"A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFECTIVENESS OF CONJUNCTIVAL AUTOGRAFT VERSUS CONJUNCTIVAL AUTOGRAFT COMBINED WITH INTRAOPERATIVE MITOMYCIN-C FOLLOWING PTERYGIUM EXCISION."

By

DR. ISHA VATSAL

Dissertation

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IN

OPHTHALMOLOGY

Under the Guidance of

DR.REKHA B.K. M.S. ,D.O.M.S.
Professor

DEPARTMENT OF OPHTHALMOLOGY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM.

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Date:

Place: Belgaum **(DR. ISHA VATSAL)**

KLE UNIVERSITY BELGAUM, KARNATAKA

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Date:
Place:

Guide :
Dr. REKHA B.K. **M.S.,D.O.M.S.**
Professor,
Department of Ophthalmology,
J.N.MedicalCollege,
Belgaum.

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Dr. R. K. Dandur **M.S., D.O.M.S.**
Professor & Head,
Department of Ophthalmology
J. N. Medical College,
Belgaum-590010
Date:
Place:

Dr. V. D. Patil **M.D., D.C.H.**
Principal,
J. N. Medical College,
Belgaum-590010.

Date:
Place:

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I bow my head in respect before God Almighty.

Dr. Isha Vatsal

LIST OF ABBREVIATIONS

MMC	Mitomycin C
CAG	Conjunctival Autograft
M	Male
F	Female
Group A	Conjunctival Autograft
Group B	Conjunctival Autograft + Mitomycin C
CF	Counting fingers
RHD	Rheumatic Heart Disease
BCVA	Best Corrected Visual Acuity
Prog	Progressive
F.Mass	Fleshy mass
Pri	Primary
Rec	Recurrent
SCH	Sub conjunctival haemmorhage
G.E.	Graft edema
S.Gran	Suture Granuloma
D.K.	Deep keratectomy
DF	Degree of freedom
Gr.Rec	Recession of graft
L.Sut	Loose suture
m	Months
F. Up	Follow up
S.Blnch	Scleral blanching
B.Hole	Button holing

ABSTRACT

BACKGROUND AND OBJECTIVES:

Pterygium is a triangular , fibrovascular encroachment of bulbar conjunctiva on to the cornea and is horizontally situated in the inter palpebral fissure on either the nasal or temporal side of the cornea. Prevalence of pterygium is high in the tropical belt of the world, especially in India where hot, sunny and dusty weather favours its growth.

Indications for treatment vary from minor cosmetic disfigurement to significant visual loss. Surgical removal remains the mainstay of treatment ,basic procedure being complete excision leaving a bare area of sclera. The recurrence rate of this traditional Bare Sclera technique ranges from 24% - 89%.

In recent two years, 2 surgical techniques have become increasingly accepted as methods likely to prevent pterygium recurrence, namely Mitomycin C application and conjunctival autograft transplantation.

Conjunctival autograft technique is reported to have recurrece rates ranging from 2% to 39%. Adjunctive use of Mitomycin C in pterygium surgery is reported to be a safe and effective procedure. Conjunctival autograft combined with intra operative application of Mitomycin C is reported to have recurrence rates ranging from 2% to 9%.

This study is undertaken to compare the recurrence rates of pterygium in conjunctival autograft technique versus conjunctival autograft combined with Mitomycin C and also to study the complications associated with the two procedures.

METHODOLOGY:

The present prospective randomized controlled trial was conducted at KLES Hospital & MRC , Belgaum, over a period of one year , from 1st January 2008 to 31st

December 2008**.** In the study, 50 eyes of 47 patients who met the inclusion criteria were included. After detailed preoperative evaluation, informed written consent was taken and they were randomized into two groups to receive either conjunctival autograft or conjunctival autograft combined with intraoperative application of 0.02%(0.2 mg/ml) Mitomycin C for 1 minute ,following excision of pterygium. All 50 eyes completed the study with a minimum follow up of 4 months. A detailed documentation of the post operative complications and recurrence at the end of the study was done.

OBSERVATIONS AND RESULTS:

The majority of patients in our study were in the age group 40-49 years (32%). Mean age in Group A was 43.2 years (range 20-62 years) and in Group B was 45.2 years (range 30-65 years). Out of the 50 eyes of 47 patients who presented to us with pterygium, 22 (44%) were that of men and 28 (56%) were that of women. Out of the 50 cases 47 (94%) were primary pterygium and 3 (6%) were recurrent pterygium. Among 50 cases, only 1 (2%) temporal pterygium was included in the study. Majority (56%) of the eyes with pterygium in this study were those of outdoor workers.

A total of 22 (44%) eyes had intra operative and post operative complications in the study. Out of these 22 eyes, 10 (40%) eyes belonged to Group A and 12 (48%) eyes to Group B. The difference was not statistically significant (p value = 0.5). Among the significant complications, there were 4 cases of Granuloma formation (8 %) (2 in CAG group and 2 in CAG + MMC group), 3 cases of Superficial Punctate Keratitis (CAG + MMC group) and 1 case of scleral blanching(CAG + MMC group.)

Of the 50 cases, there were no recurrence seen in any eye in both the groups after a minimum follow up period of 4 months and maximum period of 11 months.

CONCLUSION:

From our study, we conclude that both Conjunctival Autograft technique and Conjunctival autograft combined with intraoperative application of 0.02%Mitomycin C for one minute following Bare sclera excision of pterygium are equally effective in preventing the recurrence of pterygium. Both the procedures appear to be safe and acceptable as adjuvants in pterygium surgery.

Key words: Pterygium; recurrence; randomized; Conjunctival Autograft; Mitomycin C; complications.

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INTRODUCTION

Pterygium is a horizontally oriented triangular growth of abnormal tissue that invades the cornea from a base in the canthal region of the bulbar conjunctiva. Pterygium takes its name from the Greek word 'Pterygos' meaning wing. It was first described by Hippocrates , Galen and others.

Much has been speculated , believed and written about it but the definitive etiology and mode of development continues to elude the best of researchers. It is one of the most common conjunctival diseases among the ophthalmic pathologies and one of the most obvious of Ophthalmopathies(sun related conditions)[(1)]. UV light induced damage to the limbal stem cell barrier with subsequent conjunctivalization of the cornea is the currently accepted etiology and hence more common in outdoor workers.

It is extremely common being worldwide in distribution. Incidence is more in tropical and sub-tropical countries. " India , a tropical country where heat and dust are environmental synonyms, is an ideal home for pterygia. India forms a part of the "Pterygium belt" as described by Cameron.

It causes chronic irritative symptoms, cosmetic complaints and decreased vision as the pterygium encroaches the visual axis or induces astigmatism. Indications for surgery include visual impairment , cosmetic disfigurement, motility restriction, recurrent inflammation and interference with contact lens wear.

Although the diagnosis of pterygium has been extremely easy , it remains an unresolved disease with unsatisfactory outcomes and frequent recurrences. Recommended surgical management includes simple excision and excision with adjunctive measures like post operative Beta radiation, Argon laser therapy,

instillation of anti-metabolites, conjunctival autograft, amniotic membrane transplantation etc.

The traditional method of simple excision by bare sclera technique has recurrence rates ranging from 24% to 89%.

In recent two years, 2 surgical techniques have become increasingly accepted as methods likely to prevent pterygium recurrence, namely Mitomycin C application and conjunctival autograft transplantation.

After the excision, bare sclera can be covered by a conjunctival autograft. This procedure has recurrence rates ranging from 2% to 39%.

Adjunctive use of Mitomycin C in pterygium surgery is reported to be a safe and effective procedure . Conjunctival autograft combined with intra operative application of Mitomycin C is reported to have recurrence rates ranging from 2% to 9%.

This study is undertaken to compare the recurrence rates of pterygium in conjunctival autograft technique and conjunctival autograft combined with intra operative application of Mitomycin C after pterygium excision and also to study the complications associated with the two procedures.

AIMS AND OBJECTIVES

1. The purpose of this study is to investigate the rate of post operative recurrence of pterygium after conjunctival autograft versus conjunctival autograft combined with intra operative application of Mitomycin C after pterygium excision.

2. To find out the incidence of complications associated with the two procedures.

REVIEW OF LITERATURE

HISTORICAL REVIEW

The word pterygium is derived from the Greek word 'pterygos' meaning wing. Its description as a clinical entity has been recorded throughout the millennia by Hippocrates, Galen and others. Pterygium has been recognized and written about for the last 300 years.

Sushruta, the world's first ophthalmologist recorded the first pterygium removal. " With the patient in recumbent position on an operating table, the pterygium is loosened and disturbed by sprinkling powdered salt into the eye. With the patient looking laterally, a sharp hook is used to secure the growth at its upturned part. The pterygium is got rid of by scratching it with a sharp round topped instrument. Any remnant of the pterygium should be removed with a scarifying ointment to prevent recurrences."

Sushruta's technique suggests that even in ancient times the problems of pterygium management were recognized. Apparently, care was taken to remove any tissue remnants in the hope that there would be no recurrence.

Pterygium is one of the most common corneal disorders. Yet, despite great deal of research, very little is known about it .There has been no limit to the hypothesis put forward to explain its origin to the ingenious techniques to overcome it and to this day many are quoted as saying , " The disease is a mystery"

Fuchs was the first to popularize the differentiation of pterygium into either :

1. Thick, vascular ,progressive type
2. Thin, white , non progressive type

GEOGRAPHIC DISTRIBUTION

Pterygium occurs throughout the world but is more common in subtropical and tropical areas. Cameron (1983) [2] has mapped worldwide distribution and finds it more prevalent inside the 30th latitude parallel and very rare north or south of 40th parallel. Hence, a relative pterygium belt straddles the equator.

It is one of the common corneal disorders seen in Saudi Arabia

DEFINITION

A pterygium is a horizontally oriented triangular growth of abnormal tissue that invades the cornea from a base in the canthal region of the bulbar conjunctiva.

ETIOPATHOGENESIS OF PTERYGIUM

Numerous different theories have been put forth to explain the pathogenesis of pterygium.

Certain strong co-relations have been found:

1. Chronic conjunctivitis theory:

Many early writers felt that pterygium had an inflammatory basis. Friede felt that chronic conjunctivitis is the predisposing factor, influenced by exposure and tissue secretion, which leads to episcleritis from which infiltrates extend into the sublimbal region of cornea. Hill (1989) [3] concluded that pterygium is a result of chronic conjunctival inflammation from various causes.

That pterygium is inflammatory in origin is evidenced by the following findings:

- The constant presence of round cell infiltration in front of the advancing head and in the subepithelial tissue in the progressive pterygium.
- Marked increase in the goblet cell in the epithelium.
- Epithelial hypertrophy and presence of epithelial downgrowths and cysts

2. Pinguecula- Pterygium theory

This theory was first started by Richter in 1804 and supported by Fuch's who directly followed the growth of a pterygium from a pinguecula. Fuch's demonstrated that the histopathology of pinguecula is characterized by increased number of thickened elastic fibres, hyaline degeneration of the conjunctival tissue, concretions and epithelial changes ,and that similar changes also occur in pterygium along with characteristic corneal involvement.

Sugar (1949) **(4)** has been a prominent advocate of the hypothesis that pterygia develop from pinguecula. His view was that the pinguecula is a degenerative change in the sub conjunctival fascia. The degenerative process which may rise in the pinguecula then lead to the deposition of hyaline material which causes an elevation that eventually separates the epithelium in the cornea adjacent to the head of the pterygium

3. Ultraviolet radiation

Ultraviolet (UV) light is one of the major factors implicated in the pathogenesis of pterygium, although the mechanism by which UV light induces this disease remains elusive. **(5)**

Pterygium is thought to be caused by increased exposure to light, dust, dryness, heat and wind. Pterygium was seen twice as frequent among people who worked outdoors but was only one fifth as likely among those who always used sunglasses outdoors. **(6)**

There is a strong suggestion of a causal relationship between ultraviolet light exposure and the development of pterygia during the early years of life and the cumulative exposure over the next 2 to 3 decades in occupations in which there is a high component of reflected ultraviolet light. **(7)**

A possible mechanism of action of ultraviolet light has been proposed by Johnson and Overall. They have suggested that plasma proteins , especially albumin, IgG, IgA ,are affected or denatured by ultraviolet radiation as they diffuse through the cornea. This results in their deposition and accumulation. Because these proteins are concentrated in the periphery, it is not surprising that their accumulation should be first seen in that area. The distribution in the palpebral fissure is entirely consistent with a direct radiation effect, as is the superficial location.

I Karai, S Horoguchi (1984) **(8)** observed a significantly high incidence of pterygia in welders who were exposed occupationally to excess ultraviolet radiation and found a close relationship between the incidence and the length of employment as a welder .

In the Barbados eye studies, the incidence of pterygium was high in black population, for an average of 1.3% per year. Working outdoors increased the risk 1.5-fold, whereas having a darker skin complexion and using eyewear for either reading or distance substantially decreased the risk of developing pterygium. (9)

4. Chronic keratitis theory

Pinkerton et al (1984) **(10)** found IgE (100%) and IgG (73%) deposited in pterygium connective tissue stroma. Also, plasma cells and lymphocyte infiltration were seen in the same areas as the IgE and IgG. Whether chronic inflammation is a cause of pterygium or a secondary finding is unclear.

5. Human Papilloma Virus in pterygium

Pterygia have been postulated to be caused by inflammation at the junction of a conjunctival blood vessels and Bowman's membrane where the autolytic process of inflammation results in a protein degradation of amino acid mixture. This amino acid mixture has the ability to attract conjunctival vessels onto the cornea. Human

Papilloma Virus 6, 11, 16 are the postulated causative agents of this process.

Gallagher et al(2001) [11] found that HPV is involved in the pathogenesis of primary and recurrent pterygia.

Nicolai C S et al(2007) [12] in a study done in Denmark, noticed low presence of HPV DNA in pterygia and do not support the hypothesis that HPV is involved in the development of pterygia in Denmark.

6. Apoptosis and Apoptosis related gene expression

Donald TH et al (2000) [13] demonstrated the presence of apoptotic cells in the basal layer of cells of the epithelial layer, situated immediately adjacent to the fibrovascular support layer. These cells were shown to express significant levels of p53 and bax, as well as the apoptosis inhibiting protein bcl-2.

In contrast, normal conjunctival specimens displayed no bcl-2 expression and apoptotic cells were seen throughout the entire width of the epithelial layer, coupled with high levels of bax expression.

7. p53 Expression in pterygium

Nicholas Dushku et al(1999) [14] found two cell types : a p53-positive pinguecula limbal epithelial cell (a pinguecula II cell) and a p53-positive pterygium dysplasia cell (pterygium dysplasia cell).Their study data support the theory that increased p53 expression in the limbal epithelia, pinguecula, pterygium and limbal tumours indicates the probable existence of p53 mutations in these cells as an early event in the development.

8. Role of Limbal stem cells

Recently, the importance of limbal stem cells in the pathogenesis of pterygia has been reported. [15]

Growth of pterygium occurs in two stages:

1. Initial and progressive destruction of the limbal corneal conjunctival epithelial barrier.
2. Progressive active "conjunctivalization" of the cornea by tissue characterized by extensive cellular proliferation, inflammation, connective tissue remodelling and angiogenesis.

A healthy limbal stem cell population provides a stable junctional barrier that prevents conjunctivalization of the cornea. In pterygium, there is a breakdown of the limbal stem cell barrier. Altered stem cells have been found at the leading edge of the pterygium head. Inclusion of limbal stem cells in a conjunctival autograft, for the treatment of pterygium aids in the complete anatomic and physiologic reconstruction of the excised pterygium area.

Mohamed A. E. Soliman Mahdy et al [(16)] recorded a recurrence rate of 4.75 % with conjunctival and limbal stem cell autograft. This is one of the lowest reported recurrence rate so far and may be due to the use of a very thin conjunctival graft devoid of Tenon's tissue in addition to incorporating a part of the adjacent limbal stem cells in the graft.

9. Molecular factors in pterygium

Certain molecular factors have been reported to play a role in the pathogenesis of pterygium like Heparin-binding epidermal growth factor, Insulin-like growth factor binding protein-3 , Human{alpha}" defensins and S100 A8 and A9 .

Heparin-binding epidermal growth factor (HB-EGF), a potent growth factor capable of stimulating altered cell growth and anchorage independence, has been implicated in the pathogenesis of pterygia.[(17)]

Identification of the low level of expression of IGFBP3 (insulin-like growth factor binding protein-3) in pterygium suggests that the pathway controlling cell

proliferation has lost an important control mechanism, which may explain the continued growth of pterygium.[18]

The upregulated expression of human {alpha}" defensins and S100 A8 and A9 in tear fluids of patients with pterygium indicates that they may be part of the response of the ocular surface to the formation of this fibrovascular tissue or the accompanying inflammation. They may also serve as a useful indicator for predicting recurrence of pterygium. [19]

10. Angiogenesis Factor

The presence of pterygium angiogenesis factor has been proposed which develops following repeated irritation at the limbus following any cause. The repeated insult causes vascular engorgement which causes release of proteolytic enzymes which cause destruction of the Bowman's membrane. The altered proteins so formed can then act as angiogenic or pterygiogenic factors.

