# Comparison of suture versussutureless technique using dry amniotic membrane graft and conjunctival limbal autograft in primary pterygium surgery

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## **Abstract**

Objectives: To assess the clinical outcome and patient comfort with dry amniotic membrane graft and conjunctival limbal autograft after excision of primary pterygium and compare the postoperative outcome using suture or sutureless technique. Materials and Method: This randomized clinical trial was done on 80 patients with primary pterygium attending ophthalmology outpatient department. Patients who fulfil inclusion and exclusion criteria were randomized to four groups to receive either CLAG or dry after excision of primary pterygium with or without suture after surgical excision. Intraoperatively, the clinical outcomes assessed were button hole and graft tear. Post operatively, we evaluated graft loss, graft edema and recurrence after surgery on postoperative day one, 1 week, 1 month and 6th month. The standard procedure was followed for pterygium excision by single surgeon and one of the above graft was used.. The graft was secured to bare sclera using 8-0 vicrylor autologous serum. Results: The patient's age ranged from 36-69years (mean age, 52.4 years). 45 males and 35 females were included in the study. The intra operative complications noted were button hole (15%) in CLAG group and graft tear (10%) in dry AMG group. Recurrence rate was (6.66%) in CLAG and (16.66%) in dry AMG group. Postoperative patient comfort was more in suturelesstechnique (23.8%) as compared to suture technique (68.9%). Conclusion: Conjunctival limbal autograft with autologous serum is the best technique after pterygium excision with fewer complications and good cosmesis. Dry amniotic membrane graft can be used as an adjunctive therapy in patients with conjunctival scarring, double headed pterygium and glaucoma patients requiring filtering surgery.

Key Words: Pterygium, dry amniotic membrane graft, conjunctival limbal autograft.

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### INTRODUCTION

Pterygium is an common conjunctival degeneration frequently seen in tropical and subtropical areas where exposure to ultraviolet sunlight is high<sup>1</sup>. The invasion of

pterygium into the corneal surface can lead to significant visual morbidity caused by irritation of the ocular surface, irregular astigmatism, obstruction of the visual axis, and loss of corneal transparency.<sup>2</sup> Indications for surgical excision include visual loss due to involvement of the central cornea, irregular astigmatism, restriction of ocular motility and atypical appearance with features of squamous neoplasia.<sup>3</sup> Management of pterygium includes conjunctival limbal (CLAG), amniotic membrane grafting (AMG) and the use of adjuvant therapies like mitomycin C, 5-fluorouracil, anti-vascular endothelial growth factor agents and βirradiation. <sup>4</sup>The technique of excising a pterygium without repairing the remaining defect is called bare sclera excision. This technique is no longer recommended because of its high rate of recurrence, which ranges from

38% to 88%.5 Recurrence is the most common complication after pterygium excision and various techniques have been implemented to reduce it. Many studies have noticed decreased recurrence rates with conjunctival limbal autograft technique as healing is promoted by limbal stem cells. 6-8 Amniotic membrane can be used as an adjunctive therapy in pre-existing conjunctival scarring, double headed pterygia and glaucoma patients requiring future filtering surgery.9Complete sterilization of the AM is of utmost importance to render it safe for clinical use. Few studies using cryopreserved amniotic membrane after pterygium excision have observed higher recurrence rate due to decreased efficacy of the graft during the process of cryopreservation. <sup>10-12</sup> Dry amniotic membrane is prepared by freeze-drying the fresh AM without damaging the physical and biochemical properties and retaining the beneficial factors, such as epidermal growth factor and TGF-β1. Dry AM is less expensive as it can be maintained at room temperature when compared to cryopreservation which requires temperatures of -80°C. This makes it more usefull in the developing world and in military environments. 13 CLAG in pterygium surgery can be attached by sutures or fibrin glue or autologous in situ blood coagulum or autologous serum. The advantages of autologous serum are ready availability of patient's own blood, no additional cost, no risk of transmission of blood related diseases and no suture related complications. Few studies have shown good results with this technique. 14-

<sup>16</sup>Thus, the aim of the study is to assess the efficacy and safety of dry amniotic membrane with conjunctival limbal autograft after excision of primary pterygium and to compare the clinical outcome, patient comfort and surgical time using suture or sutureless technique using autologous serum.

