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The efficacy of suture-less glue-free amniotic membrane graft in the management of pterygium

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Abstract
Objectives: The definitive management of pterygium is surgery, but recurrence has remained a major challenge. This is to study the efficacy of suture-less glue-free amniotic membrane grafting in the prevention of recurrence and associated complications
Materials and methods: It was a prospective interventional noncomparative study conducted between June 2016 and February 2017. Twenty-one consecutive patients with 21 various grades and types of pterygia were studied. The patients had pterygium excision with adjunctive suture-less dehydrated glue-free amniotic membrane (Bio DO ptix amniotic extracellular matrix by Bio Diogics Cordova, Tennessee, USA) graft.
Results: There were 10 (47.2%) males and 11 (52.4%) females with a ratio of 0.9:1. The mean age was 36.3±8.74 years. The mean follow-up period was 14.6±3.09 months. Six (28.6%) of the patients had recurrent pterygia while 15 (71.4%) had primary pterygia. Three (14.3%) cases were stage 2 nasal pterygia, 14 (66.7%) were stage 3 nasal pterygia, 4 (19.0%) were stage 4 nasal pterygia. During post-operative follow up, 3 (14.3%) cases of pterygia reoccurred in three patients, two with recurrent pterygia and one had primary pterygium. There were 5 cases of pyogenic granuloma. Four of the pyogenic granulomas resolved with the of topical 0.1% Dexamethasone while one which did not resolve by the conservative management was surgically excised.
Conclusion: The prevalence of pterygium reoccurrence was 14.3%. Suture-less glue free amniotic graft appeared efficacious in the management of pterygium in this study

Keywords: Pterygium, amniotic membrane, reoccurrence

Introduction
A pterygium is a triangular fibro vascular degenerative bulbar conjunctival growth occurring in the palpebral fissure and extending onto the cornea[1]. It is one of the most common surgical presentations to the eye clinic.

It is common in the tropical climates and is thought to be the response to persistent dryness and exposure to ultraviolent rays [1]. A prevalence as high as 22% has been reported in the equatorial areas and less than 2% in latitudes above 40 degrees [2]. In Nigeria, Ukponmwan *et al* [3] reported a prevalence of 12.5% among motorcycle drivers and 7.9% among indoor workers. In another study in Southeastern Nigeria, a prevalence of 19.3% was found also amongst motorcycle riders [4]. It accounted for 9% of clinic attendees in a tertiary eye clinic in Ibadan, Southwest Nigeria [5].

It has the potential to compromise vision and distress a patient cosmetically, functionally, and symptomatically. The encroachment of the lesion onto visual axis and the alteration of the contour of the cornea inducing astigmatism lead to visual impairment. A study in Ogun State, Nigeria, the authors [6] observed that pterygium accounted for 19% of visual impairment and 4% of blindness. Lawan *et al* [7] reported a mean astigmatism of 2.12±1.09 Diopter Cylinder (DC) among 45 eyes of 33 patients which significantly reduced to 0.72±0.5DC after surgery.

The definite management is surgery, but pterygium removal may go hand-in-hand with aggressive recurrence unless adequate measures are taken to prevent recurrence at the time of surgery [8]. Surgical procedures employed for management of pterygium include bare scleral closure, simple conjunctival closure, and use of sliding conjunctival flaps, conjunctival autograft, and cryopreserved or lyophilized amniotic membrane graft. Reoccurrence rate as high as 88% [9] has been reported following a bare scleral pterygium excision. Adjunctive use of chemotherapeutic agents such 5 Fluorouracil (5-FU), Mitomycin C (MMC) and anti-vascular endothelial growth factor (anti-VEGF); radiotherapy, conjunctival autograft,

amniotic membrane graft, lamellar keratoplasty have been known to reduce the rate of reoccurrence [10].

