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## Comparison Study between Intralesional Injection of Mitomycin C with Bare Sclera Excision of Pterygium and Conjunctival Auto Grafting Technique

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### ABSTRACT

Background: Pterygium is a fibrovascular tissue that abnormally invades the cornea from the conjunctiva.

- Aim of the work: Comparison Bare sclera technique of pterygium excision immediately after injecting it with MMC and conjunctival autografting without using MMC regarding recurrence rate and other complications.
- **Methods:** This prospective interventional study included 40 cases of pterygia from September 2017 to March 2019. cases were divided into two groups: Group 1 included 20 eyes received 0.1 ml [0.01%] of intrapterygial mitomycin-C [MMC] injection, then excision with bare scleral Group 2 included 20 eyes with simple excision then covering the bare sclera with a conjunctival autograft from superior bulbar conjunctiva.
- **Results:** The mean age was 45.175 and 45.4 years in Group 1 and 2, respectively, [P = .527]. There were 7 [35%] males and 13 [65%] females in Group 1 and 8 [40%] males and 12 [60%] females in Group 2 [P = .744]. The regression rate was 5% in each Groups [P = 1]. Postoperatively, scleral hypo vascularity occurred in 5 eyes [25%] in Group 1 while never in Group 2 [P = .009]. Graft necrosis noticed in 2 cases [10%] in group 2.
- **Conclusion:** Both techniques resulted in a negligible [5%] recurrence rate. Although conjunctival graft with a significant reduction of complications as scleral hypo vascularity but with more surgical time.

Keywords: Conjunctival Graft; Intrapterygial injection; Mitomycin C; Pterygium.

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\* Main subject and any subcategories have been classified according to the research topic.

### INTRODUCTION

Pterygium is an abnormal growth of epithelial and fibrovascular tissue invading the cornea from the conjunctiva<sup>[1]</sup>. Prevalence rates range from 0.7% to 31% worldwide, more common in tropical areas older age, male sex, and outdoor activity<sup>[2]</sup>. Surgical removal is the main stay to manage the pterygium, especially in the diminution of vision due to astigmatism or involvement in the visual axis, beauty deformation, discomfort not relieved by conservative measures, and restriction causing limitation of ocular motility<sup>[3]</sup>.

Recurrence of pterygium is considered the main postoperative complication. The recurrence risk is related to age, race, morphology, and type of surgery<sup>[4]</sup>. The recurrence rate is with varying rates from 25% to 90% in just excision without covering the conjunctival defect. Therefore, using augmented drugs [e.g., Mitomycin-C, 5-fluorouracil, bevacizumab<sup>[5]</sup>, ranibizumab<sup>[6]</sup>, aflibercept<sup>[7]</sup>, cyclosporine A<sup>[8]</sup> and interferon  $\alpha 2b^{[9]}$ ] or other techniques with the covering of the bare area is mandatory<sup>[10]</sup>.

Other maneuvers including conjunctival auto graft<sup>[11-13]</sup>, limbal–conjunctival auto graft<sup>[14-15]</sup>, conjunctival flap<sup>[16-17]</sup>, and graft of amniotic membrane<sup>[18]</sup> have been reported.

Excision of pterygium with conjunctival autografting is the standard procedure with a minimal regression rate. However, some authors reviewed regression rates of 21%–40% and sutures-related complications as discomfort, inclusion cyst, granuloma, and sloughed graft<sup>[19]</sup>.

MMC has been used as adjunctive in pterygium surgery since 1963 with different concentrations and forms, i.e., postoperative drops<sup>[20-21]</sup>, intraoperative application<sup>[11-12]</sup>, single-drop installation at the end of operation<sup>[22]</sup>, and preoperative intrapterygial injection<sup>[14,23-24]</sup> with reduction of the recurrence rate but not without serious visionthreatening complications<sup>[25]</sup>.

Preoperative intrapterygium injection of MMC into the head of pterygium 1 month before bare sclera excision of pterygium is valuable with minimal complications<sup>[26]</sup>. In my scientific research, I used intrapterygial injection 0.1 ml of 0.01% MMC

with bare scleral excision in one setting and comparing it to the standard technique conjunctival autograft without using MMC.

### AIM OF THE WORK

The study aimed to compare between bare sclera technique of pterygium excision immediately after injecting it with MMC and conjunctival autografting without using MMC.

### PATIENTS AND METHODS

The current work is a prospective interventional randomized study that enrolled patients of a primary pterygium from September 2017 to March 2019 at the Department of Ophthalmology, El-Hussein hospital, Al-Azhar University, Egypt.

The study protocol had been approved by the ethics Board of Al-Azhar University, and all surgeries were performed after prior written informed consent. Code no is 3154-10-9-2017.

**Inclusion criteria:** Primary nasal pterygium with corneal involvement 2 mm or more indicated for surgery due to vision diminution, ocular restriction, intractable irritation, or disfigurement.