Risk factors for pterygium Site:

The nasal part of the bulbar conjunctiva is more affected than the temporal part. Various explanations are given for its prediliction for nasal side.

According to Dr. Sabri Kamal (1980) of Egypt:-

1. It is more exposed to direct irritation than the temporal conjunctiva.
2. The normal flow of the tears is from temporal to nasal side towards the punctum and carries with it any dust particles entering the conjunctival sac and accumulates in lacus lacrimalis. This probably leads to more irritation of the nasal conjunctiva.
3. Greater exposure of the nasal inter palpebral conjunctiva to ultraviolet radiation (Cameron 1965).
4. Greater bowing of the lateral two third of upper lid and consequent protection

by longer lashes.

5. Greater curvature of nasal fibres of orbicularis oculi causing a greater squeezing effect upon nasal subconjunctival tissue (Sugar 1949).
6. Presence of 2 anterio ciliary arteries on the nasal side and only 1 on the temporal side. It is considered due to this fact that any irritant shall lead to greater hyperemia on nasal side and may play an important role in production of pterygia commonly on nasal side.(Wolf 1950)
7. Excess of sub conjunctival tissue on nasal side than temporal.
8. Pinguecula develops more often on nasal side than temporal side.

Age:

The disease affects mostly adults between age of 25 - 40 years. Incidence is highest in the age group of 20 to 49 years. Duke Elder reports congenital pterygium.

Sex:

The disease is more common in males than females with a ratio of incidence 2:1. This may be due to the fact that males are exposed more to the external environment of sunlight and dust.

Occupation:

The disease is commonly seen in people with outdoor activities and who are more exposed to sunlight. e.g. farmers, fishermen. Welders are also at an increased risk due to exposure to ultraviolet rays.

Environmental factors:

Heat, dry atmosphere, high winds, exposure to sunlight and abundance of dust were incriminaited by many authors to be the etiological factor for pterygium (Fuch 1892, Anderson 1954, Redmond 1956). Although dryness and dust are probably potent etiological factors, they cannot explain the frequent occurrence of the condition

in humid areas. Elliot believed in mechanical irritation by dust particles enhanced by tear flow from lateral to nasal side, as an etiological factor.

Hereditary factors:

The inheritance is autosomal dominant with a lower penetrance , but it would appear that it is not the actual lesion which is transmitted but rather the tendency of the eye to react in this way to environmental stimuli. Some researchers also suggest a genetic predisposition due to an expression of vimentin, which indicates cellular migration by the keratoblasts during embryological development. These cells also exhibit an increased p53 expression , likely due to a deficit in the tumor suppressor gene. This gives the impression of a migrating limbus because the cellular origin of the pterygium is actually initiated by the limbal epithelium. **(20)**

Blood Group:

"O" blood group is more commonly associated with pterygium according to Beattle (1947)

MORPHOLOGY AND PHYSICAL CHARACTERISTICS

Pterygium may be subdivided into four types based on clinical characteristics, pathology and suspected pathogenesis.

1. True pterygium
2. Pseudo pterygium
3. Recurrent pterygium
4. Malignant pterygium

True pterygium

A true pterygium lies in the inter palpebral aperture and is firmly attached to the corneal stroma throughout its entire length.

Pseudo pterygium

It is a fibrovascular scar arising in the bulbar conjunctiva and extending onto the cornea. Unlike a true pterygium, it is the result of previous external ocular inflammation. Pseudopterygium formation is often seen after chemical burns, surgery, trauma, cicatrizing conjunctivitis and peripheral corneal ulceration.

It can be differentiated from the true pterygium by:

- Lying outside the palpebral aperture
- Its very loose or absent adherence to the corneal limbus such that a small muscle hook or canalicular probe may be passed under the body without resistance.

The degenerative elastoid histopathology may be present depending on the duration, anatomical location of the lesion and its chance for exposure to ultraviolet light.

Recurrent pterygium

A recurrent pterygium is secondary fibrovascular growth across the cornea from the corneo scleral defect of a previously excised pterygium.

Clinically, it appears as an elevated, growing, fibrovascular scar arising from the excision site.

Histologically, the subepithelial tissues do not contain the characteristic degenerated , amorphous connective tissue of a true pterygium.

Recurrent pterygia are more aggressive in their growth characteristics and more difficult to treat. They are more common in younger patients with thick aggressive primary prerygia. With recurrence , there is a higher incidence of growth into the visual axis and of symblepharon formation.

Recurrence time

Most recurrences seen in the first few months are preceded by blood vessels from the cut edge of the conjunctiva and are oriented in the same axis as an original pterygium. Lawrence et al defined the recurrence of pterygium as an encroachment of fibrovascular connective tissue across the limbus onto the cornea for any distance. The study also suggests that there is a 97% chance for a recurrence within 12 months of removal.

Malignant pterygium

When the progression is faster so that fleshy, highly vascular growth encroaches the cornea over a large area in comparatively shorter duration of time, it is termed as malignant pterygium because of its exuberant growth. It is common in young individuals.

Natural History and Morphological characteristics .

A pterygium begins in the inter palpebral space. In its earliest stages , it is indistinguishable from a pinguecula, appearing as a raised ,yellow , fleshy mass on the bulbar conjunctiva situated 1 to 2 mm peripheral to the corneal limbus. When single, a pterygium is almost invariable nasal. The appearance of engorged radial vessels over the nascent pterygium and adjacent limbus often signals a period of rapid growth.

As the mound of tissue grows and moves towards the cornea, the involved bulbar conjunctiva becomes increasingly taut. Invasion of the cornea is heralded by the appearance of a subepithelial halo or cap just anterior to the apex of the pterygium. Once it reaches the cornea, growth is much slower.

At this stage the pterygium is readily divisible into three parts : the cap, the apex (head) and the body.

The **body** consists of the raised triangular portion of the pterygium that has its base towards the canthus.

The **head** forms the apex of the triangle that invades the cornea just posterior to the sub epithelial cap.

The **cap** appears as an arcuate greyish white avascular zone that represents the leading edge of the lesion.

For unknown reasons the growth of a pterygium may stop at any stage during its evolution or it may continue to increase in size.

Clinically, pterygium is of 2 types:

1. **Progressive pterygium**

There is further growth of pterygium which encroaches the cornea more. The lesion becomes more vascular and there is appearance of cap in front of the apex.

2. **Non progressive/ Regressive pterygium**

The growth of the pterygium may stop (non progressive type) characterized by decreased vascular injection, flattening of the mound and fading of the sub epithelial cap. Older , static lesions are often associated with an arcuate line of iron deposition in the superficial cornea (Stocker's line). On the other hand it may show signs of regression like an anaemic appearance of the pterygium and no infiltrations. In such cases the pterygium looks like a thin, flat membrane.

HISTOLOGICAL CHARACTERISTICS

Histologically and ultra structurally, pterygium, pinguecula and actinic degeneration of the skin are very similar.

Austin and co-workers [21] described the histological characteristics of pterygium as :

- Hyalinization of the subepithelial connective tissue of the substantia propria.
- Diffuse or lobular collections of eosinophilic granular material with an associated increase in the number of fibroblasts and other cells.
- An increased number of thickened and tortuous fibres that stain strongly with elastic stains (elastotic material).
- Concretions within the hyalinized and granular areas that may show either eosinophilia or basophilia.

The body of the growth is made up of vascular, areolar tissue, which is compact in old case and is loose in the early stages in which there is rapid growth. In the neck of the growth the blood vessels are connective tissue. Also present are newly formed tubular glands and larger spaces lined with epithelium, both of which may result in formation of cysts.

Grading of pterygium:

A. Slit lamp grading : Based on relative transluscency of the body of pterygium

- Grade T1 (Atrophic) - A pterygium in which episcleral vessels underlying the body of the pterygium are unobscured and totally distinguishable.
- Grade T2 (Intermediate) - A pterygium in which episcleral vessel details are indistinct or partially obscured.
- Grade T3 (Fleshy) - A thick pterygium in which episcleral vessels underlying the body are totally obscured.

B. Based on the amount of encroachment of the pterygium on the cornea:

- Grade 1: Less than 1/4 th of corneal diameter
- Grade 2: 1/4th to 1/2 of corneal diameter
- Grade 3: more than 1/2 of corneal diameter

CLINICAL SIGNS AND SYMPTOMS

SYMPTOMS:

- Chronic irritative symptoms- non specific
- Cosmetic disfigurement
- Lacrimation
- Diminution of vision- due to growth involving the visual axis and astigmatism
- Diplopia- very rarely due to limitation of movements in horizontal direction, a fleshy progressive mass may hinder nasal movements and atrophic contracted pterygia hindering the lateral movements.

SIGNS

A pterygium begins in the inter palpebral space. It appears as a triangular, fleshy, vascular growth with blunt apex. The three parts are cap, apex (head) and body.

A progressive pterygium looks fleshy and vascular. A greyish white cap is present at the apex representing its leading edge

A regressive pterygium looks like a thin, flat, less vascular or avascular membrane.

Complications of Pterygium

1. Cystic degeneration: The primary degenerative changes with destruction of part of its tissue are responsible for cystic space formation.

2. Recurrent inflammation
3. Recurrence- following surgical removal
4. Granuloma formation- After excision of pterygium especially when tenon's capsule is traumatized, an exuberant growth of granulation tissue occurs to produce a red fleshy granuloma.
5. Neoplastic transformation- Though rare, benign transformation like benign melanoma, epithelioma, fibroblastic sarcoma have been reported.
6. Symblepharon – In post operative period symblepharon can occur, due to bare areas on cornea and conjunctiva especially with a wide area of excision, and later this may interfere with normal ocular motility producing subjective sensation of diplopia in lateral gazes.
7. Astigmatism with the rule: As growth continues, it exerts some tractional force on the cornea, especially in regressive period with fibrosis causing astigmatism with the rule due to flattening of the horizontal meridian of the cornea.

DIFFERENTIAL DIAGNOSIS OF PTERYGIUM

1. Pseudopterygium
2. Pinguecula
3. Epithelioma
4. Bowen's tumor
5. Epithelial hyperplasia
6. Conjunctival intra epithelial neoplasia
7. A corneal macropannus
8. Limbal dermoid

PROPHYLAXIS

Prophylaxis should have an influence on preventing the incidence of pterygium. Protection of the eyes by dark glasses when exposed to the sun/ irritating environmental conditions is advisable. Cameron (1964) in Australia found that the rate of incidence reduced from 15% to 3% among those who had worn glasses constantly since before the age of 15 years.

A change of smoke and dust filled environment is also found to be helpful.

TREATMENT

1. MEDICAL
2. SURGICAL

Medical Treatment

Medical treatment has been tried from the earliest times, but found to be unsatisfactory. Beard and Dimitry in 1945 tried application of sodium chloride for treatment of pterygium.

Mild irritative symptoms may be managed with topical lubricants or a mild topical anti histamine/vasoconstrictor. A mild topical corticosteroid may be useful for moderate to severe vascular injection and irritative symptomatology.

Role of Hyaluronidase in pterygium

Rohathi and Trivedi (1971) **(22)** studied the beneficial effects of hyaluronidase in pterygium surgery. Meyer and Palmer were the first to isolate the main intercellular substance , Hyaluronic acid.

The enzyme liquifies the tissue cementing substance, hyaluronic acid. 1 ampoule of Hyalase is dissolved in 2cc of distilled water. A sub conjunctival injection is given at the neck of pterygium twice a week with 25 g needle pointing away from the limbus with subsequent ballooning of the pterygium away from the sclera. Up to six injections may be given (biweekly).

Surgical Treatment

Surgical removal remains the mainstay of treatment for pterygium. Sushruta, the world's first ophthalmologist recorded the first pterygium removal. Excision with simple closure of the wound was described by Von arlt (1850-74). A lamellar corneal graft applied to the denuded area of the cornea after excision was first suggested by Magitol (1916). Bare sclera excision was suggested by D'Ombrain (1948). Excision with plastic repair with a movable conjunctival flap was tried by Compodonico (1922) The principles of surgical techniques for pterygium are:

1. Complete removal of pterygium leaving a bare sclera.
2. Ways of suppressing the re growth of sub conjunctival tissue.
3. Ways of restoring barrier function of limbus.
4. Biological contact inhibition

Numerous surgical procedures have been recommended for pterygium excision, including bare sclera excision, bare sclera excision with adjunctive measures like Mitomycin C , beta irradiations, excision with conjunctival autograft, amniotic membrane graft etc.

An ideal pterygium surgery should achieve three principal goals:

- A low recurrence rate
- Absence of complications
- Satisfactory cosmesis

Indications for Surgery:

1. Cosmetic disfigurement.
2. Rapidly progressive pterygium , when there is a danger of involvement of the visual axis.
3. Astigmatism greater than 3 diopters.
4. Patients not comfortable with medical line of treatment.
5. Interference with ocular motility and development of diplopia.

The different surgical techniques for treatment of pterygium are:

1. Avulsion Technique

In the seventh century, Paluus and Aegeneta described the avulsion technique. With a small hook the pterygium is seized; a needle with a horse hair and a strong thread in its eye is transfixed trough the middle. With the thread, the growth is raised, and with the horse hair, it is sawed off the globe centrally. At the medial canthus it is cut off with a scalpel.

A refined method was described by Zolli (1979) [(23)] . The bulbar conjunctiva at the edge of the scleral portion of pterygium is incised with Westcott's scissors and this portion is freed from the underlying sclera by blunt dissection. The freed portion of the pterygium is then grasped with toothed forceps and torn from the cornea and a second forceps grasps the peri limbal tissue 90 deg away to give counter traction. Residual tissue is scraped off from the corneal surface and the surface is polished with a diamond burr.

2. Excision

Simple excision was done by Scarpa (1811). Excision of pterygium has also been combined with the closure of the wound by undermining the normal conjunctiva

and approximating the wound margins. (Von Arlt)

Simple excision by techniques of Arlt and Czemark

This is the simplest method and consists of extirpation of all the fibrovascular proliferation and suturing the upper and lower cut edges of the conjunctiva. Czemark recommends passing suture through the superficial layers of cornea.

3. Excision - Bare Sclera technique

One of the most popular methods for removal of primary pterygium is excision of all remnants, leaving the underlying bare sclera exposed. The excision of a superficial layer of corneal tissue at the time of pterygium removal was recommended by Castroviejo. The goal in bare sclera technique is smoothness of the surface of the excision.

The technique was described by D'Ombrain (1948). [24]

Anaesthesia

Following the application of topical anaesthesia , 1.5 ml of 2% lignocaine is injected under the body of pterygium by means of a 26 gauge needle.

Partial Superficial Keratectomy

A speculum is inserted. A fine hook is passed through the neck of the pterygium at the limbus and the conjunctiva is lifted up. A sharp blade (Desmarres knife or Bard Parker knife, no. 15) is used to make incision into the clear cornea approximately 0.75mm in front of and parallel to the edges of the head of pterygium. The depth of penetration is just below the Bowman's membrane.

Transition at the limbus:

The approach of dissection to the limbal plane is signalled by a shift in the transparency of the bed to a more opaque state and frequently also by bleeding. It is important to change over to Westcott's conjunctival scissors at this point so as to

avoid continuing the dissection along a deeper level than required.

Excision of Pterygium

The body of the pterygium is separated from the underlying sclera. Two horizontal incisions are then made in the normal conjunctiva above and below the pterygium. The pterygium is excised and the bare sclera is scraped with a knife from horizontal muscle to the limbus removing any tags of pterygium tissue. Cautery is applied on the bare sclera if any bleeding vessel is seen.

Recurrence rate: 25% to 89%

4. Modified Mc Gavic's technique

D.K.Sen (1970) [(25)] advocated the use of Mc Gavic's technique. Pterygium is seized with a plain forceps about 4mm from the limbus and horizontal incisions are made in the bulbar conjunctiva cutting down to the sclera along the upper and lower borders of pterygium. Between the two incisions pterygium is carefully dissected off the sclera preserving the conjunctiva as much as possible. Now the reflected conjunctiva is stroked back into the position and the edges of the horizontal incisions are secured by two interrupted sutures.

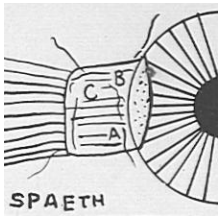
5. Z Plasty

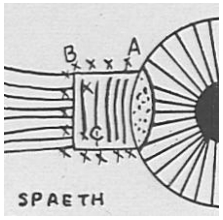
It was described by Wilson & Bourne (1988).[(26)] After removal of the pterygium, a flap of normal conjunctiva is interposed between the body of the pterygium and the corneal limbus. The authors argue that this serves as a barrier to the regrowth of the pterygium and allows preservation of the superior bulbar conjunctiva for use in conjunctival autograft procedure in case of recurrence.

