"THE EFFICACY OF AUTOLOGUS FIBRIN (BLOOD) VERSUS SUTURES IN ATTACHING CONJUNCTIVAL AUTOGRAFT AFTER PTERYGIUM SURGERY-A ONE YEAR RANDOMIZED CLINICAL TRIAL."

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LIST OF ABBREVIATIONS

CAG	-	Conjunctival Autograft
M	-	Male
F	-	Female
Group 1	-	Conjunctival Autograft with autologus blood
Group 2	-	Conjunctival autograft with 8-0 vicryl suture
CF	-	Counting fingers
BCVA	-	Best Corrected Visual Acuity
Prog	-	Progressive
F. mass	-	Fleshy mass
SCH	-	Subconjunctival Hemorrhage
GE	-	Graft edema
GC	-	Graft congestion
GB	-	Graft blanching
GR	-	Graft retraction
GW	-	Graft wrinkling
NO	-	Nebular opacity
SGH	-	Sub graft hemorrhage
F. Up	-	Follow up
B. hole	-	Button holing
ZES	-	Zeku County Epidemiological Study
HES	-	Henan County Epidemiological Study

ABSTRACT

Background and objectives

Pterygium is a triangular sub epithelial in growth of degenerative bulbar conjunctival tissue over limbus onto cornea.The prevalence in India is 2.4-30%.

Surgery is always considered the treatment of choice for pterygium. Age old procedures included simple excision (bare sclera) technique which was associated with high rate of reccurence (80%) which would be more aggressive than the primary lesion. So, pterygium excision with limbal stem cell autograft is considered standard procedure now which has a proven least reccurrance rate.

Sutures have been used traditionally to adhere graft in position but it requires surgical expertise, a longer operating time, post operative discomfort and local complications like scarring, infection, foreign body granuloma etc.

Later fibrin glue was used in place of sutures which reduced operating time and post operative complications associated with sutures but since it is a plasma derived product it may produce possible hypersensitivity reactions, a risk of transmission of viral diseases and the availability and economic considerations are not in the reach to all sections of population.

Since it is a new approach and there is no literature evidence available to test the efficacy of conventional method using sutures with the new method using autologus fibrin(blood) in adhering graft after pterygium surgery as only one case series is done in Indian set up this present study is planned.

Methods

Patients with primary pterygia were enrolled into study after taking an informed and written consent. The demographic data of the patients was noted in predesigned proforma by the investigator.

After taking history and preliminary ophthalmological examination pterygia were graded according to grading system developed by Tan & Associates as Grade1(atrophic) with episcleral vessels under body of pterygium not obscured and clearly distinguishable,

Grade 3(Fleshy)episcleral vessels totally obscured or

Grade 2(between 1 & 3).

Subjects were then randomized into 2 groups according to computer generated randomized charts as follows,

Group 1—Conjunctival autograft with autologus fibrin(blood).

Group 2—Conjunctival autograft with sutures.

PROCEDURE/INTERVENTION:

Pterygium tissue was excised and bare sclera replaced by conjunctival autograft.

In Group 1 autograft was adhered to underlying episcleral bed by autologus fibrin (patient's own blood from limbal vessels).

In Group 2 the graft was adhered by 8-0 vicryl sutures.

Patients were examined on 1st post op. day, then after 1 week, 6 weeks & 3 months after surgery.

Results

In this study the mean age in Group 1 was 50.5 +/- 14.81 years with range being 30 to 80 years, and in Group 2 the mean age was 48.9 +/- 13.23 years with range being 30 to 72 years.

The mean operative time in group 1 was less compared to group 2 (22.1+/- 5.43 vs 25.2 +/- 2.61 minutes) with range in group 1 being 15 to 33 minutes and in group 2 being 18 to 30 minutes.

Conclusion and interpretation

The present study showed better efficacy of autologus fibrin adhesive in conjunctival autografting among the patients undergoing pterygium excision, in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Also, it significantly reduced the surgical time with fewer post operative complications.

Key words:

Pterygium, Conjunctival autograft, Suture, Autologus blood.

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INTRODUCTION

Pterygium is a common disorder in many parts of the world, with reported prevalence rates ranging from 0.3-29%[1]. Pterygium was first described by Hippocrates,Galen and others. The word Pterygium is derived from Greek word 'Pterygos' meaning 'wing'. It is described as a triangular wing shaped encroachment of the bulbar conjunctival tissue on to the cornea[2].It has its base in the canthal region. It can range from being small & atrophic to large,rapidly growing fibrovascular degeneration which has ability to distort corneal topography.