Human amniotic membrane has anti-inflammatory properties and is known to suppress inflammation and formation of fibro vascular tissues and has been used with success to cover the bare sclera after pterygium excision [10]. It serves a useful alternative to conjunctival tissue in situations where there is a large conjunctival defect and shortage of healthy conjunctival tissue to cover the bare sclera commonly seen in multi recurrent pterygia. Reports from several studies on the use of adjunctive amniotic membrane therapy for pterygium excision have shown different recurrence rates varying between 2% [11], 3.8% [12], 6% [13], to 40.9% [14] and 64% [15].

Amniotic membrane (AM) can be prepared fresh or preserved using either freeze-drying of the membrane (dry AM) or cryopreservation. Fresh AM is more commonly used in the developing world, where preservation techniques are not easily performed [8]. The use of fresh AM is less advantageous, not only because it must be used in a limited time and does not exploit the size of the membrane for multiple tissue transplantations, but also poses a greater risk of transmitting infection [16]. Cryopreservation or freeze-drying methods prolonged the lifespan of the amniotic membrane and therefore can be used outside the centre where is prepared.

There is scanty literature on the use of amniotic membrane in pterygium management Nigeria and to best of knowledge there is no report on the use of suture-less glue-free dry amniotic membrane as an adjunct following pterygium excision in Nigeria.

Therefore, this study is to report the efficacy of suture-less glue-free dry amniotic membrane graft in the management of pterygium with respect to the prevention of recurrence.

Materials and Methods

It was a prospective interventional noncomparative study. The study was carried out in compliance with the Helsinki Declaration. Approval was obtained from the University of Port Harcourt Ethics Committee and from the patients with a written informed consent.

Adults aged 20 years and above with at least grade 2 pterygia either primary or recurrent were included in the study. Patients with comorbid cicatricle conjunctival lesions and diabetes mellitus were excluded.

All participating patients had detailed ocular examination including visual acuity, slit-lamp examination and funduscopic. The study was conducted between June 2016 and April 2017

Surgical procedure

All the surgeries were performed by the same surgeon (GIN). Subconjunctival anaesthesia with 2% lignocaine (Xylocaine) containing 1:10 000 adrenaline (epinephrine) was used for all patients. The head of pterygium was first separated at the limbus and dissected towards the central cornea with a spring scissors. After excising the head and most of the body of the pterygium, subconjunctival Tenon's tissue was separated from overlying conjunctiva, undermined, and excised extensively upward and downward towards the furnaces, and medially towards but not reaching the caruncle. Caution was taken not to damage the medial rectus muscle. Cautery was applied to bleeders. The conjunctiva above and below the pterygium was trimmed to create a rectangular area of bare sclera. Residual fibro vascular tissue over the cornea was removed either by toothed forceps or by gentle scrapping with a No 15 Baird-Parker blade.

A rectangular conjunctival defect of approximately 5 × 7 to 6 × 8 mm or even larger was created. This bare scleral area was then covered with dry commercially amniotic membrane (Bio DOptix amniotic extracellular matrix by Bio Diogics Cordova, Tennessee, USA), which was oriented with basement membrane side up without the application of any suture nor glue.

Postoperative follow up

Postoperatively, Maxitrol drops (Alcon) four times daily, ointment maxitriol nocte with oral diclofenac 50mg twice daily (for 3 days) were given. The patients were on the topical steroid for 3 months, but the frequency was gradually tailored down. Patients were followed up at day 1, one week, then monthly to the fourth month, then bimonthly from the fourth month to 1 year. Thereafter, regular follow ups at 3months interval were encouraged. Complications such as pyogenic granuloma, inclusion cyst, or scleral thinning were recorded. Recurrence was defined as any fibro vascular growth beyond the limbus onto the cornea and was assessed by another observer (HON) by slit lamp examination.

Statistical analysis

The data were analyzed using the Statistical Package for Social Sciences (SPSS-16 IBM, Armonk, New York, USA). Univariate analysis and the parametric method were used to calculate frequency, percentage, and 95% confidence intervals (CI.), Chi-square were done to ascertain the statistical significance of the results.

