterygium recurrence, granuloma formation, subgraft hemorrhage, and graft edge dehi-

science did not significantly differ between the groups, but these inferences were not robust.

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### Ethics approval

This study was reviewed and approved by the Department of Health XI Cluster Ethics Review Committee (DOH XI CERC reference P14053102).

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