Recurrence rate: 50%

1. Spaeth's rotation

Raizada et al [27] described the technique of Spaeth rotation. A rectangular area of the conjunctiva containing the pterygium is shaped and then the direction is changed 90 degrees, either up or down.



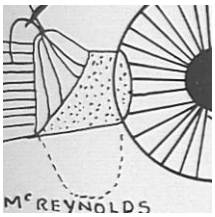


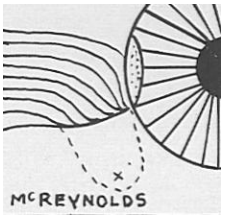
After the head of the pterygium is torn from the cornea by a suture, three sides of the rectangle are outlined by incising the conjunctiva with sharp scissors. A suture is passed through each corner of this island and then anchored in the episclera and conjunctiva of the next corner of the defect in the direction the flap is to be rotated. The "island" is then completed by incising its lower margins, and the sutures are secured. The block is thus caused to rotate to the anchored corners.

2. Transplantation methods

In this procedure, head of the pterygium is dissected and transplanted under the conjunctiva away from the limbus so that any future growth is innocuous. Desmarres (1851) detached the pterygium and fastened it inferiorly making an opening in the conjunctiva in this region.

Mc Reynold conceived the idea of passing the head of the pterygium beneath the conjunctiva without cutting it and fastening it with suture near the insertion of the inferior rectus, beneath lower bulbar conjunctiva.





Nehr (1939) on the other hand transplanted it beneath the upper bulbar conjunctiva.

Recurrence rate: 60 % – 70%

8. Conjunctival flaps and grafts

(a.) Sliding flaps

Introduced by Mc Coombe and co-workers.[28]

After removal of the pterygium, conjunctiva is undermined with scissors. A 10mm vertical incision, starting 3mm from limbus is made in the upper bulbar conjunctiva. 7-0 vicryl suture is passed through tip of the triangular flap of conjunctiva, through superficial layer of sclera near the lower border of the conjunctival defect at about 3 mm from limbus and then through the free border of the lower conjunctiva. Conjunctival flap is brought down by tying this suture. Second suture applied by 7-0 vicryl at the upper limit of the sliding flap is passed through the sclera and conjunctiva and then tied. Two additional sutures are used to close the inferior aspect of the horizontal gap. A bare sclera of about 3mm is thus left between the limbus and the border of the sliding conjunctival flap.

(b.) Free graft

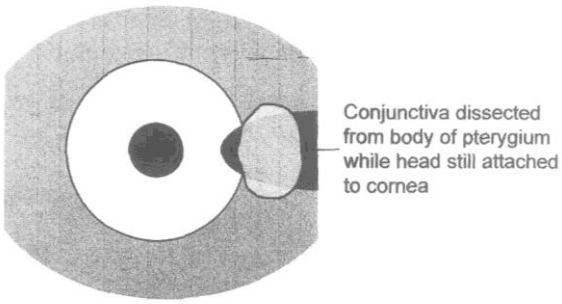
A free graft is an autograft of conjunctival tissue obtained from the same or fellow eye. The aim is to transplant the epithelium with its substantia propria but without Tenon's capsule. It is always limbus based. These grafts provide the best anatomical and functional results.

The surgical technique was introduced by Kenyon KR et al(1985) [29]

Surgical technique

Peribulbar block is given. A wire speculum was used to separate the lids. A superior rectus bridle suture is inserted using 4-0 black silk and clipped to the drapes.

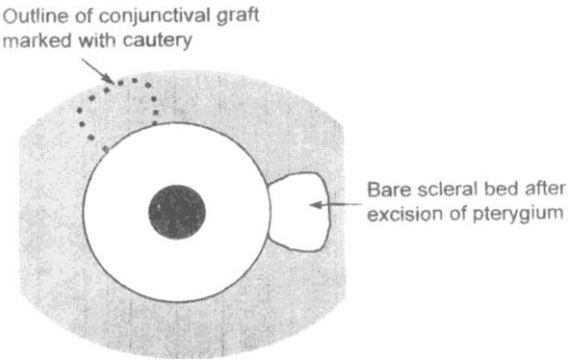
The body of the pterygium with the involved Tenon's capsule is excised, taking care to ensure the safety of the underlying medial rectus muscle and the overlying conjunctiva.



The abnormal tissue at the limbal end of the pterygium is aggressively resected.

Harvesting the graft

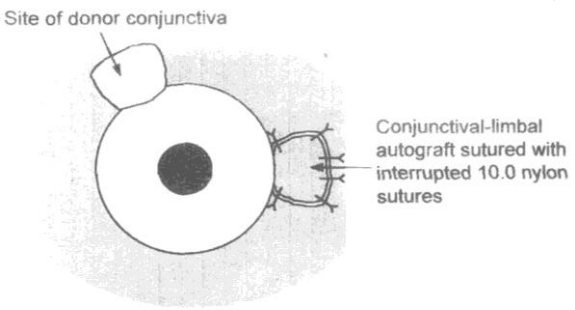
The size of the conjunctival graft required to resurface the exposed scleral surface is determined using Castroviejo calipers in 3 directions - extent across the limbus, maximum circumferential extent of the bed, and maximum distance from the limbus. The bridle suture is used to rotate the globe downwards exposing the superior limbus and conjunctival surface. The measured dimensions are marked onto the superotemporal conjunctiva using several cautery spots



Using a Pierse-Hoskins forceps and Westcott scissors, the graft is excised starting at the forniceal end. Care is taken to obtain as thin a graft as possible without button-holing. Once the limbus is reached, the graft is flipped over onto the cornea and the tenon's attachments at the limbus are meticulously dissected. The flap is then excised using a Vannas scissors, taking care to include the limbal tissue.

Placement of the graft

After excision, the conjunctival-limbal graft is slid onto the cornea. Without lifting the tissue off the cornea, it is rotated and moved onto its scleral bed with fine non-toothed forceps. A limbus-limbus orientation is maintained. The graft is smoothened out in its bed and the position of the graft is secured using interrupted 10-0 nylon sutures.



Recurrence rate: 9% to 39%

Complications of graft:

1. **Graft edema** may result secondary to inadequate debridement of the graft. All tenon's capsule remnants should be excised to avoid retraction and post operative edema. Edema usually subsided in the first week with topical steroid therapy.
2. **Graft Necrosis** is a rare complication occurring when the graft is misplaced with epithelial side down or if the recipient bed is avascular.
3. **Sclerocorneal dellen** occurs due to an oversized graft or persistent edema. Excessive use of the diamond burr or blade to resect the head of the pterygium produces a rough surface with poor lubrication and subsequent dellen formation.
4. **Epithelial Inclusion Cysts** are typically transparent and encapsulated .They appear 1 or 2 months post operatively and mat be produced by inclusion of epithelial debris beneath the conjunctival graft. Treatment includes excision of the involved conjunctiva and marsupalization of the cyst.
5. **Subconjunctival Haematomas** usually subside spontaneously without consequence, except for short term cosmetic appearance.
6. **Subconjunctival fibrosis** may occur at the donor site. The fibrosis is triggered by the abnormal exposure of Tenon's capsule and can cause problem that is usually cosmetic, although involvement of extra ocular muscle in the scar tissue may cause diplopia.
7. **Corneoscleral Thinning:-** It is more common in recurrent pterygia. Tendencies to use deep keratectomies to remove the head of the pterygium are the main cause of exaggerated scraping.

9. Lamellar keratoplasty/ Penetrating keratoplasty

This procedure is advocated for recurrent pterygium. The surgeons should regard the recurrent lesion as considerably different from the original one. Subconjunctival fibrous tissue is more abundant and is tightly bound to underlying sclera. There is often significant residual scarring and thinning of the cornea. Lamellar keratoplasty can be used to replace the damaged tissue.

10. Adjunctive Therapy

Since the description of the use of radon for the treatment of pterygium in 1940 by Burnam and Neil , adjuncts to surgery such as radiotherapy , chemotherapy and argon laser have been advocated to decrease the rate of recurrence. Beta irradiation as a treatment modality for pterygium was first developed by King in 1950. Mecham in 1962 tried instillation of antimitotics for pterygium. Argon Laser Photocoagulation was used in pterygium by Caldwell in 1985

Beta irradiation

Beta radiation has been used effectively to lower the rate of recurrence. The mechanism of action is through the inhibition of mitosis in rapidly dividing vascular endothelial cells.

With the introduction of a Strontium applicator for ophthalmological use in 1950, Strontium -90 has become the standard source of beta radiation. The ^{90}Sr plaque is a concave metal disc about 1-1.5cm in diameter which is hollow and filled with an insoluble strontium salt. The side placed on the eye is a very thin and delicate silver film that will contain the strontium but allow the beta particles to escape. The dose of radiation to the conjunctiva is controlled by the time that the plaque is left in contact with the surface. The maximum radiation occurs within a 2.0mm radius from the tip of the applicator. If a dose of 1800-2200 rad is given to the pterygium bed, the

anterior surface of the lens receives 70-90 rad, while the posterior retina receives 4-8 rads.

A.U.Herbstein and JK Donovon(1968)[30] used a modified Desmarres-Mac Reynolds transplantation bare sclera technique followed immediately by irradiation with 2000 rad beta rays. After removal of the pterygium they cleaned the bare scleral area. Haemostasis was attained. The beta ray plaque was applied long enough to give a surface dose of 2000r, which means an application time of 3 3/4 min with strontium 90 plaque.

Recurrence rate : 3 - 11 %

Complications:

- Chronic pain
- Photophobia
- Scleral necrosis
- Secondary cataract,
- Scleral infectious ulceration and endophthalmitis

Tarr and constable (1980) [31] reported delayed scleral necrosis and ulceration which led to pseudomonas endophthalmitis and evisceration.

Argon Laser

Following surgical excision , any early evidence or recurrent pterygium is treated with 50 micrometer of laser burns to the neovascular fronds. Spot size of 50 micrometer is applied at the limbus in a pattern of 4 parallel rows. Conversion of laser light into heat energy produces a thermo ablative effect. The power is adjusted to limit conjunctival epithelial burning and shrinkage

Recurrence rate: 12%

Complications:

- Scleral necrosis
- Scleromalacia
- Secondary iritis
- Cataract

Chemotherapy

Thiotepa

The nitrogen mustard N, N', N" triethylene – thiophosphoramide (thiotepa or TPA) is an alkylating agent with active anti mitotic properties. Its mode of action is by inhibition of vascular endothelial proliferation. It was introduced by Mecham in 1962 as an adjunct topical therapy. Concentration of 1:2000 (15mg in 30ml of Ringer's solution) is given every three hours in day time for 6 weeks.

Complications

- Prolonged conjunctival injection
- Allergic reactions
- Bacterial corneoscleritis
- Permanent eyelid depigmentation

Mitomycin C

Topical Mitomycin C for pterygium was first reported by Kunimoto and Mori in 1963.

It is an anti metabolite with anti proliferative effect on cells showing the highest rate of mitosis by inhibiting DNA synthesis. It is produced by Streptomyces caesopitosus. The drug is also referred as Mitomycin C to differentiate it from Mitomycin A and B which under certain conditions are also produced by Streptomyces caesopitosus.

Mitomycin C is present in a blue violet crystalline powder form and is soluble in water. Following reconstitution of the powder with distilled water, it has a pH of 6-8. According to P S Mahar and G E Nwokora [32] the reconstituted solution is stable for 1 week at room temperature and 2 weeks at 4 deg C. The solution is applied with the help of a surgical sponge, soaked till its maximum absorbent capacity.

Regimes used are:

1. Bare sclera excision with intra operative application of Mitomycin C in a concentration ranging from 0.2 mg/ml to 0.4mg/ml for 1 – 5 min.
2. Bare sclera excision with post operative use of MMC drops in concentration of 0.2mg/ml , twice daily for 5 days.

The above procedures may also be combined with conjunctival autograft.

Gupta Ved P and Saxena T (2003) [33] compared single drop Mitomycin C regime with other Mitomycin C regimes in pterygium surgery. They compared recurrence rates in 4 groups. The recurrence of pterygium was observed in 70 % patients in Group 1(bare sclera group), 20% in group 2 (bare sclera excision with single drop instillation drop instilllation of Mitomycin C 0.02% at the end of surgery) , 20 % in group 3 (0.02% Mitomycin C drops post operatively for 5 days) and 15 % in group 4 (bare sclera excision was followed by intra operative application of 0.02% of Mitomycin C.)

Complications

Minor complications :

- Ocular pain
- Photophobia

- Lacrimation
- Lid edema
- Foreign body sensation(secondary to superficial punctate keratitis)

Major complications: rare

- Scleral ulceration
- Necrotizing scleritis
- Perforation
- Uveitis,
- Cataract
- Glaucoma
- Symblepharon formation.

An avascularized sclera has been reported as the most common ocular complication following bare sclera excision with post operative Mitomycin C 0.02% **(34)**

Cano-para et al observed characteristic avascular sclera following intra operative Mitomycin C 0.01% for 5 min. **(35)**

Contraindications for topical use:

Mitomycin C should not be used in:

- One eyed patients
- Very old patients
- Pregnant women
- Those with predisposing condition to corneal ulceration or poor healing such as immunocompromised patients, Sjogren's syndrome, atopic keratoconjunctivitis, acne rosacea or herpetic keratitis.

Comparison of conjunctival autografting with currently used adjunctive therapies for primary pterygium

Conjunctival autograft	**Mitomycin C**	**Beta radiation**
Operating microscope required	No microscope required	No microscope required
Additional operating time	No additional operating time	No additional operating time
No specific drug/radiation required	Specific medication Required	Strontium -90 required
No significant complications	Short term and long term complications	Long term complications
Standardized technique	Dosage is controversial	Lack of standardization
Low recurrence rates	Low recurrence rates	Variable recurrence rates

MATERIALS AND METHODS

This study is a randomized controlled trial to compare the effectiveness of conjunctival autograft versus conjunctival autograft combined with intra operative application of 0.2mg/ml of Mitomycin C for 1 min following pterygium excision.

Source of Data:

Patients attending ophthalmic OPD and IPD in KLE Prabhakar Kore Hospital and MRC, Belgaum.

Study Design:

A one year Randomized Controlled Trial

(Computer generated randomization, Block of 2)

Sample Size: 50

(25 eyes in each group)

This study included 50 eyes of 47 patients who had progressive growth of pterygium with ocular irritation and other symptoms related to growth.

All patients were followed up for a minimum period of 4 months and a maximum period of 11 months.

INCLUSION CRITERIA:

1. Patients who are willing to participate in the study and have signed the informed consent.
2. Patients diagnosed to have pterygium.
3. Patients diagnosed to have recurrent pterygium.
4. Patients diagnosed to have pterygium with significant cosmetic disfigurement or impaired vision or ocular irritation.

EXCLUSION CRITERIA:

1. Patients with history of autoimmune systemic disease, collagen vascular disorders, conditions with poor wound healing, pregnant & lactating women and patients with significant ocular pathology e.g. Conjunctivitis, corneal ulcer and uveitis.
2. Pseudopterygium
3. Previous limbal surgery (other than pterygium surgery)
4. Patients who have not signed the informed consent.

METHODOLOGY

Preoperative Evaluation

History

- Visual acuity recording
- Slit lamp examination
- Refraction
- Anterior segment photography

After slit lamp examination, pterygium was graded on the basis of amount of encroachment of the pterygium on the cornea

- Grade 1: Less than 1/4 th of corneal diameter
- Grade 2: 1/4th to 1/2 of corneal diameter
- Grade 3: more than 1/2 of corneal diameter

Any patient having a nasal and temporal pterygium in the same eye was diagnosed to have ‘ Double head pterygium’.

Following investigations were done for all the patients:

- Intraocular pressure
- Lacrimal sac patency
- Keratometry
- Schirmer's test to rule out dry eye state
- Bleeding time, Clotting time
- Random blood sugar
- Blood Pressure
- Urine albumin and sugar

Method of Randomization

After taking informed consent all eligible patients were randomized into two groups; Group A and Group B based on Computer Generated Randomization, Block of 2. The randomization table was obtained from website www.randomization.com, after feeding the entries to the software. The first generator randomizes each subject to a single treatment (either Conjunctival autograft or Conjunctival autograft combined with Mitomycin C) by using the method of randomly permuted blocks.

Group A: Conjunctival Autograft following pterygium excision

Group B: Conjunctival autograft combined with intra operative application of 0.2mg/ml Mitomycin C for 1min. following pterygium excision.

