Efficacy of Combined Use of Mitomycin C Intraoperatively and Conjunctival Autograft with Fibrin Glue in the Surgical Management of Primary Pterygia

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Abstract

Purpose: This study will evaluate the efficacy of combined intraoperative use of Mitomycin C and Conjunctival autograft with fibrin glue in the surgical Management of primary Pterygia.

Methods: Fourteen patients with primary Pterygia were enrolled in this study. They had undergone pterygium excision with bare sclera technique followed by intraoperative Mitomycin C 0.02% application to the bare sclera using a medication-soaked filter paper for duration of two minutes with copious irrigation of the ocular surface by balanced salt solution. Finally conjunctival graft is fashioned and secured in place using fibrin glue.

Patients: Were followed-up for a minimum of 8 months (mean, 13 months). The possible intraoperative, postoperative complications and recurrence rate were documented.

Results: After a mean follow-up of 13 months, there were no recurrent cases. There were no intraoperative complications. Postoperative complications include early total graft dehiscence developed in 1 eye treated with repositioning with glue and suture and two cases of conjunctival cysts on the graft which required no intervention. Four cases suffered temporarily from excessive lacrimation, ocular pain and photophobia. No detectable serious-vision threatening complications like permanent conjunctival defects, scleral ulceration, scleral perforation, iridocyclitis, glaucoma or cataract. The mean age of the patients was 36 years.

Conclusion: Combined intraoperative use of Mitomycin C and Conjunctival autograft with fibrin glue in the surgical Management of primary Pterygia seems to be safe and effective method for prevention of postoperative pterygium recurrence. Certainly, larger numbers of patients with longer follow-up period is a must to assess the recurrence rate of this method.

Key Words: Primary pterygia – Mitomycin C – Conjunctival autograft – Fibrin glue – Surgical management.

Introduction

PTERYGIUM is a usually benign growth of the conjunctiva that extends from the nasal side of the sclera. It can involve the central cornea, thus compromising vision and cosmetic appearance of the involved eye. It is more common in men and has been thought to be caused by ultraviolet light (such as sunlight) exposure, low humidity and dust. Pterygia consist of elastotic degeneration of collagen along with fibrovascular proliferation. The neck of the pterygium connects the advancing head to the body of the pterygium [1].

One of the major limitations of pterygium excision is the high rate of postoperative pterygium recurrence after the bare sclera technique. Recurrence is the most common undesirable outcome of pterygium excision. Several factors increase the recurrence rate after surgery, such as: The activity of the pterygium, individual susceptibility and repeated surgeries [2].

The more often the surgery is performed, the more likely it is that the pterygium will recur. To avoid repeated surgeries, the fibrovascular activity of an impending recurrent pterygium should be stopped before it can progress to a true recurrence [2].

Because the recurrence of pterygium has been attributed to fibroblast proliferation and migration, several modalities were evaluated as adjunctive therapies, such as: radiation, Mitomycin C (MMC), 5-fluorouracil (5-FU), combined with simple excision to reduce the recurrence rate [3].

According to the pathophysiology of recurrent pterygium and the role of fibrovascular proliferation, Injection of Avastin which is anti VEGF was postulated to decrease or inhibit the fibroblastic activity thus lowering the recurrence rate [3].

Various surgical techniques exist for the management of pterygium. Conjunctival autografts
have been demonstrated to yield the best results in lowering recurrence rate and in safety. It is also more economical, only requiring a short additional surgical time when combined with fibrin glue application [4].

Amniotic membrane closure and conjunctival autografts seem to be equally effective in the prevention of recurrence of primary Pterygium. Due to the larger area of subconjuctival fibrosis in case of the recurrent pterygium, a larger defect area is created after the excision of pterygium tissue and a larger graft is needed to close this defect [5].

Mitomycin C (MMC) uses, intraoperatively or postoperatively, is one of the adjunctive treatments that can significantly reduce the rate of pterygium recurrence [2].

MMC is an antibiotic isolated it was isolated by Hata et al., from Streptomyces caespitosus in 1956. It is an alkylating agent that is bioreductive because it undergoes metabolic activation through a cytochrome P-450 reductase mediated reaction to create an alkylating agent. MMC damages cells by cross linking DNA, forming covalent bonds with the guanine in DNA. MMC inhibits the synthesis of DNA, RNA, and protein and is radiomimetic in many of its actions [6].