Epidemiological studies, suggest an association with chronic exposure to sunlight, with an increased geographical prevalence within a periequatorial 'pterygium belt' of latitudes of 378 north and south of equator. [3,4,5] As described by Cameron India forms a part of 'pterygium belt'.

Risk factors for pterygium include areas with more ultraviolet radiation , hot, dry, windy, dusty and smoky environments.[5,6] There is also a role of hereditary factor.

The currently accepted theory is UV light induced damage to the limbal stem cells and subsequent conjunctivalisation of cornea. When deeper parts of limbal epithelium are damaged an abnormal corneal surface is produced. The characteristic changes here are conjunctival epithelial ingrowth, vascularisation and inflammation as seen in pterygia.[7]

Clinical features include chronic irritation, deterioration of vision as pterygium encroaches the pupillary axis or induces astigmatism and cosmetic blemish.

Anti-inflammatory drugs and lubricants reduce discomfort but do not cure the disease. Hence surgical removal is treatment of choice.[7] Indications for surgery are visual impairment, motility restriction, recurrent inflammation, cosmetic disfigurement.

Earlier methods of pterygium excision like bare sclera technique or Mc Reynolds operation were associated with high recurrences. Current surgical methods to prevent pterygium recurrence include conjunctival autograft, limbal and limbal-conjunctival transplant, conjunctival flap and conjunctival rotation autograft surgery, amniotic membrane transplant, cultivated conjunctival transplant, adjunctive therapies such as Beta radiation, thiotepa, 5-FU, Mitomycin C,lamellar keratoplasty, and the use of fibrin glue.[8,9]

All the above techniques involve the use of sutures or fibrin glue and are therefore vulnerable to associated complications.[8] Recent reports favour the use of fibrin glue above sutures with improved comfort, decreased surgical time, reduced complications and granuloma formation and chronic inflammation, where as plasma derived fibrin glue has the potential risk of prion disease transmission and anaphylaxis in susceptible individuals.[8,10-13,14,15] Sutureless 'laissez-faire' grafting has been used successfully in gingival grafts and represents a similar mucosal membrane tissue environment to the conjunctiva of the eye. [8,16]

This study is undertaken to evaluate efficacy and safety of the use of the autologus fibrin glue in comparison with sutures(8-0 vicryl) in the attachment of a conjunctival autograft in primary pterygium surgery as sutureless and glue free limbal conjunctival autografting is safe, effective and economical option. [1]

AIMS AND OBJECTIVES

Primary Objective:-

1. To study efficacy of autologus fibrin (blood) versus sutures in graft adherence.

Secondary Objectives:-

1. To compare post operative complications in the two groups(Autologus fibrin[blood] and sutures).
2. To compare operating time in the two groups(Autologus fibrin[blood] and sutures).

REVIEW OF LITERATURE

The word pterygium is derived from a Greek work ‘pterygion’ meaning ‘fin’ and ‘pteryx’ meaning wing. It is a fibrovascular growth indicative of subconjunctival degenerative tissue which encroaches the cornea involving the bowman’s layer and superficial stroma mostly on the nasal side.Histologically there is elastotic degeneration of the subconjunctival tissue.

Fuchs was the first person to classify pterygium into

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

The contractile forces of pterygium cause significant flattening of the horizontal meridian(with the rule astigmatism) , the amount of astigmatism being proportional to the size of the pterygium.[17] When not treated it encroaches the the pupillary axis and can cause significant disturbance in visual acuity.

Review of the history

Pterygium has been recognized and written about for the last 300 years. Pterygium as a clinical entity was first described by Hippocrates around 400 BC, he treated it with eyedrops made of zinc, lead, copper, iron, bile juices, urine and maternal milk. Application of topical medications was even supported by Celsus (25 BC) and Galenus (129 AD) . Avicenna (1000 AD) proposed cutting pterygium with scissors. It was also described by Vegbhatt (India 300 AD), Paul Aegineta (Greek 7th century), Al Rhazes (Arabia 932 AD), Avicenna (Greece 980-1036AD) and Chakradatta (India 1060 AD). [17]

Recently in nineteenth century its mention was also made by Scarpa, Travers, Desmarres, Knapp, Klein, Prince, Boeckman, Wright, Hobby, Alt, Mackenzie and others. [17]