### AIMS AND OBJECTIVES

- 1. To compare the surgical outcomes and postoperative symptoms with dry amniotic membrane graft and conjunctival limbal autograft after excision of primary pterygium.
- 2. To compare the clinical outcome and patient comfort between suture and sutureless technique.

# **MATERIALS AND METHODS**

This randomized control trial included 80 patients attending ophthalmology outpatient department over a period of one year. Institutional review board approval was obtained and the study followed the tenets of the declaration of Helsinki. The inclusion and exclusion criteria are as follows

### **Inclusion Criteria**

Patients of either sex above 18 years.

## • Patients with primary pterygium

### **Exclusion Criteria**

- Patients with recurrent pterygium.
- Double headed pterygium
- Patient with known immunodeficiency status.
- Patients with acute ocular infections
- Patients with associated systemic conditions like DM, HTN, TB.

A written informed consent was obtained from patients who fulfil the inclusion and exclusion criteria. Comprehensive ophthalmic examination including visual uncorrected best and corrected acuity measurement, refraction. tonometry, slitlampbiomicroscope and dilated fundus examination was done. 80 patients were randomized to four groups to receive either CLAG or dry AMG (Amniocare, Biocover laboratories) after excision of primary pterygium with or without suture after pterygium excision.

- Group A: CLAG with Suture (CLAG)
- Group B: CLAG with Autologous serum (CLAG-AS)
- Group C: dry AMG with Suture (AMT)
- Group D: dry AMG with Autologous serum (AMT-AS).

The clinical outcomes were evaluated intraoperatively for button hole, graft tear and graft loss( graded as yes/no) and postoperatively for graft oedema, graft loss and recurrence (graded as yes/no) on day 1, at 1 week, 1 month and at 6th month.

**Surgical technique:** All surgeries were performed by the same surgeon and peribulbar anaesthesia was used for all patients (3ml lignocaine 2% +2ml bupivacaine 0.5%). The eye undergoing surgery was prepared and draped in the usual sterile fashion. After insertion of a lid speculum, intrapterygial injection of 0.1ml lignocaine was injected to delineate the fibrovascular tissue. The head of the pterygium was peeled off using blunt dissection and body excised. The subconjunctival fibrovascular tissue over the sclera within exposed area was removed by scissors and the cornea was polished. The bare sclera was measured with calliper and a same sized conjunctival graft was harvested from the superotemporal bulbar conjunctiva after subconjunctival injection of anaesthetic. Meticulous dissection was done around the limbus to harvest conjunctiva without damaging the limbus and the graft was the placed on the bare sclera with orientation of limbal side in the graft towards limbus. For dry AMG transplantation, the pre processed freeze dried amniotic membrane (Amniocare, biocover labs) was cut to the size 0.5mm greater than the bare sclera. The graft was placed over bare sclera and hydrated with saline, edges were buried below the conjunctiva. For securing the graft, 8-0 vicryl was used in suture group and in sutureless technique, autologous serum from host episcleral tissue was allowed to ooze and grafts were placed over it for 10 minutes. The eye was bandaged for next 24 hours and postoperatively analgesic tablets were prescribed. On postoperative day 1, all patients received an identical regimen of antibiotic steroid combination (moxifloxacin 0.5% + fluoromethalone 0.1% ophthalmic solution)four times per day, and tapered off within 1 month.

**Statistical Analysis:** All demographic data including age, sex, occupation and the clinical outcomes were compared between conjunctival autografts and amniotic membrane grafts using the chi square ( $\chi 2$ ) test, SPSS software version 14.