Fibrin glue is a blood-derived product that is absorbable, safe, relatively easy to use, and can be kept at room temperature or in a refrigerator. Ever since the introduction of fibrin glue in ophthalmology, its major use has been in pterygium surgery. Fibrin glue has been used frequently in attaching conjunctival autografts. Studies have demonstrated reduced operating time, postoperative discomfort and inflammation. Reduced recurrence rate has also been reported for conjunctival autografting in pterygium surgery with the use of fibrin glue compared with the sutures.

Fibrin glue includes a fibrinogen component and a thrombin component, both prepared by processing plasma [7].

The commercially available products are produced from pools of plasma, usually contain high yields of fibrinogen consequently, and produce firm coagulums. Fibrin glue forms a smooth seal along the entire length of the wound edge and thereby provides greater postoperative comfort to the patient with fewer complications [8].

Tisseel® (baxter immuno, vienna, austria) was the first fibrin sealant approved by the US FDA for use in the USA. Fibrin sealant is now FDA approved for use as a topical hemostat, sealant and adhesive [8].

All fibrin sealants in use have two major ingredients, purified fibrinogen (a protein) and purified thrombin (an enzyme) derived from human or bovine (cattle) blood. Many sealants have two additional ingredients, human blood Factor XIII and an aprotinin, which is derived from cows' lungs. Factor XIII is a compound that strengthens blood clots by promoting crosslinkage of fibrin strands. Aprotinin is a protein that inhibits the enzymes that break down blood clots [8].

Patients and Methods

Following informed consent, 14 consecutive patients with primary nasal pterygium were enrolled in this study (Table 1). Approval for this study was obtained from the Research Ethics Board of King Abdul-Aziz University Hospital in Saudi Arabia and from the Department of Ophthalmology in Dr Bakhsh Hospital in Jeddah, Saudi Arabia. The study adhered to the tenets of the Helsinki Declaration.

They had undergone pterygium excision with bare sclera technique. The surgery was performed using an operating microscope. Xylocain 10mg/ml with adrenaline 5µg/ml was used for topical, subconjuctival and sometimes subtenonal anaesthesia. An eye speculum was placed between the eyelids.

The pterygium head was detached from the cornea, and the pathologic conjunctiva with the underlying Tenon’s tissue was excised with scissors.

The incisions were made in the cornea 1 to 2mm central to the leading edge of the pterygium and deep enough to include Bowman’s layer. The incisions were extended into the adjacent conjunctiva for 5 to 6mm posterior to the surgical limbus and 1 to 2mm beyond the superior and inferior conjunctival folds. The cornea was scraped clean, the sclera cleared from connective tissue and any bleeding vessels were cauterized.

This was followed by intraoperative Mitomycin C 0.02% application to the bare sclera using a medication-soaked filter paper for duration of two minutes with copious irrigation of the ocular surface by balanced salt solution. Finally Conjunctival graft was harvested at the superotemporal limbus and secured in place using fibrin glue, (Baxter, AG) 2ml.

Patients were followed-up for a minimum of 8 months (mean, 13 months). The possible intraoperative, postoperative complications and recurrence rate were documented.
Fibrin glue preparation:

- The two components of fibrin glue can either be applied simultaneously or sequentially, depending on the surgeon’s preference.

- The kit contains fibrinogen, thrombin, aprotinin and CaCl₂. The components of fibrin glue are loaded into two syringes with tips forming a common port (e.g., Duploject® syringe). When injected, the two components are mixed in equal volumes at the point of delivery. The setting time is dependent on the concentration of the thrombin component.

- The thrombin converts the fibrinogen to fibrin by enzymatic action at a rate determined by the concentration of thrombin. The more concentrated thrombin solution, thrombin 500, produces a fibrin clot in about 10 seconds and the more dilute thrombin solution, thrombin 4, results in a clot in about 60 seconds after glue application to the surgical field. As mentioned earlier, both the extrinsic and the intrinsic mechanisms of blood coagulation are bypassed but the physiological final common pathway of coagulation is replicated. Factor XIII (present in the fibrinogen component of the glue) cross links and stabilizes the clot's fibrin monomers while aprotinin inhibits fibrinolytic enzymes, consequently resulting in a stable clot.