The first surgical removal of pterygium was given by Sushruta (India)- the world's first ophthalmologist before 1000 AD. In Sushruta Samhita it is described as- "With the patient recumbent on an operation 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 loosened upturned part, and is held up with a toothed forceps, or a threaded needle is to be passed from below the part which would be held up with the thread. The pterygium is then scratched with a sharp round topped instrument. The root of the pterygium should be pushed as under from the black outline (cornea) of the eye to the medial canthus and then excised and removed. Any remnant of the pterygium should be removed with a scarifycing ointment to prevent recurrences". [17]

Celsus (Rome 50 AD) proposed a method where he passed a needle and thread beneath the pterygium and with sawing motion separated the tissue. [17]

Epidemiology

Prevalence:

The epidemiological studies around the world have shown that the prevalence rates range from 0.3% to 37.46%. [3,18] A study in 1984 reported prevalence of only 0.3%. In the Blue Mountains Eye Study, Panchapakesan found that 266 participants aged 49 years or older; prevelance being 7.4% [19]. The prevalence from a number of populations in Urban Caucasians in Victoria, Australia was 1.2%. [20] A population based study by Marcus Ang in 2012 at Singapore studied the prevalence and risk

factors of pterygium in a multiethnic Asian population and reported that Malays (15.5%) have a higher prevalence of pterygium as compared with Indians (7%) and Chinese (7%). [21] Chennai Glaucoma study found prevalence of pterygium in South Indians to be 9.5%. [22]

Age:

It affects adults , incidence being highest between ages 20-49 years. A study has reported 5.2% prevalence in people aged 50 and older in Wardha, India [23]. Congenital pterygium has been mentioned by Duke Elder.

A prevalence study in 5147 in Victoria over the age of 40 (range 40-101 years) found a high rate of pterygium of 2.83% which tended to increase with age, with 6.4% of those aged 80-89 years had pterygium. [20] ZES (Zeku County Epidemiological Study), there was independently associated risk of pterygium with persons aged 70-79 years, compared with those aged 40-49 years (OR, 2.0; 95%CI:1.4-2.8) [24] In HES (Henan County Epidemiological Study), prevalence increased with increasing age (Chi square test of trend <0.01).[25]

Sex:

With a ratio of 2:1 the disease is more common in males compared to females, reason being increased exposure in males to sunlight and dust.

Reports on whether gender is related to pterygium have been debated. [26] The ZES found a statistical significance and found that women had a higher risk level than men (OR,1.5;95%CI:1.2-2.0). [24]

Geographical distribution:

It is said to occur more commonly in area called "Pterygium Belt" which is a geographic latitude 40 degrees north and south of the equator. A prevalence of 22% is reported in this area. [27, 28] Internationally, relationship between decreased incidence in upper latitudes and relatively increased incidence in lower latitudes persists. In continental United States, prevalence rates vary from less than 2% above the 40th parallel to 5-15% in latitudes between 28-36 degrees. A relationship is thought to exist between increased prevalence and elevated levels of ultraviolet light exposure in lower latitudes. [27, 28]

Hereditary:

The inheritance is autosomal dominant with poor penetrance, it is not the actual lesion which is transmitted but the tendency of the eye to react to various environmental stimuli. There is also genetic predisposition to expression of vimentin, which indicates cellular migration by the keratoblasts during embryological development. Cells even exhibit increased p53 expression, likely due to deficit in tumor suppressor gene.

Also a mention is made by Beattle (1947) that there exists an association of pterygium with blood group O individuals.

Educational level and socioeconomic status:

The level of education is directly proportional to socioeconomic status. For Chesapeake Bay watermen, more than 8 years of education was found to be beneficial in protecting from pterygium (OR,0.42;95%CI:0.28-0.62). [26, 29]

In ZES and HES , it was found that fewer years of education (<3 years) had a positive effect on pterygium (OR,1.6;95%CI:1.1-2.4) as did a low socioeconomic status (OR,1.9;95%CI:1.5-2.4). [24, 25]

Environment:

Heat, dry atmosphere, high winds, exposure to sunlight and abundance of dust were said to be the etiological factors for pterygium by many authors. Elliot believed that mechanical irritation by dust particles enhanced by tear flow from lateral to nasal side to be etiological factor.