Definitions for purposes of this study [13]

Stage 1 pterygium: Apex of the pterygium is on the limbus

Stage 2 pterygium: The apex is between the limbus and pupillary margin

Stage 3 pterygium: The apex of the pterygium is on the pupillary margin

Stage 4: The apex of the pterygium is on the visual axis

Results

There were 10 (47.6%) males and 11 (52.4%) females with a ratio of 0.9:1. The mean age was 36.3±8.74 years. Six (28.6%) of the patients had recurrent pterygia while 15 (71.4%) had primary pterygia. Three (14.3%) cases were stage 2 nasal pterygia, 14 (66.7%) were stage 3 nasal pterygia, 4 (19.0%) were stage 4 nasal pterygia (Fig 1).

The mean follow-up period was 14.6±3.09 months. During the follow-up period, 3 (14.3%) cases of pterygia reoccurred in three eyes, two with recurrent pterygium and the other was primary pterygium. The recurrence rate for primary pterygia was 6.7% while recurrence rate for recurrent pterygia was 33.3%. Two of the recurrent cases were noted at the 3rd month postoperative visit while one occurred after one-month postoperative period. There were 5 cases of pyogenic granuloma. Four of the pyogenic granulomas resolved with the of topical 0.1% Dexamethasone while one which did not resolve by the conservative management was surgically excised.

Table 1: Clinico-demographic data of the patients

Variable		Frequency (n)	Percentage (%)
Age (years)	<30	01	4.8
	30 — 40	10	47.6
	41— 50	06	28.6
	51— 60	04	19.0
Gender	Male	10	47.6
	Female	11	52.4
Eye	Right	13	61.9
	Left	08	38.1
Stage	1	0	0
	2	03	14.3
	3	14	66.7
	4	04	19.0

Discussion

This was the first reported use of adjunctive suture-less dehydrated amniotic membrane without the use any adhesive with pterygium excision in Nigeria. It was essentially a minimally invasive conjunctival surgery. The process is usually fast as there is no suturing compared with when using other forms of amniotic membrane or conjunctival grafts. With sutured grafting postoperative discomfort is more. Buttonhole, necrosis, inflammation, giant papillary conjunctivitis and granuloma formation is more commonly seen while with non-sutured technique all these problems are less commonly seen. The patients in this study did not notice any unnecessary foreign body sensation associated with sutures. In this study a recurrence rate of 14.3% was noted. This is comparable with a recurrence rate of 14.8% reported by Prabhasaw *at et al* [16], though with bigger cohort of 54 eyes. This is lower than findings in other studies which reported recurrence rates of 40.9% [14] and 64% [15] respectively. Of these studies, the cohort in the study by Essex and colleagues [15] has comparable sample size with this study. The studies by Tananuvat and Martin; and Essex *et al* [15] were all primary pterygia while the study by Prabhasaw *at et al* [16] had both primary and recurrent pterygia. The recurrence rate of 33.3% for recurrent pterygia in this study is slightly lower than 37.5% reported by Prabhasaw at [16]. The recurrence rate in this study is however higher than 2%, 3.8% and 6% reported in other studies [11-13]. However, the cohort with recurrence rate of 6% was followed up only for 3 months which we consider very short compared with our study with at least one year follow up. The cohorts with the recurrence rates of 2% and 3.8% respectively consisted only of primary pterygia unlike our study with both primary and recurrent pterygia. None of these cohorts however use suture-less amniotic membrane.

In a case series of 9 eyes with primary pterygia and managed with excision and suture less amniotic membrane graft with Resure sealant, Bondalapati and Ambati[18] reported no recurrence after a mean follow up of 29.4 weeks No major complications were noted in this study. Five eyes developed wound granuloma with 4 of them resolving spontaneously while one was excised. Therefore, the use of this relatively minimally invasive procedure appeared efficacious in the management of pterygium.

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