- For sequential application, thrombin is first applied on to the area of interest, followed by a thin layer of fibrinogen. In a minute or two, coagulation starts and by two or three minutes, polymerization is complete.

- Alternatively, when apposition is required between opposing surfaces, thrombin solution may be applied to one and fibrinogen to the other surface.

- In all of these cases, prior to application of the glue, the surgical field must be dried meticulously. After application, the tissue is pressed gently over the glue for 3 minutes for firm adhesion. At the end of the procedure, pad and bandage is applied after instillation of antibiotic drops [9].

Indications for the removal of the Pterygia in the study group were:

- Significant ocular irritation unresolved by medical therapy.

- Impaired ocular cosmoses.

- Reduced visual acuity from induced astigmatism or encroachment of the pterygium to or over the visual axis.

- Continued documented progression, so that it can be assumed that eventual visual impairment is likely.

Those patients who were suspicious to have malignancy, diabetes mellitus or any other endocrine disorder, those with history of any other associated ocular disorder rather than pterygium and those wearing contact lenses were excluded.

All cases were performed by me from February 2012 to January 2013 in the Department of Ophthalmology in King Abdel Aziz University Hospital in Jeddah, and in the Department of Ophthalmology in Dr Bakhsh Hospital, Jeddah, Saudi Arabia.

For all patients a thorough ophthalmic examination was performed including:

- Visual acuity testing using Snellen chart.

- Applanation tonometry.

- Slit-lamp examination.

- Fundus examination.

Demography:

| Table (1): Demographic data of the patients. |
|------------------|------------------|
| Patients No      | 14               |
| Sex (M/F)        | 10/4             |
| Age (years)      | 35.9±11.23 (18~54) |
| Follow-up period (Months) | 11.4±2.036 |
corneal epithelial status, and intraocular pressure (IOP), were recorded.

Postoperatively, the eyes were patched for 3 days. During the first postoperative week, dexamethasone eye drops (Maxidex) were given six times daily together with Fucithalmic eye ointment (fucidic acid) three times daily. Dexamethasone was taper-off over the next 5 weeks, and no additional antibiotics were given. Patients were advised to wear sun glasses for the first month postoperatively.

The results of pterygium excision in concerning the recurrence rate (Table 2) can be classified into 4 grades [10]:

**Grade 1:**
The conjunctiva has a normal appearance with no signs of recurrence.

**Grade 2:**
Lesions have some fine episcleral vessels at the surgical site.

**Grade 3:**
Lesions have fibrovascular tissue at the area of excision but do not involve the cornea; grade 3 lesions and recurrence in the conjunctiva are more likely to progress to a true recurrence.

**Grade 4:**
Is a true recurrent pterygium with fibrovascular tissue covering the excision area and invading the cornea.

Postoperative complications and side effects (Table 3) including; excessive lacrimation, mild superficial punctate keratopathy and ocular pain and photophobia were reported. Also Serious-vision threatening complications like permanent conjunctival defects, scleral ulceration, scleral perforation, iridocyclitis, glaucoma and cataract were reported too.

Patients were questioned specifically about the side effects. Side effects were graded absent, light and severe (-, +, ++) according to the severity of the patients discomfort.

Complications were graded as absent, light and severe (-, +, ++) according to the severity of the clinical finding.

**Results**

Patients were followed-up for minimum of 8 months (mean, 13 months). No recurrent cases had been encountered as shown in (Figs. 1,2), (Table 2).