Surgical Method

Pre-operative Preparation:

- Peribulbar anaesthesia was given
- Cleaning and draping of the surgical field with 5% povidone iodine solution followed by a wash in the conjunctival cul de sac.
- All surgeries were performed under operating microscope

Group A: Conjunctival Autograft Technique

Intrao perative procedure

- A wire speculum was used to separate the lids. A superior rectus bridle suture was inserted using 4-0 black silk and clipped to the drapes.
- The body of the pterygium with the involved Tenon's capsule was excised, taking care to ensure the safety of the underlying medial rectus muscle and the overlying conjunctiva.
- The abnormal tissue at the limbal end of the pterygium was aggressively resected.
- The size of the conjunctival graft required to resurface the exposed scleral surface was determined using Castroviejo calipers in 3 directions - extent across the limbus, maximum circumferential extent of the bed, and maximum distance from the limbus. The bridle suture was used to rotate the globe downwards exposing the superior limbus and conjunctival surface.
- Using a Westcott scissors, the graft was excised starting at the forniceal end. Care was taken to obtain as thin a graft as possible without button-holing. Once the limbus was reached, the graft was flipped over onto the cornea and the tenon's attachments at the limbus was meticulously dissected. The flap was

then excised taking care to include the limbal tissue.

- After excision, the conjunctival-limbal graft was slid onto the cornea. Without lifting the tissue off the cornea, it was rotated and moved onto its scleral bed with fine non-toothed forceps. A limbus-limbus orientation was maintained. The graft was smoothened out in its bed and the position of the graft was secured using interrupted 10-0 nylon sutures.
- The superior rectus bridle suture was removed.
- Two drops of an antibiotic were put in the conjunctival cul de sac and the eye was firmly patched.

Group B : Conjunctival Autograft technique combined with intra operative application of 0.2mg/ml of Mitomycin C for 1 min.

Preparation of Mitomycin C

- Mitomycin C was prepared by adding 10ml of sterile water into 2 mg vial of Mitomycin C. This gave the concentration of 0.2mg/ml of Mitomycin C.
- The reconstituted solution was stored in refrigerator at 4 deg C and was used with one week.
- At the time of surgery, a sterile surgical sponge of 2mm*2mm of size was taken and dipped into 2 cc of this solution till its maximum absorbent capacity.

Intra operative procedure

- After excising the pterygium, surgical sponge dipped in Mitomycin C was put on the bare sclera for a period of 1 min. After 1 min a thorough wash was given with 100ml of normal saline.

- Conjunctival autografting (as described above) was done.
- Antibiotic drops were put in the eye and eye was firmly bandaged.

Post operative advice:

In both the groups post operatively topical antibiotic – steroid eye drops (Ciprofloxacin and Dexamethasone eye drops) were used for six times a day for two weeks and then tapered over next 4-6 weeks. Lubricating drops were used four times/day for four weeks. Any suture suspicious of forming a suture granuloma was removed.

Post operative Follow-up:

All patients were followed up regularly for a minimum period of 4 months(15^{th} day, 1^{st} month and 4^{th} month.) All eyes were examined on slit lamp for any complications and recurrence of pterygium. At every follow up visit, patients were assessed for the following parameters – visual acuity, any adverse effect of the drug, any surgical complications and post operative recurrence. Anterior segment photography (for selected cases) was done.

Criteria for recurrence:

Fibrovascular growth in the position of the previously excised pterygium crossing the limbus and extending onto the cornea for at least a distance of 0.5mm.

Statistical analysis was done with the Chi Square test. 'p' value, if less than 0.05 was considered significant.

OBSERVATIONS AND RESULTS

In our randomized study on 50 eyes of 47 patients, 25 eyes underwent Conjunctival autograft and 25 eyes underwent Conjunctival autograft combined with 0.2 mg/ml intraoperative Mitomycin C application for 1 min.

Table 1: Age Distribution

AGE(YRS)	GROUP A	GROUP B	TOTAL	% ge
20-29	5	3	8	16
30-39	3	7	10	20
40-49	10	6	16	32
50-59	4	5	9	18
60-69	3	4	7	14
Total	**25**	**25**	**50**	**100**

Out of the 50 eyes of 47 patients, 16 eyes (32%) belonged to the age group of 40 – 49 years of age, 10 eyes(20%) belonged to 30 – 39 years of age, 9 eyes(18%) belonged to the age group of 50-59 years , 8 eyes (16%) belonged to the age group of 20-29 years and 7 eyes(14%) belonged to the age group of 60 – 69 years of age.

Mean age in Group A was 43.2 years (range 20-62years)

Mean age in Group B was 45.2 years (range 30-65 years)

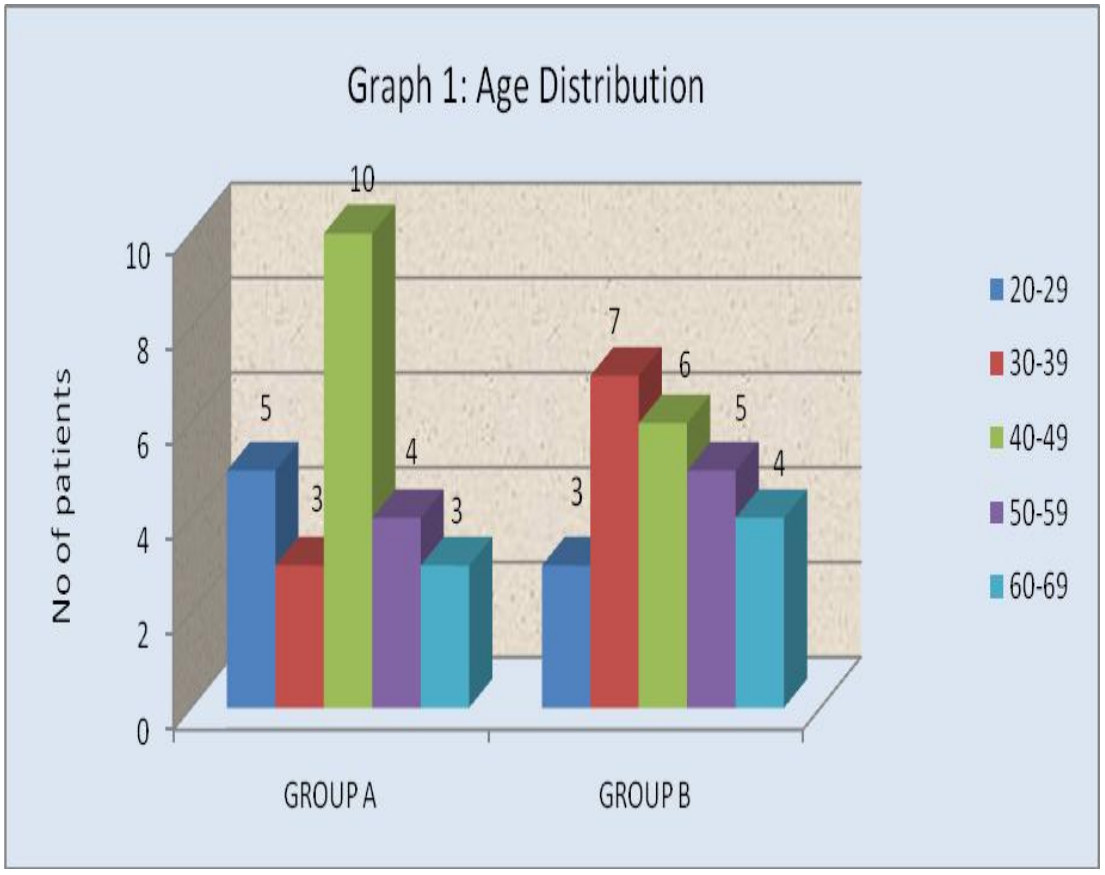
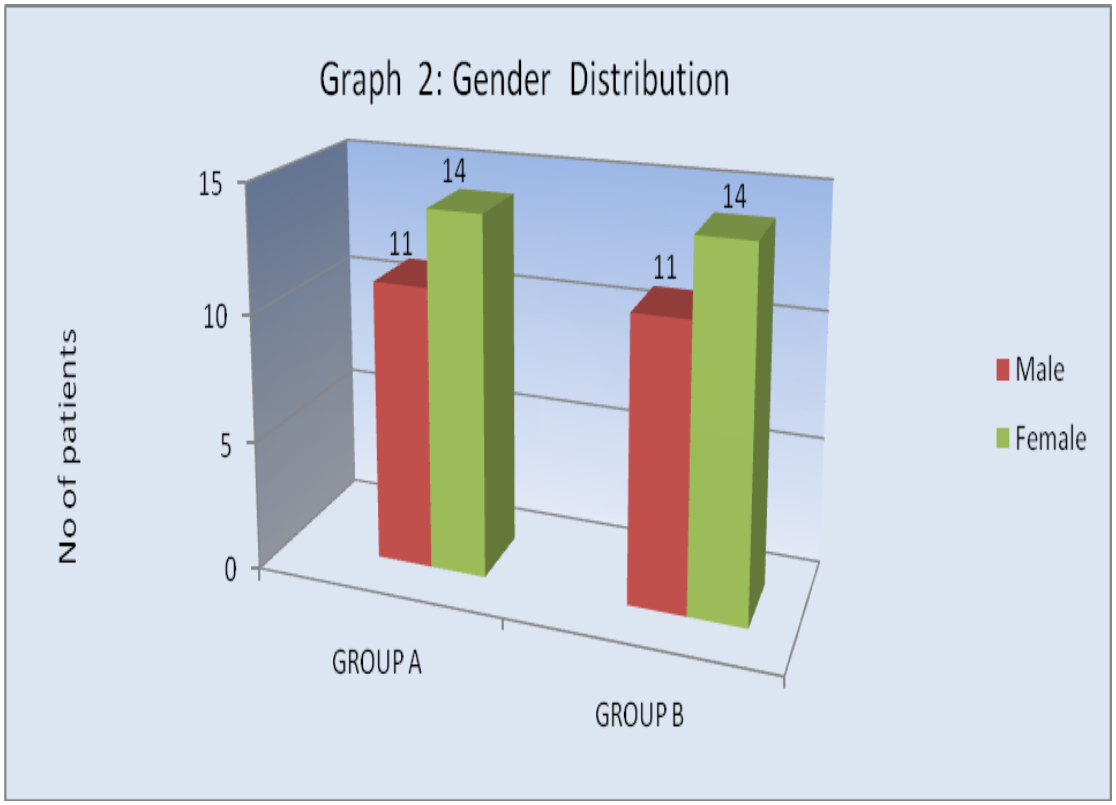

Graph 1: Age Distribution
No of patients
0
2
4
6
8
10
5
3
10
4
3
3
7
6
5
4
GROUP A
GROUP B
20-29
30-39
40-49
50-59
60-69

Table 2 : Sex Distribution

GENDER	GROUP A	GROUP B	TOTAL	%ge
Male	11	11	22	44
Female	14	14	28	56
Total	**25**	**25**	**50**	**100**

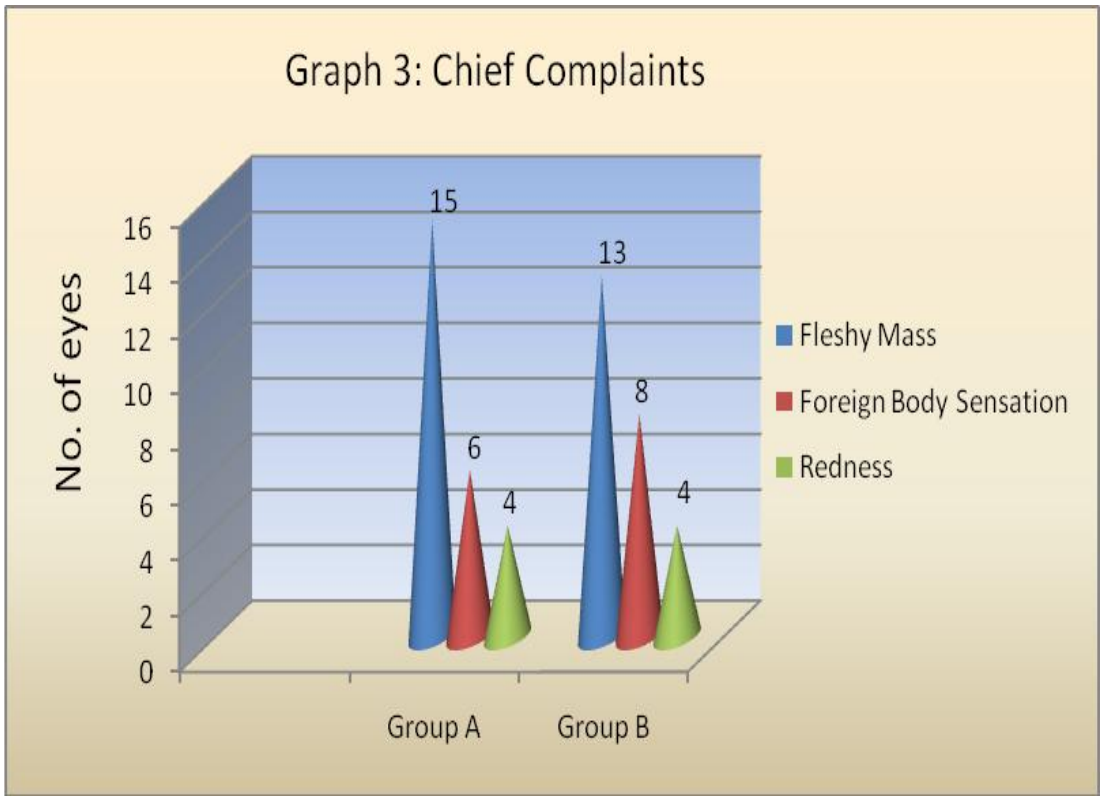


Out of the 50 eyes , 22 (44%) were that of men and 28(56%) were that of women.

In both Group A and Group B, 11 (44%) eyes each were that of men and 14 (56%) eyes each were that of women.

Table 3: Chief Complaints

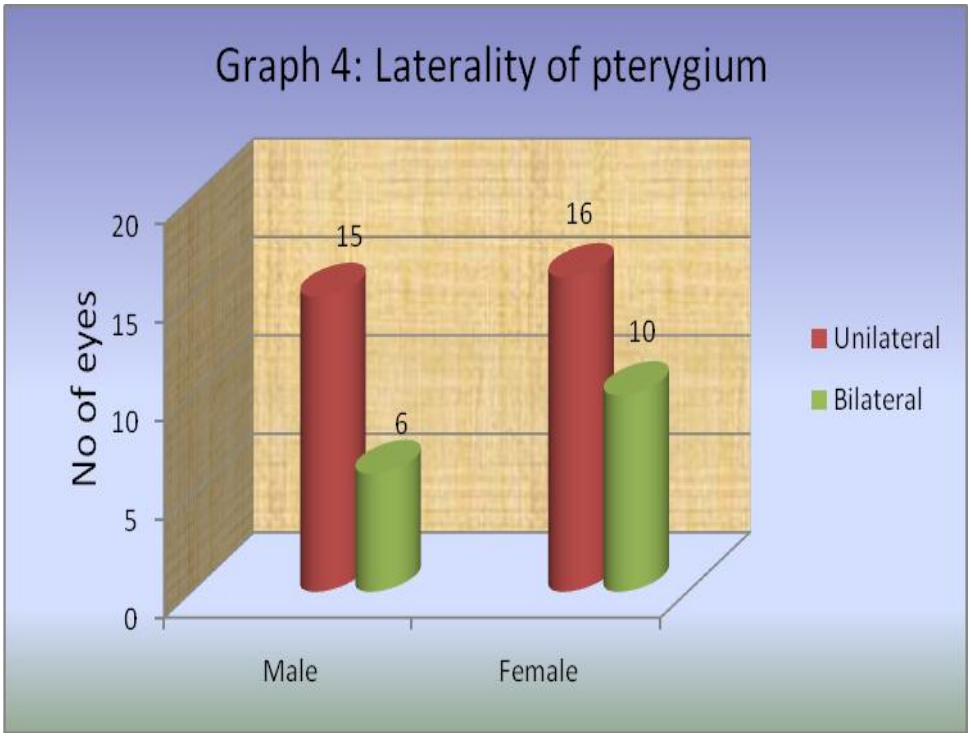
SITE	GROUP A	GROUP B	TOTAL	%ge
Fleshy Mass	15	13	28	56
Redness	4	4	8	16
Foreign body sensation	6	8	14	28
Total	**25**	**25**	**50**	**100**



In our study 56% of the eyes presented with chief complaints of a fleshy mass in the eye. Out of this 56%, 60 % of the patients were female who complained of cosmetic disfigurement. 28% of the patients presented with foreign body sensation whereas 16% presented with redness of eyes.