One study in Australia found higher rates of pterygium in rural population compared to their urban counterparts (6.7% and 1.7%) respectively as a result of sun exposure. [20] Lower rates were associated with using sunglasses outdoors and using prescription glasses. [30]

Occupation:

It is seen more commonly in people exposed to sunlight and dust like farmers and fishermen. Also role of ultraviolet rays as etiological factor is proven by finding more risk of developing pterygium in welders.

Dry Eye :

A study found environmental factors associated with dry eye, such as ultra violet light quantities and a dusty polluted environment, which are implicated in pterygium formation. [31] There is found an association between pterygium and shortened tear break-up time and schirmer's test. [26]

Pathogenesis

Hereditary

The detection of potential tumor suppressor gene involvement in pterygium has raised possibility of a 'two hit' mechanism (Knudson's theory) in its pathogenesis, the 'first hit' being tumor suppressor gene inactivation which may be inherited and the 'second hit' may be inflicted by environmental factors, such as viral infections or ultra violet rays. [32]

Since so far no gentic locus is identified showing association with pterygium further research is required in genetic susceptibility for pterygium to arrive at a safer conclusion. [32]

Ultraviolet radiation

Ultra violet light is one of the major factors implicated in the pathogenesis of pterygium as there is strong correlation between pterygium development and exposure to sunshine. Some reports state that solar light exposure in combination with exposure to dust or sand lead to chronic ocular surface inflammation. [32] Pterygium was found two times more frequently in people who worked outdoors but only in one fifth in those who always used sunglasses outdoors.[33]

A possible mechanism of action of ultraviolet light has been proposed by Johnson and Overall. They suggest that plasma proteins, mainly albumin, IgG, IgA are denatured by ultraviolet radiations as they diffuse through the cornea which results in their deposition and accumulation.The distribution on palpebral fissure and superficial location is consistent with direct radiation effect. Another study states that at molecular level Ultraviolet rays create active free radicals which attack and

deactivate various macromolecules. [32] Free radicals however can be deactivated by tear film proteins including lactoferrin.

The stocker's line which is present along the head of the pterygia lacking growth potential, may represent abnormal local iron metabolism along the advancing head of pterygium. Iron itself may be associated with increased free radical formation through biochemical reactions (Fenton's). [32]

One study showed high incidence of pterygia in welders who were occupationally exposed to high amounts of ultraviolet radiations and showed close relationship between incidence and length of employment as a welder. [34]

In Barbados eye study, 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 either for reading or distance substantially reduced the risk of developing pterygium. [30]

Detection of high pterygium prevalence in sailors or fishermen, who lived in environments exposed to increased amounts of scattered light from reflective surfaces like sea surface but devoid of dust pointed towards solar light involvement in pterygium formation. It was suggested that scattered light might follow alternative (transcameral) optical paths when entering the eye, thus hitting limbal cells from their inner surface. [32]

Studies have even suggested nasal location of pterygium as an indication for pathogenic role of solar light, since light can be reflected onto nasal corneoscleral limbus from lateral nasal wall and nasal bulbar conjunctiva is more exposed to sunshine since brow hair is shorter nasally.[32]

Limbal stem cells

The importance of limbal stem cells in pterygium pathogenesis has been proven as one study showed genetic alterations in stem cells on chronic exposure to UV light. [35] Limbal stem cells act as a junctional barrier at the limbus preventing conjuntivalisation of cornea. Pterygium is developed when there is breakdown in this barrier which is substantiated by the finding that limbal stem cells are found at the leading edge of head of pterygium.

Growth of pterygium involves firstly progressive destruction of conjunctival and corneal epithelial cells at the limbus followed by active 'conjunctivalisation' of the cornea by tissue with extensive cellular proliferation, inflammation, connective tissue remodelling and angiogenesis.

A study by Mohammed A.E. Soliman Mahdy et al recorded a recurrence rate of 4.75 % with conjunctival and limbal stem cell autograft. [36] This is the lowest recurrence rate noted till date which might be due to including part of adjacent stem cells in the graft and graft being thin, conjunctival tissue devoid of Tenon's layer. Inclusion of limbal stem cells in the graft helps maintain the excised part both anatomically and physiologically.

Certain studies on immunohistochemistry found that limbal basal stem cells immunostain for multiple metalloproteinases (MMP-1, MMP-2, MMP-3, MMP-9, membrane type 1-MMP and membrane type 2-MMP) in contrast to normal conjunctival, limbal and corneal cells which stain only to MMP-1. This altered MMP expression of limbal epithelial cells enables them to invade and dissolute Bowman's layer leading to firm adhesion of the lesion on the cornea. [32]

Angiogenesis

Prolonged ultraviolet exposure causes biological changes in the bowman's membrane and leads to formation of altered proteins which act as 'angiogenic' or 'pterygiogenic' factors which produce vessel ingrowth and formation of pterygium.