<table>
<thead>
<tr>
<th>Cases</th>
<th>Post operative pterygium excision recurrence grading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>Grade 2</td>
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<tr>
<td>Case 2</td>
<td>Grade 1</td>
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<td>Case 3</td>
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<td>Case 4</td>
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<td>Case 5</td>
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<td>Case 6</td>
<td>Grade 2</td>
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<td>Case 7</td>
<td>Grade 2</td>
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<td>Case 8</td>
<td>Grade 1</td>
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<td>Case 9</td>
<td>Grade 1</td>
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<td>Case 10</td>
<td>Grade 2</td>
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<td>Case 11</td>
<td>Grade 2</td>
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<td>Case 12</td>
<td>Grade 1</td>
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<tr>
<td>Case 13</td>
<td>Grade 2</td>
</tr>
<tr>
<td>Case 14</td>
<td>Grade 1</td>
</tr>
</tbody>
</table>

**Complications:** There were no intraoperative complications.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Absent (–)</th>
<th>Light (+)</th>
<th>Severe (++)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive lacrimation</td>
<td>6 (42.85%)</td>
<td>6 (42.85%)</td>
<td>2 (14.28%)</td>
</tr>
<tr>
<td>Photophobia</td>
<td>7 (50%)</td>
<td>6 (42.85%)</td>
<td>1 (7.14%)</td>
</tr>
<tr>
<td>Ocular pain</td>
<td>7 (50%)</td>
<td>6 (42.85%)</td>
<td>1 (7.14%)</td>
</tr>
<tr>
<td>Superficial punctate keratopathy</td>
<td>12 (85.72%)</td>
<td>2 (14.28%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Conjunctival cysts on the graft</td>
<td>12 (85.72%)</td>
<td>2 (14.28%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Conjunctival dehiscence</td>
<td>13 (92.85%)</td>
<td>(0%)</td>
<td>1 (7.14%)</td>
</tr>
<tr>
<td>Scleral perforation</td>
<td>14 (100%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>14 (100%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
<tr>
<td>Cataract</td>
<td>14 (100%)</td>
<td>(0%)</td>
<td>(0%)</td>
</tr>
</tbody>
</table>

Postoperative complications (Table 3) include, early total graft dehiscence developed in one case treated with repositioning with glue and suture, two cases of conjunctival cysts on the graft which required no intervention and four cases suffered temporarily from excessive lacrimation, ocular pain and photophobia treated conservatively. No detectable serious-vision threatening complications like permanent conjunctival defects, scleral ulceration, scleral perforation, iridocyclitis, glaucoma or cataract with the study cases.
Clinical results:

Fig. (1): Pterygium excision with Mitomycin C, conjunctival graft and fibrin glue preoperative and postoperative results.

Fig. (2): Pterygium excision with Mitomycin C, conjunctival graft and fibrin glue preoperative and postoperative results.

Discussion

Pterygium surgery has been a challenge in the past. My goal with this study was to implement pterygium surgery that was safe, easy to perform and with satisfactory recurrence rate.

Pterygium is typically treated by surgical excision. However, the postoperative recurrence rate is high with simple excision and many methods have been developed to reduce this rate, including β-irradiation, application of Mitomycin C, human amniotic membrane (HAM) transplantation, and autologous conjunctival grafting or limbal conjunctival autografting [5].

An evaluation of efficacy of combined use of Mitomycin C intraoperatively with Conjunctival autograft and fibrin glue in the surgical management of Primary Pterygia was the target of the study.

To the best of my knowledge, no study has yet been reported or published regarding the use of Mitomycin C intraoperatively with Conjunctival autograft and fibrin glue in the surgical management of Primary Pterygia. There is only one study which used this method but only for recurrent Pterygia not the primary ones.

Intraoperative use of Mitomycin C as adjunctive medication during pterygium surgery on the basis
of its antifibroblastic activity to prevent recurrence after excision had been used since 1988 [11].

Tahery and Lee, in 1989 had hypothesized that MMC even with short exposure times, has the ability to suppress cellular proliferation completely since its action is relatively cell-cycle nonspecific when compared with 5-Flourouracil and similar drugs [12].

Mitomycin C gained popularity as a postoperative adjunctive therapy to pterygium excision [11,13,14]. However, reports on serious side-effects such as delayed epithelial healing, scleral or corneal melting, fungal or bacterial keratitis, endophthalmitis and cataract formation were a concern [15-18].

Intraoperative MMC, unlike postoperative MMC therapy, provides the surgeon direct control regarding localization, concentration and duration [19,20]. Combined with bare sclera excision it is technically simple and fast. Unlike earlier studies, where saturated sponges were used, Lam et al., [21] tried to apply the same amount of MMC on each eye by the means of standard sized filter paper soaked in MMC. MMC concentrations between 0.02 and 0.1% and duration between 2 and 5 minutes are reported. They chose 0.04% and 3 min to have maximum efficacy with a reasonable safety.