Table 4: Laterality of Pterygium

Laterality	Males	Females	TOTAL	%ge
Unilateral	15	16	31	65
Bilateral	6	10	16	35
Total	21	26	47	100

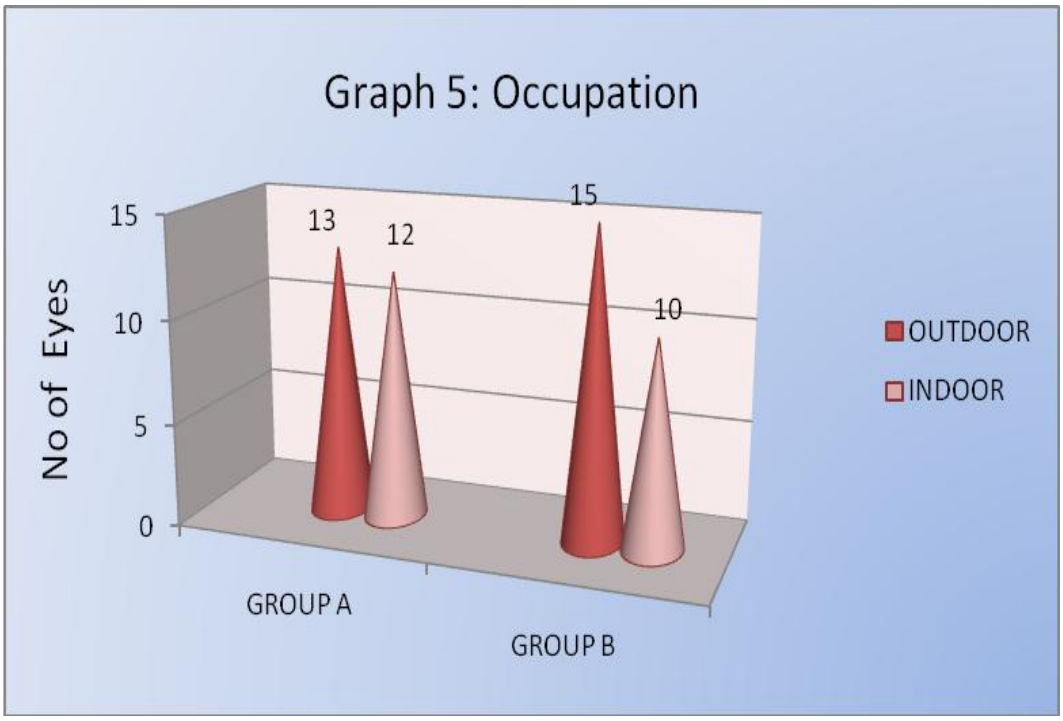


Out of the 47 patients in our study, there were 31(65%) patients who presented to us with unilateral pterygium and 16 (35%) with bilateral pterygium. All patients with bilateral pterygium had nasal pterygium except one patient who had a nasal pterygia in right eye and a temporal pterygia in left eye. The nasal pterygia was included in the study.

1 patient with bilateral pterygium had a temporal pterygium too along with the nasal pterygium (Double head pterygium) and the temporal pterygia was included in the study.

Table 5: Occupation

ACTIVITY	GROUP A	GROUP B	TOTAL	% ge
Outdoor	13	15	28	56
Indoor	12	10	22	44
Total	**25**	**25**	**50**	**100**



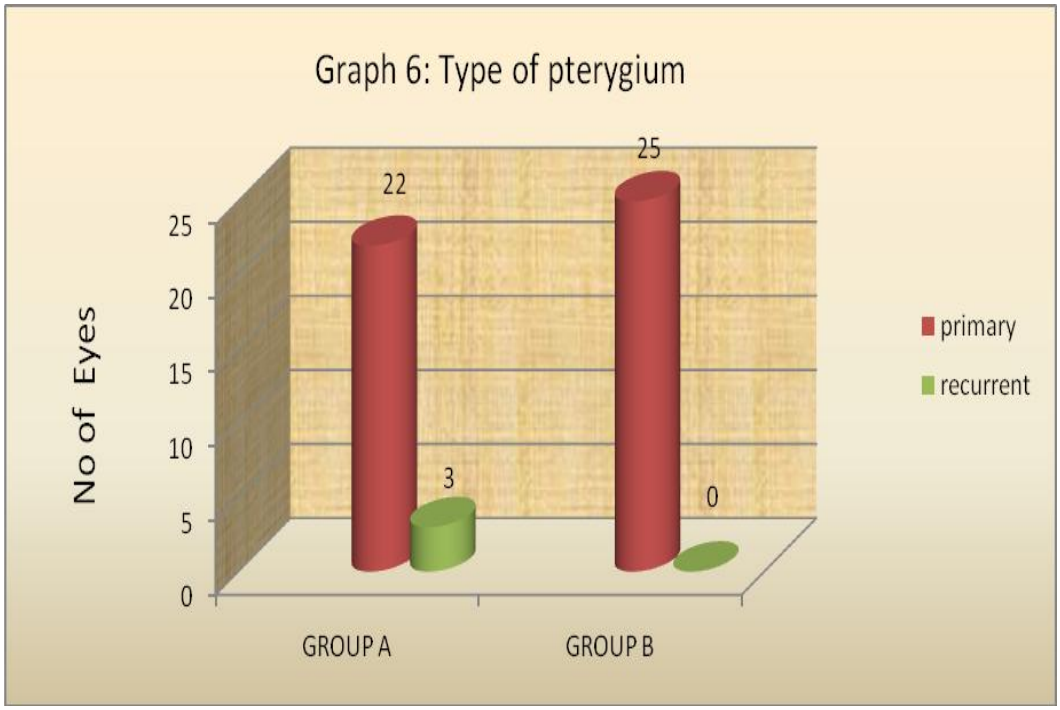
Out of the 50 eyes involved in the study, 28 eyes(56%) were exposed to the external environment of dust, wind and smoke as they were mainly outdoor workers.

22 (44%) of the eyes were those of indoor workers.

Majority (56%) of the eyes with pterygium were mainly of outdoor workers. This is due to more exposure to heat, dust, wind and solar radiation.

Table 6 : Type of Pterygium

Type	GROUP A	GROUP B	TOTAL	%ge
Primary	22	25	47	94
Recurrent	3	0	3	6
Total	**25**	**25**	**50**	**100**



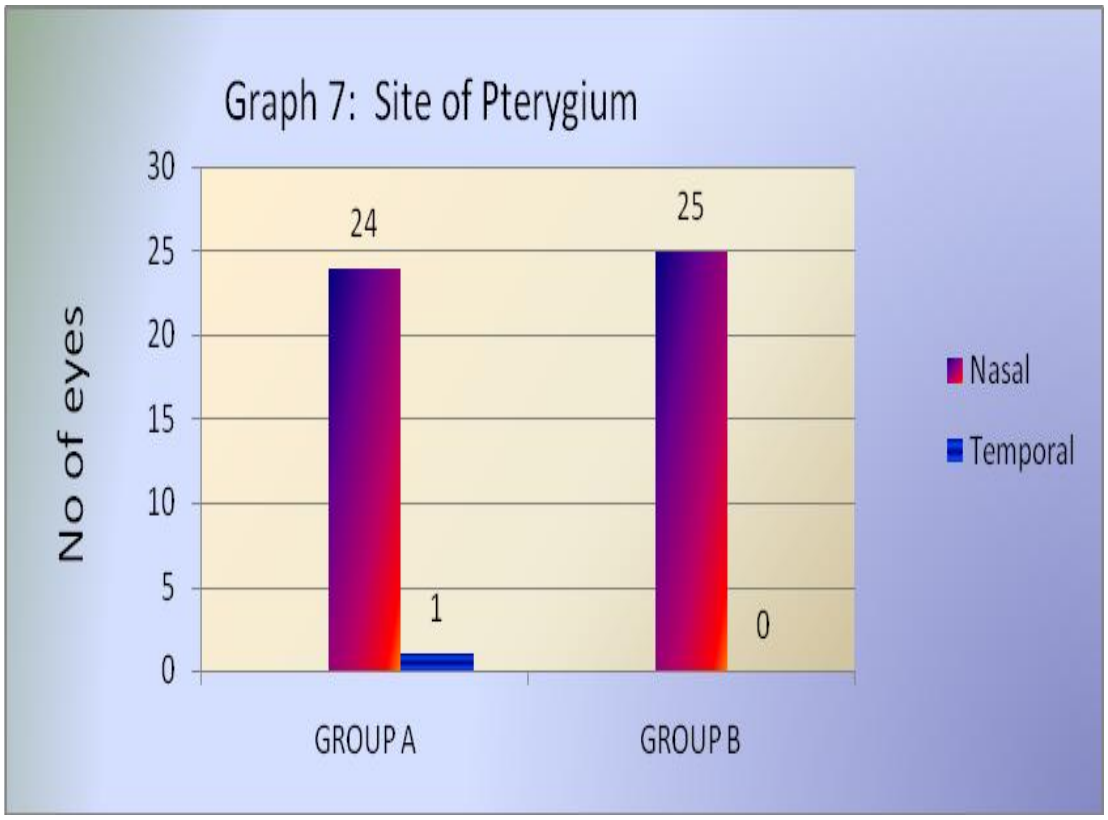
Out of the 50 operated cases, 47 (94%) were primary pterygium and 3 (6%) were recurrent pterygium.

In Group A, out of 25 cases, 22 (88%) were primary pterygium and 3 (12%) were recurrent pterygium.

In Group B , all 25 cases(100%) were that of primary pterygium.

Table 7: Site of pterygium

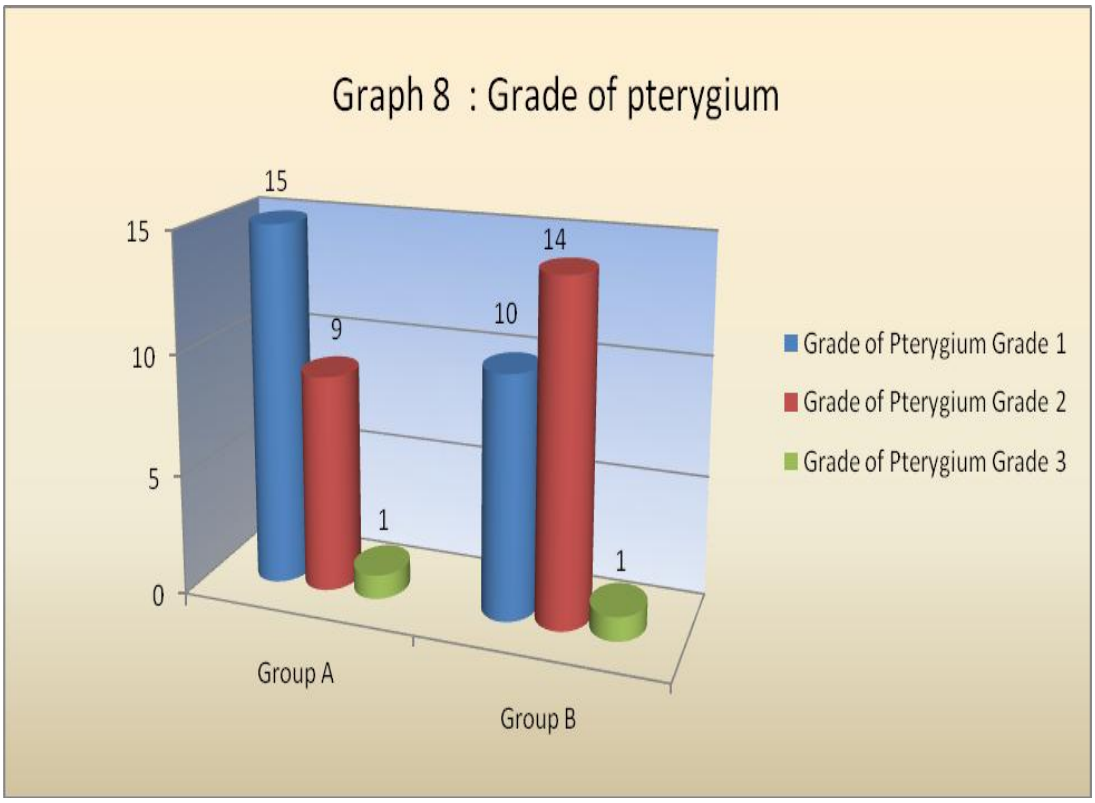
Site	GROUP A	GROUP B	TOTAL	%ge
Nasal	24	25	49	98
Temporal	1	0	1	2
Total	**25**	**25**	**50**	**100**



Most of the patients presented to us with nasal pterygium. There were 49 (98%) cases of nasal pterygium in comparison to only 1 (2%) case of temporal pterygia.

Table 8: Grade of Pterygium

Grade of pterygium	Group A	Group B	Total	%ge
Grade 1	15	10	25	50
Grade 2	9	14	23	46
Grade 3	1	1	2	4
Total	25	25	50	100



Out of the 50 eyes, 25 (50%) eyes presented to us with Grade 1 pterygia and 23(46%) eye with Grade 2 pterygia. Only 2(4%) eyes had Grade 3 pterygia.

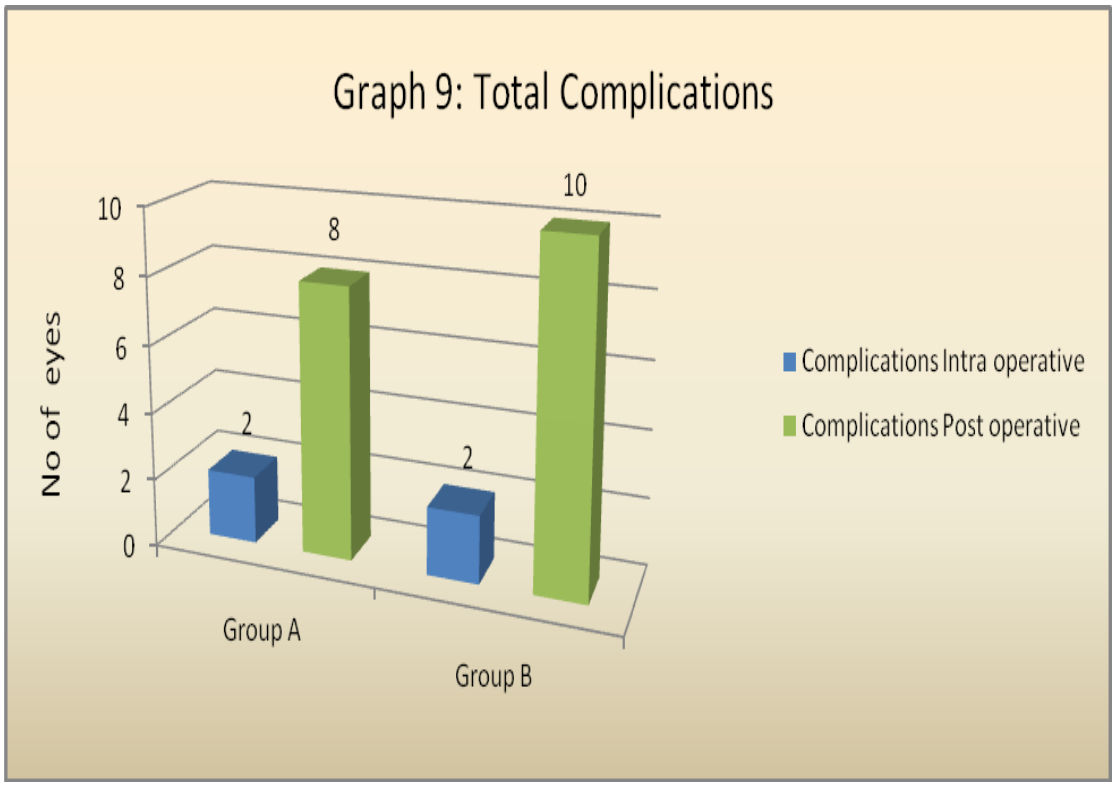
Table 9: Comparison of pre and post operative BCVA

Best Corrected Visual Acuity	No of patients		Total	%ge
	Group A	Group B		
Post operative improvement in vision	1	1	2	4
No change in vision postoperatively	24	24	48	96
Total	**25**	**25**	**50**	**100**

In 48 (96%) of the eyes , there was no change in the best corrected visual acuity post operatively while in remaining 2(4%) eyes there was significant improvement in vision.