Inflammation

1. Chronic keratitis theory- Pinkerton et al (1984) found IgG(73% and IgE(100%) deposited in pterygium connective tissue stroma. [37] Even plasma cells and lymphocytic infiltration was seen in the same areas as IgG and IgE.
2. Chronic conjunctivitis theory- Evidence for inflammatory origin of pterygium are

   1] Marked increase in goblet cells in the epithelium. 2] Epithelial hypertrophy and presence of epithelial downgrowths and cysts. 3] Round cell infiltration at the advancing head and in subepithelial tissue of progressive pterygium.

   Friede felt that chronic conjunctivitis is the predisposing factor , influenced by exposure and tissue secretion, which leads to episcleritis from which infiltrates extend into sublimbal region of the cornea.

Ocular surface disorders

Richter in 1804 proposed that pterygium grows from pinguecula. Fuch's supported this by demonstrating thickened elastic fibres, hyaline degeneration of the conjunctival tissue, concretions and epithelial changes histopathologically in pinguecula and proving that similar changes even occur in pterygium. Sugar (1949)

proposed that pinguecula is a degenerative process in the subconjunctival tissue which might lead to deposition of hyaline material causing elevation eventually separating the epithelium in the cornea adjacent to the head of pterygium.

Another study reported upregulation of phospholipase D (PLD) types 2, 3 and 4 in the pterygium compared to normal adjacent conjunctiva. [38] Phospholipases are involved in various inflammatory processes like inflammation, cell differentiation, apoptosis and wound healing and their alterations point to their role in pathogenesis of pterygium.

Another supporting evidence for inflammation as a pathogenic agent in pterygium is expression of human alpha defensins and S 100, A8 and A9 in tear fluids of pterygium patients.

Certain studies show an association between pterygium and dry eye conditions like Tear Film Break Up Time. [39,40]

Molecular Basis

Nicholas dushku et al showed two cell types 1] p53 positive pinguecula limbal epithelial cell (a pinguecula II cell) and a p53 positive pterygium dysplasia cell . [41] Their study stated that increased p53 expression in limbal epithelia, pinguecula, pterygium and limbal tumors indicate existence of p53 mutations in these cells as an early event in the development.

There has been found increased levels of p53 expression in basal cells compared to epithelial layers reflecting increased exposure to UV light as proposed by transcameral exposure of limbal basal(stem cells) to solar light. [32] The wild type of p53 is known to increase in normal tissues in response to DNA damaging agents like

UV radiations and upregulation of p53 expression in pterygia reflects role of sun exposure in pterygium pathogenesis.[32,42]

The expression of p63 in pterygium (basal cells) resembles the patterns seen in normal limbus and is different from that seen in normal cornea where there is total absence of p63 supporting limbal origin of pterygium. [32]

Recurrent pterygia have low expression or total lack of p53 suggesting that epithelial cells escape p53- dependent cell cycle check points.

There is also notice of certain immortalized cell lines expressing telomerase, a ribonucleoprotein participating in cell division by blocking telomere shortening. This is not expressed in most adult human tissue including normal conjunctiva. But telomerase is expressed in pterygium, which attributes to neoplastic features of this lesion or, alternatively to induction by UVR.

Some studies show altered apoptotic potential of epithelial cells in pterygium. In some studies it is found that UV light induces apoptosis to normal corneal epithelium but epithelium in pterygium is resistant to this UVR mediated apoptosis. This was found due to disturbed balance between pro apoptotic factors lik bax and anti-apoptotic factors like bcl-2 . It is also found that apoptosis remains active at the basal epithelium of pterygium but not at more superficial layers. [32] In support of this Donald TH et al demonstrated presence of apoptotic cells in the basal epithelial cell layer adjacent to the fibrovascular layer and these cells showed to express significant levels of p53, bax and apoptosis inhibiting protein bcl-2. [43]

Viral etiology

The presence of viruses known to cause oculodermal infections, like Herpes simplex virus and Human papilloma virus was examined by Polymerase Chain reaction (PCR). Results pointed towards involvement of Human Papilloma Virus in pterygium although there were regional and racial differences. [32]

It is said that Human Papilloma Viruses 6, 11, 16 are responsible for autolytic process of inflammation resulting in protein degradation of amino acid mixture at the junction of conjunctival blood vessels and Bowman's membrane which has the ability to attract conjunctival vessels on to the cornea.

