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Comparison Of Conjunctival Autograft And Topical Mitomycin C In Primary Pterygium Surgery For Prevention Of Recurrence: A Tertiary Care Centre

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ABSTRACT

Background: Pterygium is a common ocular surface disorder characterized by a fibrovascular growth of conjunctival tissue onto the cornea. Surgical excision is the primary treatment, but recurrence remains a significant challenge. This study compares the efficacy and safety of conjunctival limbal autograft (CLAG) and intraoperative topical Mitomycin C (MMC) in preventing recurrence after primary pterygium surgery.

Methods: A hospital-based randomized controlled trial was conducted at the Department of Ophthalmology, IIMS&R, Lucknow, involving 70 patients with primary pterygium. Participants were randomly assigned to Group A (MMC, n=35) or Group B (CLAG, n=35). Preoperative and postoperative assessments included visual acuity, tear film tests (TBUT and Schirmer's), slit lamp examination, and recurrence grading using Prabhasawat's classification. Patients were followed for 6 months.

Results: Recurrence was observed in 8.5% of Group A and 2.8% of Group B at 6 months. The mean time to recurrence was slightly earlier in the MMC group (175.14 ± 5.26 days) compared to the CLAG group (178.43 ± 2.12 days). Postoperative complications like corneal haze were more common in the MMC group. Visual acuity improved in both groups, but CLAG had better postoperative stability and fewer complications.

Conclusion: Both CLAG and MMC are effective in reducing pterygium recurrence, but CLAG is superior in terms of lower recurrence and complication rates. It is recommended as the preferred surgical approach in primary pterygium cases.

Keywords: *Pterygium, Conjunctival Limbal Autograft (CLAG), Mitomycin C (MMC), Recurrence, Visual Acuity, Tear Film, Randomized Controlled Trial, Ocular Surface, Pterygium Surgery, Postoperative Complications.*

1. INTRODUCTION

Pterygium is a wing-shaped, fibrovascular conjunctival growth extending onto the corneal surface, primarily affecting individuals in tropical and subtropical regions due to chronic exposure to ultraviolet (UV) radiation, wind, dust, and dryness. It is characterized by elastotic degeneration of collagen and fibrovascular proliferation, and although benign, it may cause irritation, cosmetic disfigurement, and significant visual impairment due to induced astigmatism or occlusion of the visual axis [1,2].

Surgical excision remains the mainstay of treatment; however, recurrence is the most common and significant postoperative complication. Recurrence rates vary widely based on the surgical technique employed, with bare sclera excision alone showing recurrence rates ranging from 24% to 89% [3]. To combat this issue, several adjunctive techniques have been developed, including the application of Mitomycin C (MMC), conjunctival autografting (CAU), and amniotic membrane transplantation.

MMC is a potent antimetabolite derived from *Streptomyces caespitosus*, which inhibits fibroblast proliferation and angiogenesis, thereby reducing recurrence. Despite its efficacy, MMC has been associated with serious complications such as scleral necrosis, corneal melt, and secondary glaucoma, especially when used in higher concentrations or for prolonged durations [4,5].

Conjunctival autografting, particularly limbal conjunctival autograft (LCAG), introduced by Kenyon et al. in 1985, has significantly reduced recurrence rates (reported between 2% and 15%) by restoring limbal stem cells and providing a barrier to conjunctival overgrowth [6]. Compared to MMC, CAU is considered safer, with minimal complications like graft retraction or displacement [7].

Several studies have compared the efficacy of MMC and CAU in reducing pterygium recurrence, with varying outcomes. Some suggest comparable recurrence rates between the two, while others report superior results with CAU, especially in long-term follow-ups [8,9]. However, the choice between the two often depends on the surgeon's experience, the clinical scenario, and resource availability.

This study was undertaken to compare the efficacy and safety of conjunctival limbal autograft (CLAG) and intraoperative topical Mitomycin C (0.02%) in preventing recurrence after primary pterygium surgery in a tertiary care setting, with a follow-up period of 6 months. The study also evaluates visual outcomes, ocular surface parameters, and postoperative complications associated with both procedures.

MATERIALS AND METHODS

Place of Study: This hospital-based randomized controlled trial was conducted in the Department of Ophthalmology, Integral Institute of Medical Sciences & Research, Integral University, Lucknow, Uttar Pradesh.