Table 10 a: Complications

Groups	Complications		Total	%ge
	Intra operative	Post operative		
Group A	2	8	10	40
Group B	2	10	12	48



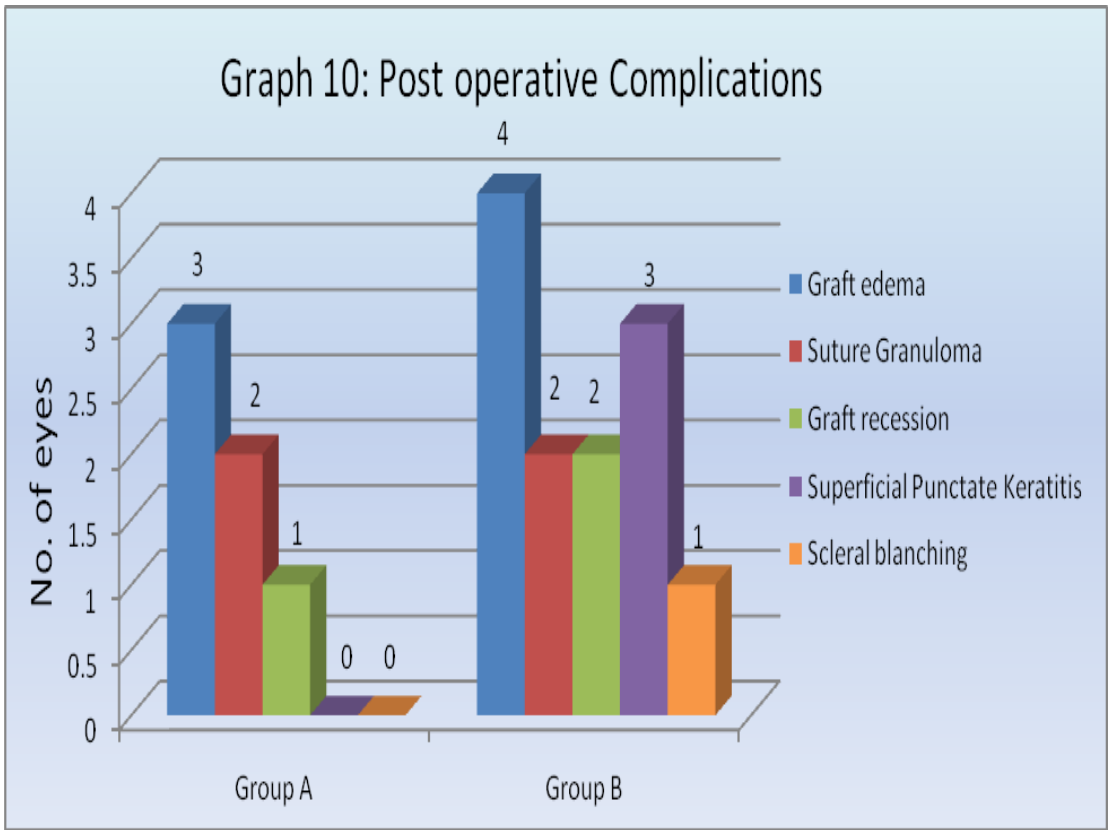
10(40%) eyes in Group A and 12(48%) eyes in Group B had complications.

Equal number of eyes (2 eyes) in Group A and Group B suffered from intra operative complications.

Post operative complications were seen more in Group B (10 eyes) than in Group A (8 eyes).

Table 10 b: Post operative Complications

Complications	Group A	Group B	Total	% ge
Loose sutures	1	2	3	6
Graft edema	3	4	7	14
Suture Granuloma	2	2	4	8
Graft recession	1	2	3	6
Sub Conjunctival Hemorrhage	2	1	3	6
Superficial Punctate Keratitis	0	3	3	6
Scleral blanching	0	1	1	2



In the present study the most common complication was graft edema which was seen in 7 (14%) of the eyes. This was followed by suture granuloma which was seen in 4 (8%) of the eyes. 3 eyes (6%) had loose sutures and the same number had graft recession.3 (6%) eyes had sub conjunctival hemorrhage. 3 (6%) eyes developed Superficial Punctate Keratitis and these eyes belonged to the Group B. Scleral blanching was seen in 1 (2%) eye of Group B.

Serious complications like scleral melting, scleral perforation, cataract formation , intra ocular pressure rise, symblepharon formation and recurrence were not seen in any of the eyes in our study.

Table 11: Studies showing recurrence rate with different concentrations of Mitomycin C with varying duration of intra operative application.

Concentration of Mitomycin C	Duration	Recurrence rate	Reference
0.02%	3 min.	6.66%	Cardillo et al 1995
0.02%	3 min.	0 %	Chen et al 1995
0.01%	3 min.	5.75%	Helal, Massiha 1996
0.04%	5 min.	5.3%	Cali, Skan et al 1996
0.02%	3 min.	2.7%	Rubinfeld et al 1997
0.04%	3 min.	8.6%	Lam ,et al 1998
0.02%	1 min	0%	Joseph F P et al 2006
0.02%	1 min	0 %	Present study

Several prospective and retrospective studies have demonstrated recurrence rates ranging from 0% to 8.6% with varied concentration and duration of application of Mitomycin C. In the present study we found no recurrence in either group.

Table 12: Recurrence

Groups	Group A	Group B
No. of recurrence	0	0
% of recurrence	0%	0%

All patients were followed for a minimum period of 4 months and maximum period of 11 months. No recurrence was seen in any of the eyes in either group.

DISCUSSION

50 eyes of 47 patients were included in our study. They were randomly assigned to either Group A or Group B. Those in Group A underwent Conjunctival autograft following pterygium excision and those in Group B underwent Conjunctival autograft combined with intra-operative application of 0.2mg/ml of Mitomycin C for 1 min following pterygium excision. Both the groups had 25 eyes each.

1. AGE:

We found a mean age of 43.2 years in Group A (range 20-62 years) and 45.2 years (range 30-65 years) in Group B. Our study showed maximum incidence of pterygium between the age group of 40 – 49 years.(32% of cases belonged to this age group). We had 34 eyes (68%) who were less than 50 years of age.

Ebrahim Mikaniki, et al[(36)] in their study on pterygium patients found mean age of 49years and 47 years in two groups. This co-relates well with our study also.

2. **SEX:**

Out of the 50 eyes of 47 patients who presented to us with pterygium, 23 (46%) were that of men and 27 (54%) were that of women.

Young et al [(37)] in a study on 115 patients found that 60 % of the pterygium patients were female. Our study also had more of female patients and concurs with Young's study.

Though the literature documents male preponderance, our study showed female preponderance in both the groups, which may be due to the fact that quite majority of patients come with cosmetic disfigurement and treatment. Also, as most of the women in our study came from rural areas and were exposed more to 'chullah'

smoke, it may point towards one of the etiological factors in development of pterygium.

3. CHIEF COMPLAINTS:

In the present study the most frequent complaint was fleshy mass followed by foreign body sensation and redness. 56% patients came with the chief complaints of fleshy mass out of which 60% were female and wanted treatment for cosmetic disfigurement. 14 eyes (28%) had chief complaints of foreign body sensation and 8 (16%) eyes had chief complaints of redness. There were no cases with complaints of diplopia.

4. LATERALITY:

65% of the patients presented to us with unilateral pterygium while 35% presented with bilateral pterygium.

Ebrahim et al **(36)** in a study on 300 patients found that 96%of the patients had unilateral pterygium and 4% of the patients had bilateral pterygium.

5.OCCUPATION :

Majority (56%) of the eyes with pterygium in this study were those of outdoor workers. This is due to more exposure to heat, dust, wind and solar radiation.

Catherine A McCarty et al **(38)** in his study found that 6.7% of the rural residents had pterygium and found 43.6% attributable risk of sunlight and pterygium. His study suggests that pterygium is a significant public health problem in rural areas, primarily as a result of ocular sun exposure.

S R Durkin et al**(39)** found a statistically significant relationship between the risk of developing pterygium and outdoor occupation.

D J Moran **(40)** in examination of more than 100 000 Aborigines and non-Aborigines in rural Australia, found a strong positive correlation between climatic UV

radiation and pterygium prevalence ,providing further evidence of a causal relationship.

Ichiro et al [8] in a study on welders who are occupationally exposed to excess U.V. light found out that 8% of the welders had pterygium in comparison to control in which the prevalence was 0.4%.

6. TYPE OF PTERYGIUM:

Out of the 50 pterygia, 47 (94%) were primary pterygium and 3 (6%) were recurrent pterygium. Out of the 3 recurrent pterygium , 1 was that of female and 2 were that of male.

In a study done by Srinivas K Rao et al [41] on 51 patients , 67.9% eyes had primary pterygium and 32.1 % eyes had recurrent pterygium.

In a study done by RG Dash et al [42]on 250 patients, 45(18%) patients had recurrent pterygium while 82% had primary pterygium.

In a study done by K atircioglu et al [43] 61% patients had primary pterygia and 39% of the patients had recurrent pterygia.

All the above studies also found a lower prevalence of recurrent pterygium in comparison to primary pterygium.

7. SITE OF PTERYGIUM

Among 50 cases ,only 1 (2%) temporal pterygium was present. However,this patient also had a nasal pterygium.

In another patient with bilateral pterygium, nasal pterygium was present in right eye where as left eye had a temporal pterygium. However, the nasal pterygium was included in the study.

Srinivas K Rao [41] in a study on 51 patients, found that pterygium was nasal in 46 (86.8%) eyes, temporal in 4 (7.5%) eyes and both nasal and temporal in 3

(5.7%) eyes. 98% of the pterygia in this study were nasal which co-relates well with the study done by Srinivas et al.

Doloezalovo [(44)] in his study on 1388 patients found only 1 case of unilateral temporal pterygium.

Sevel and Sealy's [(45)] study on 100 temporal pterygia has cautioned the ophthalmologists about an underlying conjunctival malignancy in patients with temporal pterygium situ. Malignant change should be considered if there is unusual evidence of invasion, extension and if the lesion becomes particularly vascular.

B Ramasamy et al [(46)] report a case of temporal pterygia which on biopsy turned out to be conjunctival intra epithelial neoplasia.

Careful observation of a temporal pterygium in terms of its growth and vascularity should be done which may help in early diagnosis of an underlying conjunctival malignancy.

8. GRADE OF PTERYGIUM

In our study, 50% of the eyes had Grade 1 pterygium. We had more female patients in comparison to males and they came early due to cosmetic disfigurement.

9. PRE OPERATIVE AND POST OPERATIVE BCVA

In 48 (96%) of the eyes, there was no change in the best corrected visual acuity post operatively while in remaining 2 (4%) eyes there was significant improvement in vision. Both these eyes had Grade 3 pterygium which involved the visual axis. Removal of pterygium resulted in significant improvement of vision.

10. COMPLICATIONS

In the present study we did not encounter any serious intra operative or post operative complications. 40% eyes in group A and 48% eyes in group B had

complications. The difference was statistically insignificant (Chi – Square = 0.324, DF= 1, p=0.568) but clinically significant.

Intra operative complications :

Two patients in Group A suffered from intra operative complications. In 1 patient, deep keratectomy was done during excision of the head of pterygium which healed over a period of 1 month with a macular grade corneal opacity. In another patient, during harvesting the graft, button holing occured. The defect was successfully closed and anchored to the episcleral tissue . 2 patients in Group B also had intra operative complications. There was difficulty in applying sutures in both the patients. This was due to the small size of graft harvested. Disadvantage with conjunctival autograft however, includes the need to use an operating microscope, the need for greater surgical skill with a distinct learning curve

Post operative complications :

Graft edema was the most common post operative complication in our study and was seen in 7 (14 %) of the eyes. 3 eyes in Group A and 4 eyes in Group B developed graft edema on the first post operative day. The edema gradually subsided over a period of 10 days. Starck et al **(47)** in their study have pointed out towards the possibility of graft edema in early post operative period due to limbal – fornix disorientation of the graft. However, in our study, limbal – fornix disorientation did not occur in any eye.

Suture granuloma was seen in 4 (8%) eyes in our study. 2 eyes in Group A and 2 eyes in Group B developed suture granuloma. In 3 eyes, the granuloma developed 1 month after the surgery and in 1 eye it was seen 2 weeks after the

surgery. In all the eyes the granuloma was successfully treated by suture removal at the time of diagnosis of granuloma. Zuzuki et al [48] showed that the use of silk or nylon sutures placed in the conjunctiva can cause inflammation and migration of Langerhan's cells to the cornea. This may result in a suture granuloma.

Graft Recession was seen in 3 (6%) eyes. 1 eye in Group A and 2 eyes in Group B had recession of the graft on the first post operative day. However, full anastomosis of the graft with the surrounding conjunctiva occurred in a period of 7-9 days in Group A and 14-18 days in Group B. The delay in anastomosis of the graft in Group B may be due to the use of Mitomyin C, which causes delayed wound healing.

The cause for recession of the graft may be a thicker graft which was harvested in these patients. Tan et al [49] suggested that graft retraction is a known complication in free conjunctival grafting combined with pterygium excision. This complication can be avoided by dissection of the sub conjunctival connective tissue and by oversizing the graft by an extra millimetre.

Loose suture was seen in 3 eyes (6%) in our study. Edema of the conjunctiva around the loose suture at 2 weeks arose the suspicion of suture granuloma. The sutures were removed and the patients were followed up for a period of 4 months. None of these eyes developed granuloma after the suture removal. Hence, if a suture is accompanied with edema of the surrounding area, its removal at the correct time may prevent the formation of a granuloma as seen in our study.

3 (6%) eyes developed subconjunctival haematoma under the graft site which resolved spontaneously over a period of 10 days.

In Group B, all patients developed photophobia, watering and lid edema which persisted over a period of 4-5 days. This may be attributable to Mitomycin C. 3 (6%) eyes developed **Superficial punctate keratitis** on the first post operative day and was

successfully treated with 2 hourly corticosteroid eye drops for 6-8 days. As this complication is seen only in Group B it may be due to the use of Mitomycin C. Superficial Punctate Keratitis is a well known complication of Mitomycin C. L Mastropasqua et al [(50)] in their study found that 15.5% of the patients treated with Mitomycin C developed superficial punctate keratitis in the early post operative period.

In all eyes in Group B , **scleral blanching** was noticed intra operatively at the time of application of Mitomycin C which subsided by the next post operative day. However, in 1 eye the blanching persisted for 1 week. The patient was meticulously followed up and the eye did not show any evidence of scleral thinning or scleral necrosis till 11 months of follow up.

Serious complications such as pyogenic granuloma, symblepharon formation, scleral melt or scleral avascularity were not encountered in any of the patients eye throughout the follow up period in both the groups.

All patients were followed up for a minimum period of 4 months and both the procedures seemed to be free from severe complications or recurrence, and resulted in satisfactory cosmetic appearance.

11. **Table 11** compares various study reports on recurrence rate with different concentrations of Mitomycin C (0.02% to 0.04%) and varying duration of its intraoperative application (1min to 5 min.) with the present study. Recurrence rates ranging from 0% to 8.6 % are reported. In our study no recurrence was seen in any eye in either group. However, many reports have also appeared on various complications of topical Mitomycin C. In the present study, where 0.02% MMC was applied for 1 min combined with a conjunctival autograft, no sight threatening

complications were seen. Standardization of Mitomycin C regarding its concentration and duration of application is still controversial.

Kenyon et al [29] in the first published study of conjunctival autograft transplantation, reported a secondary recurrence rate of 7.3% in patients with recurrent pterygium, and no recurrence in patients with primary pterygium. Ucakhan et al [51] in their study on 43 eyes, found no recurrence with conjunctival flap combined with intra operative application of 0.2mg/ml of MMC for 2 min. Joseph F P et al [52] in their study compared 4 groups namely, 0.2mg/ml intraoperative application of MMC for 3 min, conjunctival autograft technique, bare sclera technique and conjunctival autograft combined with intraoperative application of 0.2 mg/ml MMC for 1 min. They found a recurrence rate of 6.6% in Group 1 , 13.3% in Group 2, 46.6% in Group 3 and in none in Group 4.

In our study also we found no recurrence in any of the eyes in either group.

12. RECURRENCE

All eyes were followed up for a minimum period of 4 months and a maximum period of 11 months. None of the eyes in our study showed any evidence of recurrence.

Chen et al [53] reported the mean time to recurrence from 3 to 4.8 months and only 6 % are noted after the sixth post operative month.

O Gris et al [54] in their study on 7 patients with recurrent pterygium found that there was no recurrence after a follow up period of 14 months.

Joseph Frucht Pery et al [52] in a study on 30 patients found 0 % recurrence rate with conjunctival autograft combined with intra operative application of Mitomycin C for 1 min after a follow up of one year.

Both the surgeries in the present study, especially conjunctival graft retrieval, relocation and suturing, are time consuming, making pterygium surgery much more compound as compared with the simple "bare sclera" technique. Nevertheless, it seems that the excellent final results justify the prolonged surgery.

CONCLUSION

Pterygium is a common external ocular disease seen in tropical countries like India. Surgical removal of pterygium is met with high recurrence rates. Only the use of adjunctive treatments can reduce the recurrence, but these techniques have to be embraced with caution, due to the inherent risks and complications associated with them.

The introduction of limbal conjunctival autograft in our study was found safe and resulted in good optical outcome and no recurrence. The meticulousness with which the limbal tissue is included in the autograft in our opinion determines the success of the procedure. Disadvantage with conjunctival autograft however, include the need to use an operating microscope, the need for greater surgical skill with a distinct learning curve.