**Exclusion criteria:** All patients with rheumatic or collagen diseases, any type of glaucoma, ocular surface diseases, past ocular surface, adnexal, or intraocular surgery except phacoemulsification, recurrent pterygium, and pseudo pterygium were excluded. Patients were divided randomly into two collections of 20 eyes each.

**Group 1** Patients treated with excision of pterygium with bare sclera next to its injection of 0.1 ml of 0.01% MMC.

**Group 2** patients treated with superior bulbar conjunctival autograft had sutured over the conjunctival defect after pterygium removal.

A detailed history and comprehensive ocular evaluation were done before the operation and postoperatively periodically, including bestcorrected visual acuity, refraction, extraocular movements, tonometry, as well as anterior segment evaluation and fundus examination.

Dry eye was ruled out with Schirmer 1 test and tear film breakup time test. An image of the patient's cornea was recorded to document the size of the

### **EI-Sayed SM.**

pterygium and postoperative comparison. All surgeries were performed by the author, under local anesthesia and using an operating microscope.

**Group 1:** 0.1 ml of 0.01% [0.1 mg/ml] MMC was injected intrapterygial 2 mm away from the corneal limbus using a 28 G insulin syringe [Figure 1]. First, MMC was applied by injection into the pterygium body, which was separated from the conjunctiva and from the cornea by avulsion with the bare sclera.

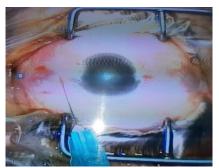


Figure [1]: 0.1 ml of 0.01% MMC was injected intrapterygial 2 mm away from the corneal limbus using a 28G insulin syringe in group 1.

**Group 2:** Patients underwent pterygium excision by avulsion technique as in group 1 followed by conjunctival autograft was performed as follows: superior bulbar conjunctiva was marked to a size larger than the defect and separated from the Tenon's capsule after subconjunctival injection of BSS with Westcott Scissors. The graft was then transposed to cover the naked sclera and fixed to the surrounding conjunctiva with 8-0 Vicryl interrupted sutures [Figure 2].



Figure [2]: The graft was then transposed to cover the bare sclera and sutured to the adjoining conjunctiva with 8-0 Vicryl interrupted sutures in group 2

A pressure eye patch was placed and retained for 24 hours after tobramycin-dexamethasone eye ointment was applied. Postoperative treatment including topical prednisolone acetate 1% with moxifloxacin 0.5% drops every 4 hours and sodium hyaluronate 0.2% drops every 2 hours for 1 month. Fluorometholone was substituted for prednisolone acetate after 2 weeks.

**Follow-up** was done on a postoperative day, weekly for 4 weeks, then every 3 monthly for 1 year. At each visit, patients were specifically examined for recurrence and other complications.



Figure [3] [A] Patient in group 1 early postoperative and one month postoperative [B] Patient in group 2 early postoperative and one month postoperative

**Regurgitation** was defined as any recurrent vessels or fibrous tissue in the excised area encroaching onto the cornea postoperatively.

Scleral ischemia was classified as follows: mild: the presence of few vessels, moderate: no visible any vessels, severe: the presence of a scleral ulcer, and very severe: all of the above with uveal exposure.

Statistical Analysis: The data collected were coded, processed, and analyzed using SPSS version 21 for Windows ® [SPSS, Chicago, IL, USA]

and the SPSS [Statistical Package to Social Sciences]. Chi-Square test was carried out for comparison of groups. Quantitative information was shown as a mean  $\pm$  SD and range. The number and percentage of quality data were presented. Student T – testing was used in two groups for comparison. P < 0.05 was regarded as significant in statistics.

### RESULTS

Forty eyes of forty cases had been enrolled with inside the work, which includes 20 eyes in every group. The cases-age ranging from 28 years to 74 years [mean: 45.175 years]. There had been 7 [35%] men and 13 [65%] ladies in Group 1 and 8 [40%] men and 12 [60%] ladies in Group 2 [P = 0.744]. IN all cases, the lesion encroached the cornea with a mean was 2.4 mm in both Groups [P = 1].

Irritative symptoms as pain, gritty sensation, watering, and photophobia noticed in 40% of cases that disappeared within one month in the MMC group, while in auto graft group occurred in 60% and disappeared within one month. Red-eye with conjunctival ecchymosis and edema was reported in both groups, 8 eyes [40%] in the MMC group and 16 eyes [80%] in the auto graft group, which disappeared within four weeks in all cases. Scleral ischemia had occurred in 5 [25%] eyes in the MMC Group. It was mild in 3 [15%] eyes [Figure 7] and moderate in 2 [10%] eyes [Figure 8]. None of the cases developed scleral ulcer or uveal exposure. This complication never occurred in the other group. The difference was statistically significant [P = 0.009].