Study Design and Duration: The study was designed as a prospective, interventional follow-up study conducted over 18 months from May 2023 to December 2024. Data collection was conducted over 12 months (May 2023 to May 2024), and data compilation, statistical analysis, and finalization of the thesis were completed within the following 6 months (May 2024 to December 2024).

Ethical Consideration: Before commencement, the study was approved by the Institutional Research and Ethical Committee. Informed written consent was obtained from all participants after explaining the nature and purpose of the study.

Sample Size and Grouping: A total of 70 patients diagnosed with primary progressive pterygium were enrolled. The sample size was determined using a rule-of-thumb formula for randomized trials. Patients were randomly assigned to two groups (n=35 per group) using the lottery method:

- **Group A**: Patients underwent primary pterygium excision with intraoperative application of 0.02% Mitomycin C.
- **Group B**: Patients underwent primary pterygium excision followed by conjunctival limbal autograft (CLAG).

Inclusion Criteria

1. Patients aged >18 years with clinically diagnosed primary pterygium.
2. Patients providing informed written consent for participation.

Exclusion Criteria

1. Patients unwilling to participate.
2. Patients with lid, conjunctival, or corneal pathology.
3. Patients with moderate to severe dry eye disease.
4. Cases of recurrent pterygium.

Preoperative Evaluation

All enrolled patients underwent comprehensive ocular examinations, including detailed medical and occupational history with documentation of sunlight exposure (indoor <6 hours/day; outdoor ≥6 hours/day). The following assessments were performed preoperatively:

- **Visual Acuity**: Uncorrected and best-corrected distance visual acuity measured using the Snellen's chart, converted to logMAR.
- **Slit Lamp Examination**: For pterygium grading:
    - Grade 1: 0–2 mm
    - Grade 2: 2.1–4 mm
    - Grade 3: >4 mm
- **Tear Film Break-Up Time (TBUT)**:
    - Fluorescein staining and cobalt blue filter observation under slit lamp.
    - TBUT Classification:

        - <5 sec: Severe dry eye
        - 5–10 sec: Mild to moderate dry eye
        - 10 sec: Normal
- **Schirmer's Test I**:
    - Performed with Whatman filter paper No. 41 in the lower fornix for 5 minutes.
    - Interpretation:
        - 15 mm: Normal
        - 10–15 mm: Mild dry eye
        - <10 mm: Moderate to severe dry eye

Surgical Procedures

Group A: Pterygium Excision with Mitomycin C Application

Mitomycin C (0.02%) was prepared by reconstituting a 2 mg vial with 5 mL distilled water. From this, 0.1 mL was mixed with an additional 0.1 mL of distilled water to obtain a 0.2 mL solution of 0.02% concentration.

Surgical steps:

- Subconjunctival anesthesia with lignocaine hydrochloride.
- Pterygium resected after conjunctival and fibrovascular tissue dissection.
- Pterygium head separated from the cornea using a crescent blade.
- Tenon's capsule excised.
- 0.02% Mitomycin C applied with arrowhead sponge for 5 minutes on bare sclera.
- Area irrigated thoroughly with normal saline.
- Conjunctiva approximated and sutured with 10-0 nylon.
- Eye patched with antibiotic ointment.

Group B: Pterygium Excision with Conjunctival Limbal Autograft (CLAG)

Surgical steps:

- Similar pterygium excision as Group A.
- Autograft harvested from superior bulbar conjunctiva ensuring absence of Tenon's tissue.
- Graft placed over bare sclera and secured with 10-0 nylon sutures.
- Postoperative care similar to Group A.

Postoperative Care and Follow-Up

Postoperative management included oral antibiotics, analgesics, and antacids. Topical antibiotic and lubricant eye drops were prescribed thrice daily for two weeks. Patients were evaluated at the following intervals:

- Day 1, Week 1, 1 Month, 3 Months, and 6 Months.

During each follow-up, the following were assessed:

- Ocular symptoms: Redness, foreign body sensation, watering, photophobia, blurring, inflammation.
- Slit lamp examination for graft integrity, inflammation, or recurrence.
- Visual acuity (UCVA and BCVA).
- TBUT, Schirmer's test, and keratometry readings.