Rodriguez et al., [22] had done a retrospective analysis of fifty eyes who underwent pterygium excision with intraoperative topical Mitomycin C 0.05% and had found that, the pterygium recurred in 4 (8%) eyes. Another four eyes (8%) had a cosmetically acceptable recurrence of <2.0mm. The only complication was a corneal dellen in one eye. So the conclusion was that Intraoperative administration of Mitomycin C at 0.05% is safe and effective in preventing pterygium recurrences.

Dennis [23] & Lam et al., [21] examined the efficacy of intraoperative Mitomycin C (MMC) in preventing recurrence of pterygium after excision and the postoperative complications encountered in 180 patients’ primary and recurrent pterygia. Recurrence of pterygia and postoperative complications such as superficial scleral melting were measured. All patients received pterygium excision with intraoperative MMC application. The midterm results of a single intraoperative application of MMC at the concentration of 0.02% for 5 minutes are encouraging. Its application as an adjunctive therapy for the surgical treatment of pterygium appeared to be safe and effective. However, because of the possibility of serious late complications, the authors suggest that this procedure be reserved for patients who have high probability of recurrence after excision of pterygium.

Anduze [24] reported 870 cases of primary and recurrent Pterygia treated with a single application of 0.1 cc of 0.4mg/ml of MMC to the subconjunctival space. The overall recurrence rate was 0.35%. A total of 60 patients were followed for a period of 10 years. No corneal, scleral, or retinal complications were found.

Yanyali et al., had performed in 2000 a randomized study in, primary pterygium. In 19 eyes, the “bare sclera technique” combined with intraoperative application of 0.2mg/mL (0.02%) Mitomycin C for five minutes was performed. The other 19 eyes taken as control group underwent surgical excision alone. 4 recurrences (21%) were observed in the Mitomycin C treated group and 11 (57.8%) in the control group. The difference between the two groups was significant (p=0.045). No postoperative complication was encountered in both groups except for recurrences [25].

Kenyon et al., [26] emphasized the method of using free autologous conjunctival grafts in pterygium surgery. This technique is considered safe, but surgically more demanding and time-consuming.

Koranyi et al., [27] found that pterygium surgery including free autologous conjunctival grafting is associated with fewer recurrences, re-operations and complications than using the bare sclera technique together with single-dose intraoperative MMC.

Katircio˘glu et al., [5] found that Amniotic membrane closure and conjunctival autografts seem to be equally effective in the prevention of recurrence of primary pterygium. Conjunctival autografts combined with Mitomycin C are as effective as the above two techniques to prevent recurrence in the treatment of recurrent pterygium.

Figueiredo et al., found that Conjunctival autograft decreased the recurrence rate for primary pterygium compared with simple excision [28].

Wong et al., [29] suggested using MMC in patients with more severe pterygia as an adjunct to conjunctival autograft to lower the recurrence rate. Combining the use of MMC with conjunctival autograft allows for decreased dosage and time of intraoperative exposure of Mitomycin, thereby making it safer for application.

The use of fibrin glue has been introduced in the treatment of pterygium. However, its role versus traditional suturing is still a matter of debate.
Koranyi et al., postulated that fibrin glue facilitates better adhesion of the graft with the underlying tissues, which may result in early graft vascularization and thus prevents recurrence. The success of autografts may also be affected by conjunctival inflammation. Sutures can cause additional trauma to the injury site and surrounding tissue, act as a nidus for infection and can usher in infectious agents along the suture tract [30].

Hall et al., compared pterygium excision with conjunctival autograft surgery using Tisseel fibrin glue versus Vicryl sutures. Both glued and sutured conjunctival autografting procedures are safe and effective methods for pterygium surgery. The glued autograft recurrence rate at 12 months was similar to that of sutured grafts. Conjunctival autograft with fibrin glue in pterygium surgery decreased surgical time and resulted in less postoperative pain in the first 48 hours [31].