The dose and duration of application of Mitomycin C is still controversial. By combining intra operative application of 0.02% of MMC for 1 min with conjunctival autograft we can reduce the corneo scleral toxicity associated with this drug and at the same time can have the advantage of both: anti fibroblastic action of MMC and limbal stem cell transplantation through autograft. The combined surgery resulted in no recurrence in our study. No sight threatening complications or serious side effects were recorded in our study with this procedure.The immediate post operative complications were more with MMC than with conjunctival autograft alone but they were tackled successfully by proper medications. However, longer follow ups are required to further establish the safety and efficacy of this treatment strategy.

In our study , both the techniques were found to be equally effective in preventing recurrence of pterygium. On reviewing the literature we feel that surgical technique could probably be the single most factor influencing recurrence.

The excellent final results obtained in our study justify the prolonged surgery. Both the techniques are safe and inexpensive and are recommended for the management of both primary and recurrent pterygia in Indian eyes. The choice of surgery depends on the surgeon's familiarity with the two procedures.

Limitations of our study may include the limited sample size and moderate follow up period.

SUMMARY

- This study is a prospective randomized controlled trial to compare the effectiveness of conjunctival autograft versus conjunctival autograft combined with 0.2mg/ml (0.02%) intra operative Mitomycin-C application for 1 minute in preventing recurrence following pterygium excision.
- Fifty eyes of 47 patients were randomized into 2 groups after a detailed ocular examination. Those in Group A underwent Conjunctival autograft following pterygium excision and those in Group B underwent Conjunctival autograft combined with intra-operative application of 0.2mg/ml of Mitomycin C for 1 min following pterygium excision.
- Both the groups had 25 eyes each.
- Mean age in Group A was 43.2 years and in Group B was 45.2 years . Maximum incidence of pterygium was seen in the age group of 40 – 49 years (32%).
- 23 (46%) eyes were that of men and 27 (54%) were that of women.
- 56% patients came with the chief complaints of fleshy mass out of which 60% were female .
- 65% of the patients had unilateral pterygium while 35% had bilateral pterygium.
- Majority (56%) of the eyes with pterygium in this study were those of outdoor workers.
- Out of the 50 pterygia, 47 (94%) were primary pterygium and 3 (6%) were recurrent pterygium.
- Among 50 cases, there was only 1 (2%) temporal pterygium.
- 50% of the eyes in this study had Grade 1 pterygium.

- In 48 (96%) of the eyes , there was no change in the best corrected visual acuity post operatively while in remaining 2(4%) eyes there was significant improvement in vision.
- In this study we did not encounter any serious intra operative or post operative complications. 40% eyes in group A and 48% in group B had complications. Difference was not statistically significant (p = 0.5) but clinically significant. Two patients in Group A had intra operative complications like button holing of the graft and deep keratectomy. There was difficulty in putting sutures in 2 patients in Group B.
- Among the post operative complications, graft edema was the most common complication and was seen in 7 (14%) eyes. Suture granuloma was seen in 4 (8%) eyes in our study. Graft Recession was seen in 3 (6%) eyes. Loose suture was seen in 3 eyes (6%) in our study Sub conjunctival hemorrhage was seen in 3 (6%) eyes. 3(6%) eyes in Group B developed Superficial punctate keratitis on the first post operative day. In all eyes in Group B , scleral blanching was noticed intra operatively at the time of application of Mitomycin C which subsided by the next post operative day but persisted in 1 eye for 1 week.
- Serious complications such as pyogenic granuloma, symblepharon formation, scleral melt or scleral avascularity were not encountered in any of the patients eye throughout the follow up period in both the groups.
- After a minimum follow up period of 4 months, both the procedures seemed to be free from severe complications or recurrence, and resulted in satisfactory cosmetic appearance.

- Thus in this study we found that conjunctival autograft following pterygium excision is equally effective in preventing the recurrence of pterygium as conjunctival autograft combined with intra operative Mitomycin C (0.02%) application for 1 min.

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DATA COLLECTION INSTRUMENT

I.D.NO

NAME

(First name) (Surname)

AGE (in yrs.)

SEX 1=Male 2 = Female

RELIGION

1-Hindu 2-Muslim 3-Christian 4-Others

ADDRESS

OPD NO.

IPD NO.

D.O.A.(dd/mm/yy)

D.O.D.(dd/mm/yy)

PROVISIONAL DIAGNOSIS:

1- RE PTERYGIUM

2- LE PTERYGIUM

3- BILATERAL PTERYGIUM

INCLUSION CRITERIA

1- met 2- not met

INFORMED CONSENT

1-taken 2- not taken

I.D.NO			

CHIEF COMPLAINTS:

1= YES 2= NO

CHIEF COMPLAINTS 1= Yes 2 = No

	Right Eye	**Left Eye**
H/O FLESHY MASS	☐	☐
H/O OCULAR IRRITATION	☐	☐
H/O BLURRING OF VISION	☐	☐
H/O REDNESS OF EYE	☐	☐
H/O PAIN	☐	☐
H/O WATERING/DISCHARGE	☐	☐
H/O DIPLOPIA	☐	☐
ANY OTHER COMPLAINTS	☐	☐

If yes:_____

HISTORY OF PRESENT ILLNESS:

PAST HISTORY:

1= YES 2= NO

1.) H/O WEARING GLASSES ☐

If yes, duration_____

2.) H/O HYPERTENSION ☐

If yes,duration_____

3.) H/O DIABETES MELLITUS ☐

If yes,duration_____

4.) H/O CORNEAL ULCER ☐

5.) H/O RED EYE ☐

6.) H/O TRAUMA TO EYE ☐

7.) H/O PTERYGIUM SURGERY ☐

8.) H/O ANY OCULAR SURGERY ☐

9.) H/O CHEMICAL BURNS ☐

10.)H/O DRY EYE ☐

11.)H/O AUTOIMMUNE DISEASE ☐

12.)H/O DRUG ALLERGY ☐

13.) ANY OTHER ☐

IF YES: _____

FAMILY HISTORY: ☐

1-Significant 2- Not significant

OCCUPATIONAL HISTORY:

1= YES 2 = NO

OUTDOOR ACTIVITY ☐

INDOOR ACTIVITY ☐

BOTH ☐

I.D.NO			

GENERAL PHYSICAL EXAMINATION:

PULSE RATE(per min.) | | | |

RESPIRATORY RATE(per min.) | | | |

BLOOD PRESSURE(in mm Hg)
Systolic | | | |

Diastolic | | | |

TEMPERATURE(in deg F) | | | |

SYSTEMIC EXAMINATION:

1= Normal 2= Abnormal

CVS: ☐ If abnormal_____

R/S: ☐ If abnormal_____

P/A: ☐ If abnormal_____

CNS: ☐ If abnormal _____

OCULAR EXAMINATION

HEAD POSTURE: ☐ 1= ERECT 2=TILTED

VISUAL AXIS: ☐ 1=PARALLEL 2= DEVIATED

FACIAL SYMMETRY: ☐ 1=SYMMETRICAL 2=DEVIATED

EXTRAOCULAR MOVEMENTS: 1=NORMAL 2=RESTRICTED

UNIOCULAR: RE ☐ LE ☐

BINOCULAR ☐

VISUAL ACUITY	RE	LE
1: 6/6 – 6/12 2: 6/18 – 6/36 3:≤ 6/60	☐	☐
ADNEXA 1- Normal 2- Abnormal If 2_____	☐	☐
CONJUNCTIVA & CORNEA PTERYGIUM 1-Present 2- Absent	☐	☐
SITE 1 – Nasal 2- Temporal 3 – Both	☐	☐
GRADE 1 –Grade 1 2- Grade 2 3- Grade 3	☐	☐
SHAPE 1- Triangular 2-Oval 3- Any other If 3_____	☐	☐
VASCULARITY 1- Vascular 2 – Avascular	☐	☐
TYPE 1- Progressive 2- Regressive 3- Atrophic		
GRADING OF PTERYGIUM GRADE 1-PTERYGIUM ENCROACHING ≤ ¼ OF CORNEAL DIAMETER GRADE 2- PTERYGIUM ENCROACHING ¼ - ½ OF CORNEAL DIAMETER GRADE 3 – PTERYGIUM ENCROACHING >1/2 OF CORNEAL DIAMETER		

ANTERIOR CHAMBER: DEPTH 1- Normal 2- Shallow 3- Deep	☐	☐
IRIS: COLOUR AND PATTERN 1- Normal 2- Atrophic Patches	☐	☐
PUPIL: SIZE 1-normal 2- Constricted 3- Dilated REACTION: DIRECT INDIRECT 1- Present 2- Absent 3- Sluggish PUPILLARY MARGIN 1-Normal 2- Abnormal POSTERIOR SYNECHIAE 1- Present 2- Absent ACCOMODATION 1-Present 2- Absent	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐
LENS: 1- Clear 2- Cataractous 3-Pseudophakia 4-Aphakia If Cataractous: 1- Immature 2- Mature 3- Hypermature	☐ ☐	☐ ☐

PRE OPERATIVE BEST CORRECTED VISUAL ACUITY(BCVA)

OD				OS			
VA	SPH	CYL	AXIS	SPH	CYL	AXIS	VA

INVESTIGATIONS

HAEMOGLOBIN(in gm %) ☐☐

BLEEDING TIME(min; sec) ☐☐ ☐☐

CLOTTING TIME(min; sec) ☐☐ ☐☐

URINE SUGAR(in mg%) ☐
1- present 2- absent

URINE ALBUMIN (in mg%) ☐
1- present 2- absent

BLOOD PRESSURE(in mm Hg)
SYSTOLIC ☐☐☐

DIASTOLIC ☐☐☐

BLOOD SUGAR(IF DIABETIC)
FBS(in mg/dl) ☐☐☐

RBS(in mg/dl) ☐☐☐

PPBS(in mg/dl) ☐☐☐

	RE	LE
INTRAOCULAR PRESSURE(in mm Hg) 1- Normal 2- High 3- Low	☐	☐

If high: With 5.5gm wt.
With 7.5gm wt.
With 10 gm wt.

LACRIMAL SAC PATENCY 1- Patent 2- Blocked	☐	☐

ANY OTHER:

K1:

K2:

DIAGNOSIS: ☐ _____

1- RE PTERYGIUM
2- LE PTERYGIUM
3- BILATERAL PTERYGIUM

TREATMENT GROUP: ☐

1- GROUP A (CONJUNCTIVAL AUTOGRAFT)

2- GROUP B(INTRAOPERATIVE APPLICATION OF 0.02% MITOMYCIN C FOR 1 MIN. FOLLOWED BY CONJUNCTIVAL AUTOGRAFT)

SURGEON'S NAME ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

DATE OF SURGERY(dd/mm/yy) ☐☐☐☐☐☐

INTRAOPERATIVE COMPLICATIONS
1-YES 2- NO

1.) HYPHAEMA ☐

2.)DIFFICULTY IN EXCISING PTERYGIUM ☐

3.)INABILITY TO GET THE CONJUNCTIVAL AUTOGRAFT ☐

4.)DIFFICULTY IN APPLYING SUTURES ☐

5.)OTHERS ☐

IF YES _____

POST OPERATIVE BEST CORRECTED VISUAL ACUITY(BCVA)

OD				OS			
VA	SPH	CYL	AXIS	SPH	CYL	AXIS	VA

POST OP FOLLOW UP	**1ST DAY**	**1ST WK**	**1 MNTH**	**4MNTHS**
VISUAL ACUITY 1: 6/6- 6/12 2: 6/18-6/6/36 3: ≤6/60	☐	☐	☐	☐
PAIN 1-absent 2- mild-moderate 3-severe	☐	☐	☐	☐
REDNESS 1-absent 2 –Conjunctival congestion 3 -Ciliary congestion	☐	☐	☐	☐
PHOTOPHOBIA 1-present 2-absent	☐	☐	☐	☐
IRRITATION 1-present 2-absent	☐	☐	☐	☐
LID EDEMA 1-present 2-absent	☐	☐	☐	☐
CONJUNCTIVA CONGESTION 1-present 2-absent	☐	☐	☐	☐
SUB CONJUNCTIVAL HAEMORRHAGE 1-present 2- absent	☐	☐	☐	☐
HEALING 1- normal 2-delayed	☐	☐	☐	☐
SUTURES 1-intact 2-loose 3-tight	☐	☐	☐	☐

SYMBLEPHARON 1- present 2-absent	☐	☐	☐	☐
CORNEA CORNEAL EDEMA 1-present 2- absent	☐	☐	☐	☐
SUPERFICIAL PUNCTATE KERATITIS 1-present 2- absent	☐	☐	☐	☐
SCLERA SCLERAL THINNING 1-present 2- absent	☐	☐	☐	☐
SCLERITIS 1-present 2 - absent	☐	☐	☐	☐
AVASCULARITY 1-present 2- absent	☐	☐	☐	☐
IRITIS 1- present 2- absent	☐	☐	☐	☐
CATARACT FORMATION 1-occurred 2-did not occur	☐	☐	☐	☐
INTRA OCULAR PRESSURE 1- normal 2-low 3- high	☐	☐	☐	☐
RECURRENCE 1-recurred 2- no recurrence	☐	☐	☐	☐
OTHERS 1- Present _____ 2- Absent	☐	☐	☐	☐

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Ms_____

You are invited to participate in our research study titled " A one year Randomized Controlled Trial to determine the effectiveness of conjunctival autograft versus conjunctival autograft combined with intra-operative Mitomycin C following excision of pterygium" conducted by Dr. Isha Vatsal, Post Graduate in M.S. Ophthalmology under the guidance of Dr. Rekha B.K., **M.S., D.O.M.S.**, Professor in the Department of Ophthalmology, J .N. Medical College, Belgaum.

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. Your participation in research is voluntary. If you decide to participate you are free to withdraw at any time.

Purpose of the Study: The purpose of research is to ascertain the safety and efficacy of the two procedures-conjunctival autograft and conjunctival autograft combined with low dose(0.02%) of intra operative application of Mitomycin C for 1 min. in preventing the recurrence of pterygium.

Procedure Involved : If you agree to enroll yourself in this study, I will ask your present, past and family history. You will be clinically examined and relevant investigations will be done. Then you will be asked to undergo either of the two procedures based entirely on computer generated randomization. You will be asked to follow up on specified dates when your progress would be monitored, documented and if necessary photographed.

Risks and Benefits : There are no major risks involved in the two procedures however some discomfort may occur, for which all precautions will be taken. Your participation may benefit you and others suffering from the same ailment in future, by helping us learn more about the disease process and better treatment modalities.

Alternatives : If you are not willing to participate you will be treated according to the existing protocol & it will not affect your relationship with this hospital.

Costs for participating in this research: The participant will have to pay for the investigations which are the part of the existing management protocol for this ailment.

Privacy and Confidentiality: No information about you or information provided by you during the research will be disclosed to others without your written permission.

Authorization to Publish Results: When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity.

Compensation: In the event of injury related to the study, treatment will be made available through KLES Prabhakar Kore Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law. The doctors and the staff will provide facilities and medical attention to you.