### RESULTS

A total of 80 eyes of 80 patients were included in the study. Patients age ranged from 38-69 years with mean patient age of 52.4 years. The male to female ratio was 1.28: 1 with 45 (56%) males and 35(44%) females. Majority of the patients with pterygium were in 5th decade (52.5%) with 33.75% males and 18.75%. In our study, pterygium was more prevalent in elderly males (table 1, graph 1)

Table 1: Age and Gender distribution

		0				
	Age in years					
	31-40	41-50	51-60	61-70	71-80	
Male	3(3.75	14(17.5	27(33.75	5(6.25	3(3.75	
	%)	%)	%)	%)	%)	
Fema	2	7(0.750/)	15	3(3.75	1(1.25	
le	(2.5%)	7(8.75%)	(18.75%)	%)	%)	
Total	5(6.25	21(26.25	42(52.5%	8(10%)	4(5%)	
	%)	%)	)	) 8(10%)		

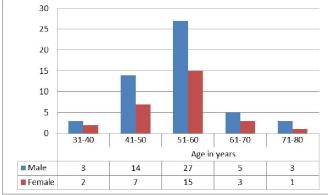


Figure 1: Age and Gender distribution

**Intraoperative complications:** Button holing was noted in 4 cases in CLAG group (3 cases in group A and 1 case in group B). 2 cases had more than 2mm button hole which was sutured with 8-0 vicryl suture and 2 cases had less than 1mm button hole which was managed

conservatively. Graft tear was noted in dry AMG group (4 cases in group C). All the tears were less than 1mm and was managed conservatively. There was no statistical significance in intraoperative complications between the groups (p 0.667) (table 2).

**Table 2:** Frequency of intraoperative complications in each group

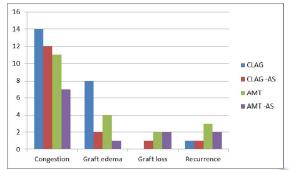
	<b>Button hole</b>	Graft tear
CLAG	3	0
CLAG- AS	3	0
AMG	0	4
AMG-AS	0	0

**Immediate postoperative period:** Graft congestion – 26 cases in CLAG group( 14 cases in group A, 12 cases in group B) and 18 cases in dry AMG group( 11 cases in group C, 7 cases in group D) had graft congestion on postoperative day one which was managed by increasing the frequency of antibiotic steroid drops. At 1 week follow up, none of the cases in either group had graft congestion. There was no statistical significance between the two techniques at postoperative day 1(P 0.384) and at 1 week (P 0.473) (table 3). Graft edema - 10 cases in CLAG group(8 cases in group A, 2 cases in group B) and 5 cases in dryAMG group( 4 cases in group C, 1 case in group D) had graft edema on postoperative day one which was managed by increasing the frequency of antibiotic steroid drops. At 1week follow up, 3 cases in CLAG group and 1 case in dryAMG had graft edema which were observed 2 weekly for 1month. At follow up visit 1month and 6<sup>th</sup>month, none of the cases in either group had graft edema. There was statistical significance between the two techniques at postoperative day 1(P 0.0324) and there was no significance at 1 week (P 0.473) (table 3). Graft loss – 4 cases in dryAMG group (2 cases in group C, 2 cases in group D)had graft loss at 1 week follow up and none in CLAG group. No further intervention was done in these patients and the course was observed with weekly follow up visits till 1month. At 6<sup>th</sup> month follow up, 2 cases of graft loss in group C had recurrence which could be due to exposed sclera. There was no statistical significance between two techniques at 1 week follow up (P 0.473) (table 3).

**Table 3:** Frequency of postperative complications in each group

	Suture group		Sutureless group		P Value	
·	Day 1	Day 7	Day 1	Day 7	Day 1	Day 7
Graft Congestion	65%	20%	45%	2.5%	0.431	0.356
Graft Edema	25%	7.5%	12.5%	2.5%	0.398	0.0373
Graft Loss	0	0	2.5%	10%	-	-

Late postoperative period: Recurrence – In our study, we had 5 cases of recurrence in dryAMG group and 2 cases in CLAG group at 6 month follow up. The recurrence rate was 16.66% in amniotic group and 6.66% in conjunctival autograft group. We found no significant differences in the recurrence rate between the two groups (p=0.282).



**Figure 2:** Frequency of postoperative complications in each group.

**Postoperative patient comfort:** Pricking sensation, redness and foreign body sensation were statistically analysed on postoperative day one and at 1 week follow up. There was statistical significance between suture and sutureless technique on postoperative day one (P 0.004) and at 1 week follow up (P 0.0032) (table 4).