Recurrence Assessment (Prabhasawat et al. Grading):

- **Grade 1**: Normal appearance at operative site.
- **Grade 2**: Fine episcleral vessels at excision site up to limbus without fibrous tissue.
- **Grade 3**: Presence of fibrous tissue without corneal invasion.

- **Grade 4**: True recurrence with fibrovascular corneal invasion.

RESULTS AND OBSERVATIONS;

Table 1 Age-Wise Distribution of Patients in Both Groups (n=70)

Age Group (years)	Group A (n=35)	Group B (n=35)	Total (n=70)	Percentage (%)
18–30	6 (17%)	8 (23%)	14	20%
31–40	7 (20%)	6 (17%)	13	19%
41–50	10 (28%)	9 (26%)	19	27%
>50	12 (34%)	12 (34%)	24	34%

No statistically significant difference in age distribution between Group A and Group B (p = 0.960).

Table 2: Distribution on the basis of laterality of pterygium in the two groups

	NASAL	TEMPORAL	BILATERAL
GROUP A (n=35)	31 (88.5%)	1 (2.8%)	3 (8.5%)
GROUP B (n=35)	32 (91.4%)	1 (2.8%)	2 (5.7%)
TOTAL (n=70)	63 (90%)	2 (2.8%)	5 (7.1%)

Laterality distribution is not significantly different between groups (p = 0.864).

Table 3: Tear Film Break-Up Time (TBUT) Distribution in Group A and Group B – Preoperative and Postoperative Follow-Up (n = 70)

TBUT (sec)	Group	Pre-op	1 Week	1 Month	3 Months	6 Months
< 5 sec	Group A	1 (2.8%)	1 (2.8%)	3 (8.5%)	3 (8.5%)	4 (11.4%)
	Group B	2 (5.7%)	1 (2.8%)	5 (14.2%)	4 (11.4%)	4 (11.4%)
6–10 sec	Group A	8 (22.8%)	11 (31.4%)	11 (31.4%)	12 (34.2%)	12 (34.2%)
	Group B	11 (31.4%)	9 (25.7%)	9 (25.7%)	8 (22.8%)	15 (42.8%)
> 10 sec	Group A	27 (77.1%)	23 (65.7%)	21 (60.0%)	28 (80.0%)	19 (54.2%)
	Group B	23 (65.7%)	25 (71.4%)	21 (60.0%)	26 (74.2%)	16 (45.7%)

(p-value = 0.744)

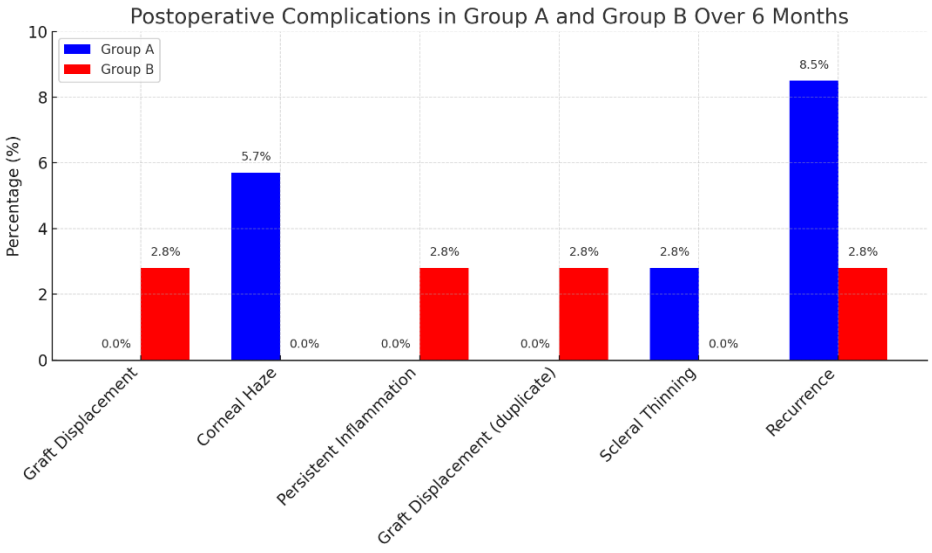
Table 4: Schirmer's Test Values in Group A and Group B – Preoperative and Postoperative Follow-Up (n = 70)