Questions:

If you have any questions about the research you may please contact:

1.)Chief investigator, **Dr. Isha Vatsal**, P.G., Department of Ophthalmology, JNMC,Belgaum. Contact No. 9964319369

2.)**Dr. Rekha B.K.**, Professor, Guide, Department of Ophthalmology, JNMC, Belgaum. Ph: 9449938997

3.)**Dr. V.D.Patil** ,Principal, JNMC,Belgaum and chairman of Institutional Ethics Committee. Ph. 0831-2471350

Consent for participation in research trial

I, Mr./Ms./Mrs _____ voluntarily agree for the participation as a subject of this study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in my own vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____

Witness Name :_____

Signature of Witness:_____

Investigators Name: _____

Signature of Investigator : _____

Date : _____

Place : _____

PHOTOGRAPHS

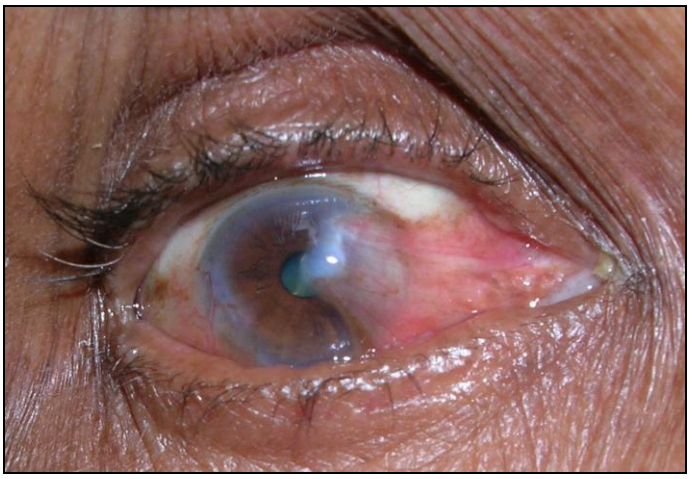

Photo 1: Grade 3 pterygium

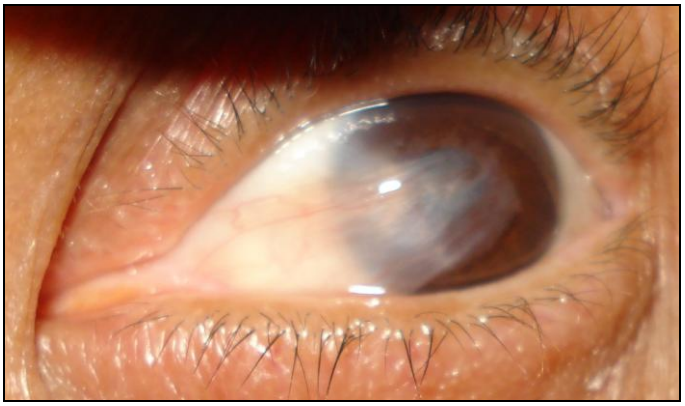

Photo 2 : Recurrent pterygium

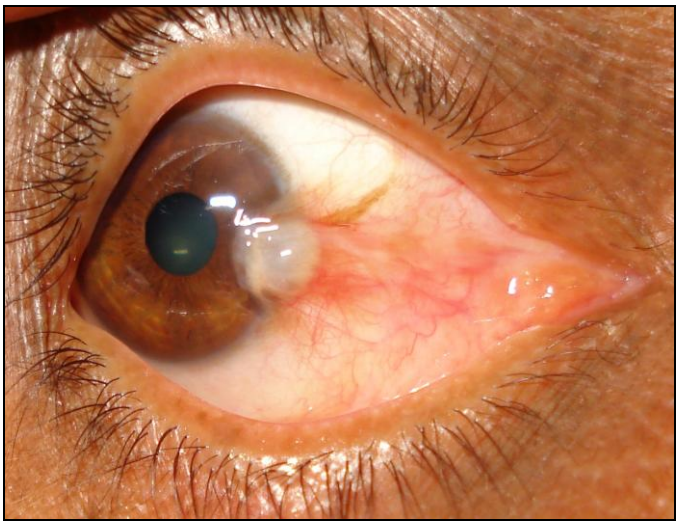

Photo 3: Cystic degeneration in pterygium

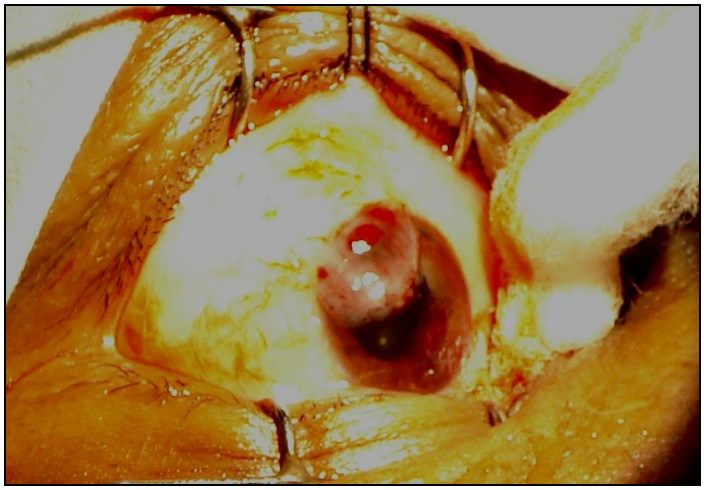

Photo 4: Harvested Conjunctival autograft

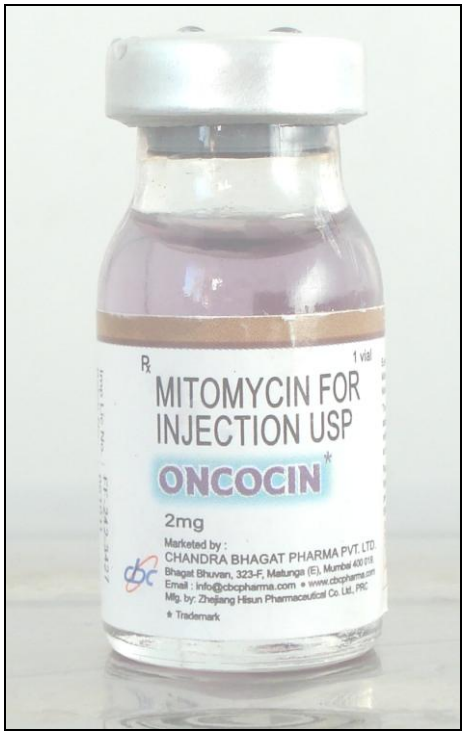

Photo 5: Reconstituted solution of Mitomycin C (0.2mg/ml)

INTRA OPERATIVE COMPLICATIONS

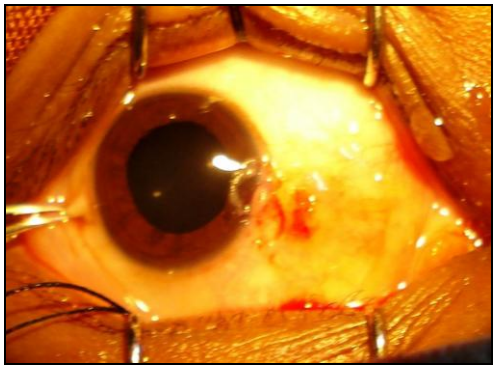

Photo 6: Deep keratectomy

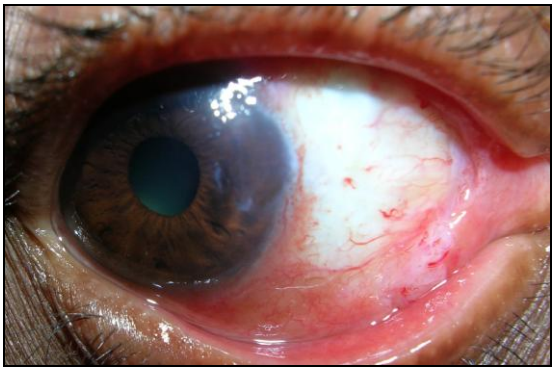

Photo 7: Scleral blanching due to MMC

POST OPERATIVE COMPLICATIONS

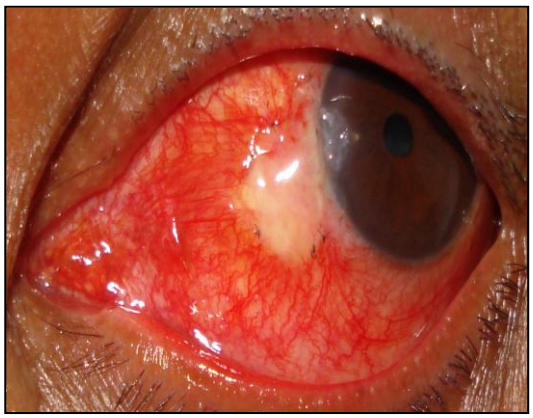

Photo 8: Graft Edema

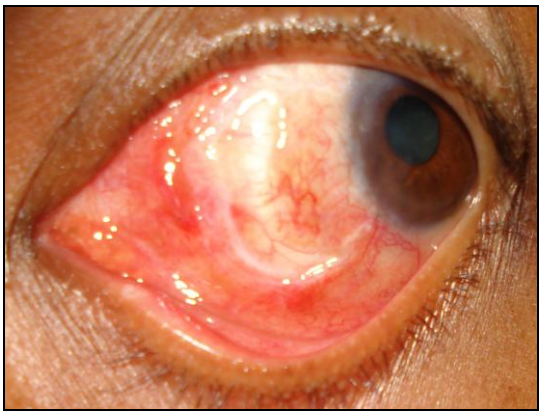

Photo 9: Graft recession

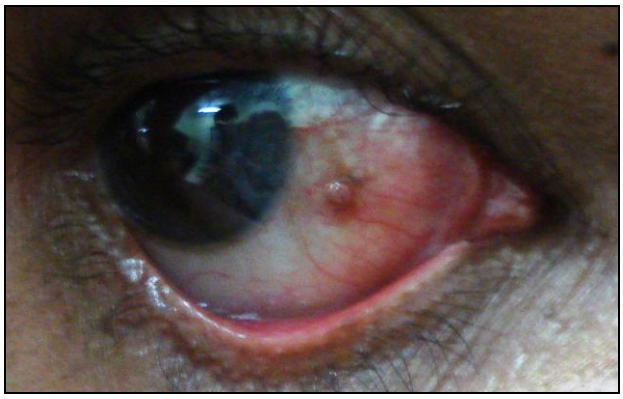

Photo 10: Suture Granuloma

GROUP A

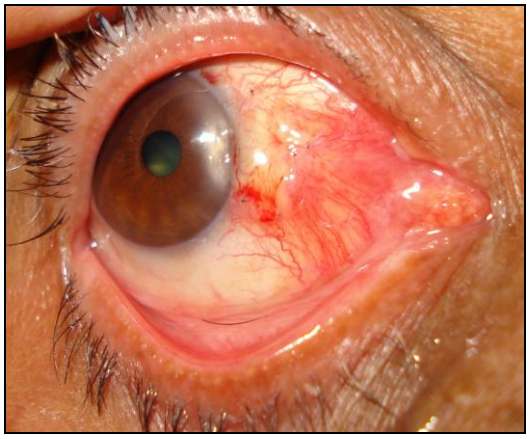

Photo 11 : 1 week post operative photograph

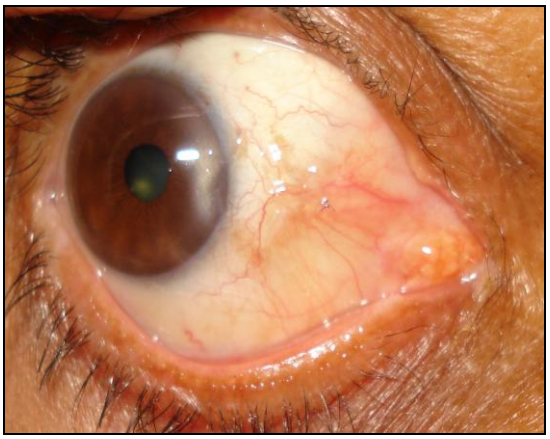

Photo 12 : 4 months post operative photograph

GROUP B

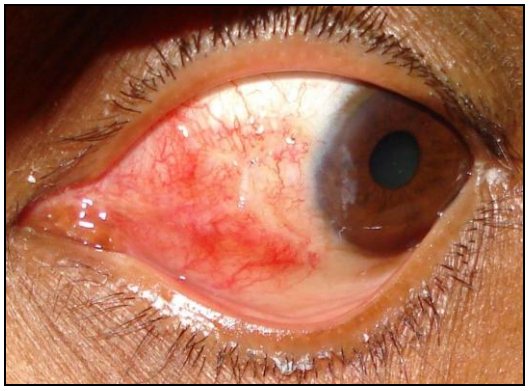

Photo 13: 1 week post operative photograph

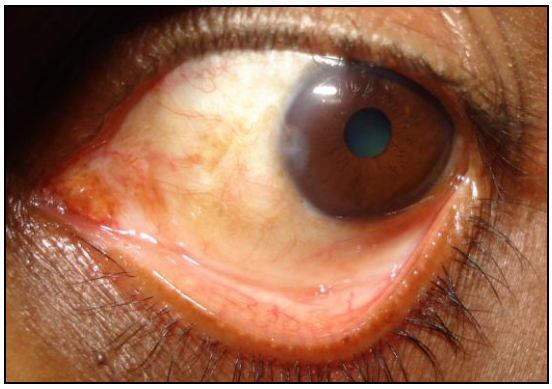

Photo 14 : 4 months post operative photograph

Master Chart of Conjunctival Autograft + Mitomycin C Group

Sl. No.	Name	I.P.No.	Age/ Sex	Occupation - Type	Place	Chief Complaints	Laterality	Type	Character	Operated Eye	Site of operated pterygium	Grade	Pre-Op Va	Complications		Recurrence	Time of Recurrence	Size of recurrence	Post Op BCVA	F. Up	Associated Features
														Intraop	Post op						
1	MEHBOOBSAAB	258841	39/M	Outdoor	Rural	FBS	U/L	Pri	Prog.	LE	Nasal	1	6/6		-	No	-	-	6/6	6 m	-
2	PARASHURAM	273394	40/M	Outdoor	Rural	F.Mass	U/L	Pri	Prog.	LE	Nasal	1	6/6		S.Blnch, G.E.	No	-	-	6/6	11 m	-
3	SARIDA R S	273393	32/F	Outdoor	Urban	F.Mass	B/L	Pri	Prog.	RE	Nasal	1	6/6		-	No	-	-	6/6	4 m	-
4	LAXMIBAI R P	273426	49/F	Outdoor	Rural	Redness	B/L	Pri	Prog.	RE	Nasal	2	6/9		-	No	-	-	6/9	4 m	-
5	BALUBAI R P	274673	65/F	Outdoor	Rural	F.Mass	U/L	Pri	Prog.	LE	Nasal	2	6/6		-	No	-	-	6/6	4 m	-
6	KALLAWWA S P	274668	60/F	Outdoor	Rural	F.Mass	U/L	Pri	Prog.	RE	Nasal	1	6/9		-	No	-	-	6/9	4 m	-
7	MAHAZAN G K	275477	30/F	Outdoor	Urban	Redness	B/L	Pri	Prog.	RE	Nasal	2	6/6		G.E.	No	-	-	6/6	4 m	-
8	SANJAY BANDU	276052	35/M	Indoor	Urban	F.Mass	B/L	Pri	Prog.	LE	Nasal	2	6/6		Gr.Rec, L.Sut	No	-	-	6/6	4 m	-
9	SHEVANTI A G	279657	55/F	Indoor	Rural	FBS	B/L	Pri	Prog.	LE	Nasal	2	6/9		G.E.	No	-	-	6/9	4 m	-
10	SAKINA P S	279617	40/F	Indoor	Rural	FBS	B/L	Pri	Prog.	RE	Nasal	1	6/6		-	No	-	-	6/6	4 m	-
11	YESUDAS D	279983	38/M	Outdoor	Urban	F.Mass	U/L	Pri	Prog.	RE	Nasal	2	6/9		SPK+ S.Gran	No	-	-	6/9	4 m	-
12	ANNAKKA D A	281136	28/F	Indoor	Rural	F.Mass	U/L	Pri	Prog.	LE	Nasal	2	6/6		SCH	No	-	-	6/6	4 m	Family history
13	GANGAWWA M	281138	35/F	Indoor	Rural	F.Mass	B/L	Pri	Prog.	LE	Nasal	1	6/6		Gr.Rec	No	-	-	6/6	4 m	-
14	KALLAPPA P	282581	69/M	Outdoor	Rural	Redness	U/L	Pri	Prog.	RE	Nasal	2	6/9		G.E.	No	-	-	6/9	4 m	-
15	SHESHAWWA V	283865	60/F	Outdoor	Rural	F.Mass	U/L	Pri	Prog.	LE	Nasal	2	6/9	Dif. sut	-	No	-	-	6/9	4 m	-
16	DATTU A L	288613	45/M	Indoor	Urban	FBS	U/L	Pri	Prog.	RE	Nasal	2	6/6		SPK+ S. Gran	No	-	-	6/6	4 m	-
17	PRABHAVATI Y	292422	55/F	Indoor	Urban	FBS	U/L	Pri	Prog.	RE	Nasal	1	6/12		-	No	-	-	6/12	4 m	-
18	SHANKAR G A	304867	58/M	Indoor	Urban	FBS	U/L	Pri	Prog.	LE	Nasal	2	6/6		-	No	-	-	6/6	4 m	-
19	AMBAKKA R G	316791	45/F	Indoor	Rural	F.Mass	U/L	Pri	Prog.	RE	Nasal	1	6/9		SPK+, L.Sut	No	-	-	6/9	4 m	-
20	SUREKHA B M	321199	29/F	Indoor	Rural	F.Mass	B/L	Pri	Prog.	LE	Nasal	3	6/36		-	No	-	-	6/18	4 m	RHD
21	PUTAPPA	322115	58/M	Outdoor	Urban	F.Mass	B/L	Pri	Prog.	RE	Nasal	2	CF-2m		-	No	-	-	CF-2m	4 m	cataract
22	ASHOK	323768	48/M	Outdoor	Urban	FBS	U/L	Pri	Prog.	RE	Nasal	1	6/9	Dif. Sut		No	-	-	6/9	4 m	-
23	GANPAT	324906	36/M	Outdoor	Urban	Redness	U/L	Pri	Prog.	RE	Nasal	2	6/6		-	No	-	-	6/6	4 m	-
24	SUMAN	326574	25/F	Outdoor	Urban	FBS	U/L	Pri	Prog.	LE	Nasal	1	6/6		-	No	-	-	6/6	4 m	-
25	PUTAPPA	328885	58/M	Outdoor	Urban	F.Mass	B/L	Pri	Prog.	LE	Nasal	2	6/24		-	No	-	-	6/24	4 m	cataract