Huerva et al., performed a study to demonstrate the long term of follow-up of the recurrence rate after conjunctival autograft for pterygium surgery. It had been found that after a long follow-up period after autograft pterygium surgery, there were no statistically significant differences in recurrence rates for the application of sutures as opposed to fibrin glue; similarly, there were no statistically significant differences between the use of autograft in primary and recurrent pterygium [32].

Pan et al., evaluated the safety and clinical efficacy of fibrin glue in pterygium surgery with conjunctival autografting. It had been found that the superiority of fibrin glue to suture in pterygium surgery with conjunctival autografting is that the use of fibrin glue can significantly reduce the recurrence rate without increasing the risk of complications. Ophthalmologists should consider the use of fibrin glue in pterygium surgery [33].

Ratnalingam et al., evaluated the recurrence rate, surgical time, and postoperative pain between conjunctival autografting with sutures and with fibrin adhesive in pterygium surgery. The use of fibrin adhesive in primary pterygium surgery with conjunctival autografts reduces the recurrence rate, surgical time, and postoperative pain when compared with sutures [34].

In my study there were no recurrent cases after a mean follow-up of 15 months.

A similar study performed by Shehadeh-Mashor R. et al., to evaluate the safety and efficacy of using fibrin glue in cases of recurrent pterygium treated with pterygium excision and conjunctival autograft combined with Mitomycin C found that at a mean follow-up of 26.5 months, there was 1 case of recurrence [35].

Also in my present study, in concerning the intraoperative complications, there were no intraoperative complications while, there were a group of postoperative complications which include early total graft dehiscence developed in 1 eye treated with repositioning with glue and suture and two cases of conjunctival cysts on the graft which required no intervention. Four cases suffered temporarily from excessive lacrimation, ocular pain and photophobia treated conservatively. No detectable serious-vision threatening complications like permanent conjunctival defects, scleral ulceration, scleral perforation, iridocyclitis, glaucoma or cataract.

Similar complications had been reported by a similar study performed in recurrent pterygia by Shehadeh-Mashor et al., [35].

Singh et al., had found that Although MMC significantly reduced the rate of pterygium recurrence to a range of less than 10%, severe complications such as corneal oedema, corneal perforation, scleral calcification, corectopia, iritis, sudden onset mature cataract, severe secondary glaucoma, incapacitating photophobia, and pain were reported by Singh and others. These complications occurred within the first postoperative period and were mostly related to uncontrolled use of high cumulative doses of MMC [11].

Serious-vision threatening-complications were reported by Hayasaka et al., [36] and by Rubinfeld et al., [16] in patients when high, cumulative dose of MMC was applied. These include permanent conjunctival defects, scleral ulceration, narcotizing scleritis, scleral perforation, iridocyclitis, glaucoma and cataract. All these complications occurred in patients exceeding the treatment schedule and with high concentration of MMC. These complications resulted in further surgeries and led to severe visual loss.

Kaufman et al., had got evidence that the bare sclera excision of pterygium results in a significantly higher recurrence rate than excision accompanied by use of certain adjuvants. Conjunctival or limbal autograft was superior to amniotic membrane graft surgery in reducing the rate of pterygium recurrence. Among other adjuvants, there is evidence that Mitomycin C and conjunctival or limbal autografts reduce the recurrence rate after surgical excision of a pterygium. Furthermore, the data indicate that using a combination of conjunctival or limbal autograft with Mitomycin C further
reduces the recurrence rate after pterygium excision compared with conjunctival or limbal autograft or Mitomycin C alone. Additional studies are necessary to determine the long-term effects, optimal route of administration, and dose and duration of treatment for Mitomycin C. Factors such as availability of resources, primary or recurrent status of pterygium, age of patient, and surgeon or patient preference may influence the surgeon’s choice of adjuvant because there are insufficient data to recommend a specific adjuvant as superior [37].

Conclusion:

I think that adjunctive use of combined intraoperative use of Mitomycin C and Conjunctival autograft with fibrin glue in the surgical management of primary Pterygia seems to be safe and effective method for prevention of postoperative Pterygium recurrence. Certainly, larger numbers of patients with longer follow-up period is a must to assess the recurrence rate of this method. In the near future it might be considered as the standard technique for pterygium excision with nil recurrence postoperatively.

References