Schirmer's Value	Group	Pre-op	1 Week	1 Month	3 Months	6 Months
>15 mm	Group A	25 (71.4%)	22 (62.8%)	20 (57.1%)	22 (62.8%)	11 (31.4%)
	Group B	25 (71.4%)	25 (71.4%)	20 (57.1%)	24 (68.5%)	10 (28.5%)
10–15 mm	Group A	6 (17.1%)	9 (25.7%)	9 (25.7%)	9 (25.7%)	8 (22.8%)
	Group B	4 (11.4%)	5 (14.2%)	5 (14.2%)	7 (20.0%)	9 (25.7%)
<10 mm	Group A	4 (11.4%)	4 (11.4%)	6 (17.1%)	4 (11.4%)	16 (45.7%)
	Group B	6 (17.1%)	5 (14.2%)	10 (28.5%)	4 (11.4%)	16 (45.7%)

(p-value = 0.948)

Table 5: Post-operative complications in the two groups over a period of 6 months

COMPARISON OF POSTOPERATIVE COMPLICATIONS IN BOTH GROUPS			
Complication Type	Group A (n=35)	Group B (n=35)	p-value
Graft Displacement	0	1 (2.8%)	0.32
Corneal haze on operated site	2 (5.7%)	0	0.005
Persistent Inflammation	0	1 (2.8%)	0.32
Graft displacement	0	1 (2.8%)	0.001
Scleral Thinning	1 (2.8%)	0	0.164
Recurrence	3 (8.5%)	1 (2.8%)	0.164



Figure; 1 Post-operative complications in the two groups over a period of 6 months

Table 6: Postoperative Clinical Features and Recurrence Pattern in Group A and Group B (n = 70)

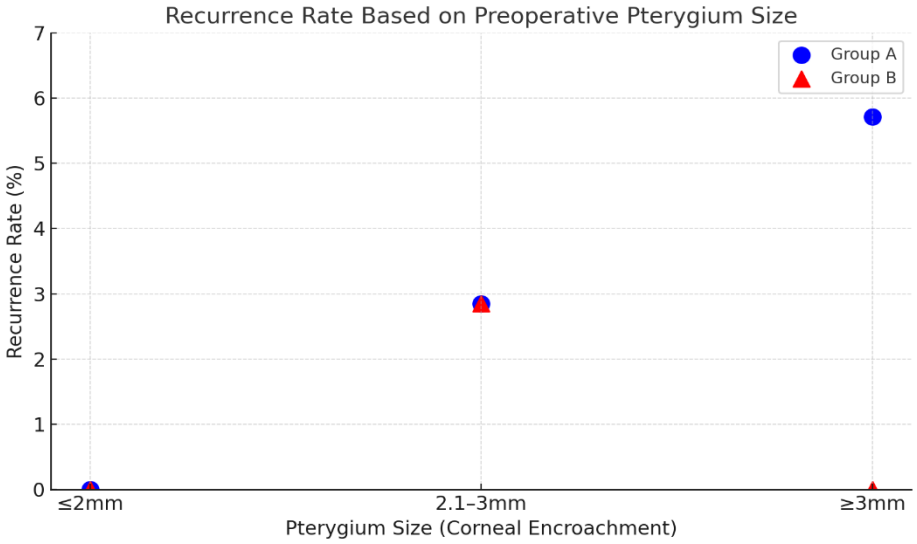
Time Point	Clinical Parameter	Group A (n=35)	Group B (n=35)	p-value
1 Week Post-Op	Redness	4 (11.4%)	2 (5.7%)	0.164
	Foreign Body Sensation	3 (8.5%)	7 (20.0%)	—
	Recurrence	0	0	—
1 Month Post-Op	Recurrence	0	0	—
3 Months Post-Op	Recurrence	1 (2.8%) – Grade 1	0	0.324
6 Months Post-Op	Recurrence	3 (8.75%)	1 (2.85%)	0.164
	Recurrence Grades	2 Grade 3, 1 Grade 2	1 Grade 3	—

Table 7: Recurrence Rate, Mean Time to Recurrence, and Age-Wise Distribution in Group A and B (n=70)