 Table 4: Frequency of Postoperative patient comfort in each group

	Suture group		Sutureless group		P Value	
	Day 1	Day 7	Day 1	Day 7	Day 1	Day 7
Pricking sensation	82.5%	45%	50%	12.5%	0.0380	0.0481
Redness Foreign	65%	32.5%	37.7%	17.5%	0.00315	0.0341
body sensation	72.5%	30%	55%	15%	0.0293	0.0448

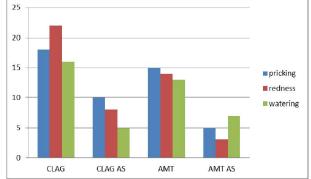


Figure 3: Frequency of postoperative complications in each group

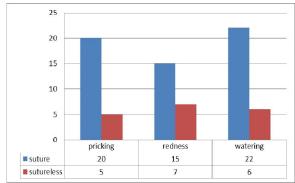


Figure 4: Postoperative patient comfort between suture and sutureless techniques

### **DISCUSSION**

Pterygium is a common ophthalmic condition and its management poses a challenge due to the high rate of recurrence after surgery. Several surgical techniques have been tried to reduce the post operative complications but conjunctival limbal autograft or AMG have gained worldwide acceptance due to good postoperative outcome.<sup>17</sup> The benefits of using AMG in pterygium surgery were first reported by Prabhasawat et al. 18 AM can be prepared fresh or preserved using either freezedrying of the membrane (dry AM) or cryopreservation.<sup>19</sup> Cryopreservation of AM leads to loss of beneficial soluble factors and decrease in its efficacy. Dry AM is made by freeze-drying fresh AM and rehydrating it before use in a freeze-dryer vacuum without prefreezing, thus resulting in improved retention of beneficial factors. Allen et al compared dried and cryopreserved AM as an ocular surface dressing and found that dried AM was superior to cryopreserved AM because of the effect of the preservation process on the tissue.<sup>20</sup> In our study, the analysis of demographic datawas similar to study conducted by Srinivasmarmula et al and Salagar K M et al. 21,22 They observed elderly males with outdoor activity had higher occurrence of pterygium.Similar observation were made in our study( 52.5% elderly males with 48% outdoor activity). In our study we also observed that intra operative and immediate postoperative complications were more with conjunctival limbal autograft as compared to amniotic membrane graft. But, there was no statistical significance at follow up visits. Mutlu et al observed that graft edema was the most frequent complication after conjunctival limbal autograft, which can be managed conservatively. 23 Sheppard JD et al noted that minor complications had no significance in graft survival.<sup>24</sup> Recurrence is a most common complication after pterygium excision and represents significant surgical problem.<sup>25</sup>In our study we noted maximum recurrences in amniotic group (16.66%) and minimum in conjunctival limbal autograft group (6.66%). Masters JS et

al and K N Jha et al observed less recurrence rates with transplantation.<sup>26,27</sup> conjunctival limbal autograft Noureddin GS et al and Allen C et al observed that dry AMG enhanced the structural properties and biochemical stability as compared to conventional cryopreserved AM. 20,28 CLAG or AMG can be attached either with sutures, or with biological adhesive like fibrin glue, which is derived from pooled human plasma or with autologous serum. Sutures may cause patient discomfort, dellen formation, symblepharon or graft rupture.<sup>29</sup> In our study we observed that securing the graft with autologous serum had less complications, better postoperative outcome and less surgical time as compared to suture technique. Suzuki et al reported that use of silk or nylon suture causes conjunctival inflammation and langerhan's cell migration into the cornea. 30 Anbari et al noted that application of autologous glue after pterygium excision resulted in less post-operative pain and shorter surgical time.<sup>31</sup> Limitations in our study include small sample size and short term follow up to monitor the recurrence rate. We observed 4 cases of graft loss during 1 week follow up visit which was conservatively managed and lead to recurrence in 2 cases. This can be prevented by surgical intervention.

### **CONCLUSION**

Conjunctival limbal autograft with autologous serum is the best technique after pterygium excision with fewer complications. It is less time consuming, inexpensive, very effective with better patient comfort and perfect cosmesis. Amniotic membrane graft can be used as an adjunctive therapy in patients with conjunctival scarring, double headed pterygium and glaucoma patients for future filtering surgeries. Freeze-dried AM is free of contamination, easy to transport and store, readily available with minimal preparation at the time of surgery. This makes its more useful in developing countries and military environments.

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