Scleral ischemia managed by patching the eye and prescription of preservative-free topical antibiotics four times daily, preservative-free topical sodium hyaluronate every hour, with a stoppage of steroids and doxycycline 100 mg tablets once daily with the healing of all cases in about three months period [Figure 9]. Tenon granuloma had occurred in a patient in the autograft group [Figure 10]. Graft necrosis was noticed in 2 cases [10%] in autograft collection. These patients were reported with graft edematous and avascular in the first ten days postoperative. Later on, it was necrotic and fell off. One of them had pterygium recurrence. [Figure 11]. Regurgitation of pterygium occurred in one eye in each group [5%] with a success rate of [95%] in both groups [P =1]. The recurrent case in group 1 occurred 1 month postoperative, while that of group 2 occurred 2 months postoperative after graft necrosis.



Figure [7]: Mild scleral ischemia



Figure [8]: Moderate scleral ischemia.



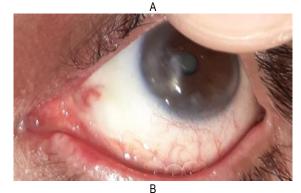


Figure [9]: Scleral ischemia moderate [A] one month post operation and [B] after improvement two months later.



Figure [10]: Tenon granuloma in one case in group 2

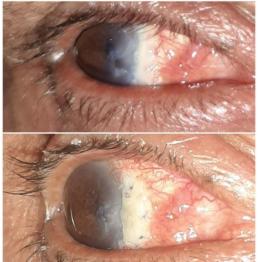


Figure [11]: Graft necrosis was noticed in one case in group 2: lower image one week postoperative with pale graft while in the upper one, the graft was sloughed off completely one month later.



Figure [12]: Recurrence case in group 1



Figure [13]: One of the success cases in group

### DISCUSSION

Many techniques were reported to reduce the recurrence of pterygium after surgery. Currently, using MMC and CAG are widespread and effective methods<sup>[10]</sup>. Although CAG is the standard technique in managing pterygium with minimal recurrence rate but with prolonged time and mild complications relating to the sutures and graft as conjunctival inflammation, tenon granuloma, inclusion cyst, and graft necrosis<sup>[19, 27]</sup>. MMC is applied before, during, or next to the operation. The occurrence of complications related to MMC is proportionally related to its concentration, frequency, and duration; these complications such as scleritis, scleral ulceration, corneal edema, iritis, glaucoma, cataract, hypotony by injury of the ciliary body, and damage to the corneal epithelium and endothelium<sup>[28-30]</sup>. Many trials that used MMC sponge application in different concentrations [0.002% to 0.4%] and different duration [2-5 min.] applied to the bare sclera after pterygium excision was evaluated, with a significant reduction of regression but not without complications<sup>[15, 31-33]</sup>. Postoperative application of mitomycin c eye drops has evaluated in many trials with variable frequency and density with a significant reduction of pterygium regression but not without serious adverse effects as [Sclera ulceration 5% to 19%, iritis 5% to 15%, corneal Dellen 3% scleral thinning 3%]<sup>[21, 34]</sup>. The disadvantages of sponge application or postoperative topical MMC are direct exposure to the cornea and healthy conjunctiva, precise dosing is difficult, and the exposure time and location of the application need further studies to be determined. The injection application directly inside the pterygium has the advantage of protecting the corneal endothelium and epithelium, allows a more precise dose, and MMC is not dilated with the tear<sup>[4]</sup>.

The author compared intraoperative subconjunctival mitomycin-C injection followed with BSE of pterygium and comparing it with conjunctival autograft with success rate was 95% in both groups [one case] in each group. The efficiency and safety of using pre-operative MMC injection in the pterygium body one month before the surgery for pterygium had been reported with a 6% recurrence after 2 years of follow up. The disadvantages of preoperational subconjunctival application are due to In the current study, the operation was in one sitting with the ability to wash MMC. In another study, preoperative injection of MMC was complicated with scleral necrosis<sup>[35]</sup>, but in my study, this complication not occurred because I used less concentration.

Persistent sclera ischemia [moderate to severe] was reported in 5.5% of cases of the MMC group<sup>[24]</sup>, but in my study, scleral ischemia was present in 25% of cases in the MMC group, but the condition was mild [15%] and moderate [10%] and not persistent, and all cases improve within 3 months.

In the current study, the researcher used a conjunctival graft from the upper bulbar conjunctiva in group 2 because it is protected from the sun damaging and the patient had glaucoma or expected to undergo glaucoma surgery were excluded. Some authors prefer using lower bulbar conjunctiva to preserve superior bulbar conjunctive for glaucoma surgery if needed in the future<sup>[36]</sup>. The postoperative trouble of scleral ischemia might also additionally advocate that in addition research can be performed the usage of decrease attention of intrapterygium MMC to lessen the occurrence of scleral ischemia even as keeping its efficacy. However, in the current work, all cases with scleral ischemia were mild to moderate with the development of conservative remedies. The boundaries of the current work covered a fairly small pattern length compared to comparative research within the literature.

**Conclusion:** Both techniques resulted in a negligible [5%] recurrence rate. Although conjunctival graft with a significant reduction of complications as scleral hypo vascularity but with more surgical time.

Financial and Non-financial Relationships and Activities of Interest

None

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