Parameter	Group A (n=35)	Group B (n=35)	p-value
Recurrence Rate			
1 Week	0 (0%)	0 (0%)	—
1 Month	0 (0%)	0 (0%)	—
3 Months	1 (2.85%)	0 (0%)	0.324
6 Months	3 (8.57%)	1 (2.85%)	0.164
Mean Time to Recurrence (Days ± SD)			
At 3 Months	74.06 ± 4.21	79.11 ± 8.21	0.019
At 6 Months	175.14 ± 5.26	178.43 ± 2.12	0.001
Age-wise Recurrence at 6 Months			
< 30 years	2 (5.71%)	1 (2.85%)	—
30–50 years	0 (0%)	0 (0%)	—
> 50 years	1 (2.85%)	0 (0%)	—

Table 8: Distribution of patients based on rate of recurrence in comparison to preoperative pterygium size.

Recurrence Rate Based on Pterygium Size			
Pterygium Size (Corneal Encroachment)	Group A: Recurrence (n=35) (%)	Group B: Recurrence (n=35) (%)	p-value
≤2mm	0	0	-
2.1-3mm	1 (2.85%)	1 (2.85%)	1
≥3mm	2(5.71%)	0	0.152



Figure; 2 Recurrence rate based on preoperative pterygium size

2. DISCUSSION

Pterygium is a chronic, degenerative condition of the ocular surface characterized by the fibrovascular proliferation of conjunctival tissue encroaching onto the cornea. Despite being a benign lesion, pterygium can lead to significant visual disturbances, cosmetic concerns, and recurrence following surgical excision, which remains a major clinical challenge. Various surgical techniques have been employed to minimize recurrence, including bare sclera excision, conjunctival autografting, and the use of antimetabolites such as Mitomycin C (MMC). This randomized controlled study compares the efficacy and safety profiles of conjunctival limbal autograft (CLAG) and intraoperative topical MMC (0.02%) in the management of primary pterygium, with special attention to recurrence rates, postoperative complications, tear film stability, and visual outcomes.

Age and Laterality Distribution

The majority of patients in both groups were aged over 50 years (34% each), with a substantial number in the 41–50 years age group (27%) (Table 1). These findings reflect the cumulative effects of environmental exposure to ultraviolet radiation, wind, and dust over time, which are well-established etiological factors in pterygium development [1,2]. Interestingly, recurrence was more commonly observed in patients younger than 30 years, particularly in Group A (2 patients) and Group B (1 patient), aligning with literature suggesting that younger individuals exhibit more aggressive fibrovascular activity and a higher risk of recurrence [10].

Most pterygia were located nasally (88.5% in Group A and 91.4% in Group B), which aligns with global epidemiological data indicating a predominance of nasal pterygia due to greater UV exposure and anatomical susceptibility (Table 2). The medial canthus has less protection from UV rays due to the nasal bridge, leading to higher incidence rates [3].

Tear Film Stability and Schirmer's Test

Tear film breakup time (TBUT) and Schirmer's test were used to evaluate ocular surface stability preoperatively and during follow-up. A significant proportion of patients in Group A exhibited TBUT <10 seconds at the 6-month mark (45.6%), compared to 28.5% in Group B (Table 3). The application of MMC, while effective in preventing fibrovascular regrowth, appears to exert toxic effects on the conjunctival epithelium and goblet cell density, contributing to tear film instability [6]. This ocular surface disruption is less pronounced in CLAG, which preserves limbal stem cells and goblet cell function, thereby maintaining better ocular surface integrity [7].

Similarly, Schirmer's test values deteriorated in both groups, but more markedly in Group A. At 6 months, 45.7% of patients in both groups had Schirmer's values <10 mm, yet the proportion of patients maintaining normal tear production (>15 mm) was higher in Group B (28.5%) compared to Group A (31.4%) (Table 4). Though these differences were not statistically significant, they suggest a trend toward better postoperative tear film preservation in the CLAG group.

Postoperative Complications

The incidence of postoperative complications was higher in the MMC group. Notably, corneal haze was observed in 2 patients (5.7%) in Group A and none in Group B (p=0.005), indicating a statistically significant difference (Table 5). Corneal haze and scleral thinning are recognized complications of MMC due to its antiproliferative effect on epithelial and stromal cells [5]. One patient in the MMC group experienced scleral thinning, reinforcing concerns regarding its safety profile, even

when applied at a concentration of 0.02% for 5 minutes. Conversely, complications in the CLAG group were limited to one case each of graft displacement and persistent inflammation, suggesting a more favorable safety profile [3,8].

Recurrence Pattern and Visual Outcomes

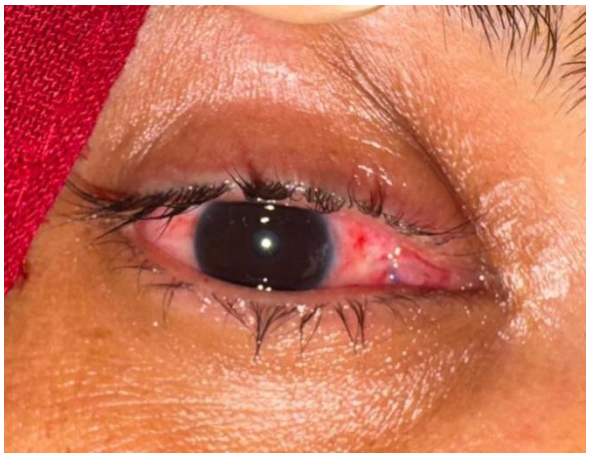
The recurrence rate was higher in the MMC group (8.57%) than in the CLAG group (2.85%), though the difference was not statistically significant (p=0.164) (Table 6). This supports the notion that while MMC effectively inhibits fibroblast proliferation, it does not provide a physical barrier against conjunctival regrowth, unlike CLAG, which restores limbal barrier function and prevents fibrovascular invasion [4]. Most recurrences in both groups were categorized as Grade 2 or 3, indicating moderate fibrovascular activity without full corneal encroachment.

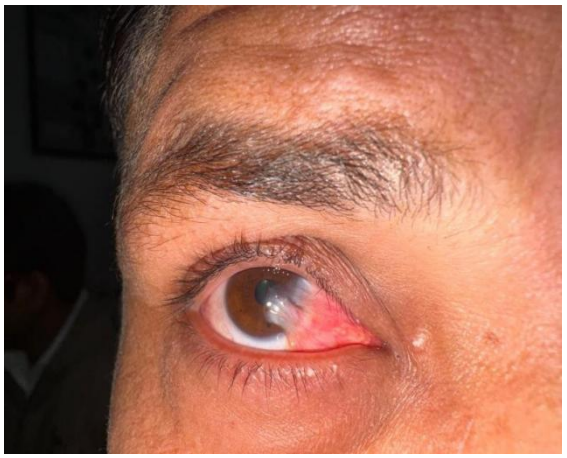
The mean time to recurrence was significantly earlier in Group A (175.14 ± 5.26 days) compared to Group B (178.43 ± 2.12 days) (Table 7), highlighting the superior durability of CLAG. Although the difference in recurrence time is modest, it may have clinical relevance in high-risk patients or those requiring long-term stability.

Visual acuity improved in both groups, with 71.4% of patients in Group A and 62.8% in Group B achieving a best-corrected visual acuity (BCVA) between 6/6 and 6/12. The slight discrepancy may be due to corneal haze in MMC-treated eyes, as epithelial toxicity can impair optical clarity [5]. Nevertheless, both interventions produced satisfactory functional outcomes.

Influence of Pterygium Size

Larger pterygium size was associated with a higher recurrence risk, especially in Group A. In pterygia with corneal encroachment ≥3 mm, 2 recurrences were observed in Group A and none in Group B (Table 8). This finding corroborates earlier studies indicating that the extent of corneal involvement is a predictor of recurrence [9]. Smaller lesions (≤2 mm) did not recur in either group, suggesting that lesion size should be a consideration when planning surgical intervention and selecting the adjunctive technique.





CONCLUSION: Conjunctival limbal autograft (CLAG) showed a lower recurrence rate and fewer complications compared to intraoperative Mitomycin C (MMC) in primary pterygium surgery. While MMC is simpler, CLAG offers better long-term outcomes and is the preferred method for recurrence prevention.

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