Gallagher et al found that HPV is involved in the pathogenesis of primary and recurrent pterygia. [44] Nicolai C S et al in a study conducted at Denmark, noticed low presence of HPV in pterygia which did not support the hypothesis that HPV is involved in development of pterygium. [45]

Cytokines and growth factors

Certain growth factors like epidermal growth factor, Heparin-binding epidermal growth factor , Insulin like growth factor binding protein-3, Human alpha defensins and S100 A8 A9, vascular endothelial growth factor, basic fibroblast growth factor, platlet derived growth factor, transforming growth factor beta were reported to be associated with pathogenesis of pterygium.

Low levels of Insulin Like growth factor IGFBP3 in pterygium suggests that pathway controlling cell proliferation has lost an important control mechanism, which explains continued growth of pterygium.[46]

Raised expression of human alpha defensins and S100, A8, A9 in tear fluids of patients with pterygium indicate that they may be part of pathogenisis of the fibrovascular growth in pterygium. They also serve as an indicator for predicting recurrence of pterygium. [47]

UVR inducible cytokines like the Interleukin 1 system acting together with tumor necrosis factor lead keratocytes to adopt a repair phenotype, the IL 6 (which promotes epithelial cell migration through induction of integrin receptors) and IL 8 (which display mitogenic and angiogenic activity). [32]

VEGF (Vascular Endothelial growth factor) was found in increased amounts in pterygium epithelium, compared to normal conjunctiva and certain results have shown a correlation between VEGF expression and post operative recurrence. [32]

Morphology

Pterygium grows as a mound of tissue towards the cornea and the overlying bulbar conjunctiva becomes taut. Invasion of the cornea is prevented initially by appearance of a subepithelial halo anterior to the apex of the cornea and growth of pterygium slows down as it reaches the cornea. The pterygium at this stage can be divided into three parts the cap- arcuate, grayish white, avascular zone that represents leading edge of the lesion, the head- apex of the triangle that invades the cornea posterior to the cap, the body- raised triangular portion over bulbar conjunctiva that has its base towards canthus.

Subdivision of pterygium based on pathology and clinical features

1. True Pterygium- lies in the interpalpebral aperture and is firmly adherent to the corneal stroma throught out its length.

2. False pterygium- A fibrovascular tissue arising in the bulbar conjunctiva and extending onto the cornea secondary to many causes leading to ocular inflammation like ocular trauma, surgical scar, chemical burns, peripheral corneal ulceration, cicatrizing conjunctivitis.

Differentiating features from a true pterygium-

a) Probe test- It has either loose or absent adherence with the underlying cornea at the limbus so a probe or muscle hook can be easily passed underneath its body at the limbus without resistance.
b) Lies outside the palpebral aperture.
c) It is associated with features of the condition leading to its formation.

3. Recurrent Pterygium- It was defined by Lawrence et al as encroachment of fibrovascular tissue across limbus on the cornea for any distance.

It is a secondary fibrovascular growth across the cornea from the corneoscleral defect arising after excising pterygium which is devoid of the subepithelial degenerated amorphous tissue of the true pterygium.

It is more common in younger patients with thick aggressive primary pterygia and are themselves more aggressive in their growth characteristics and are more difficult to treat. It can be associated with symblepharon formation.

The most common period for recurrence is the initial few months following surgery which is preceded by blood vessels growing from the cut end of conjunctiva. In a study 97% of recurrences were found within 12 months of primary pterygium removal.

4. Malignant Pterygium- It is seen as a recurrent pterygium with restriction of ocular movements to the opposite side. Here the progression of pterygium is so fast that the fleshy, highly vascular growth encroaches the cornea in comparatively a very short duration. It is a rare condition seen commonly in young individuals.

Pterygium can also be classified based on its fleshiness as fleshy/ progressive and atrophic/ stationary.

Progressive pterygium is thick, fleshy, with marked vascularity. It has an opaque infiltrative spot called cap at its advancing edge. Sometimes Stocker's line can be present in front of the apex.

Atrophic pterygium is pale, thick, attenuated with no blood vessels. Cap is also absent in atrophic pterygium.

Grading of pterygium

1. Tan et al grading- based on the translucency of the body of pterygium as seen on slit lamp

- Grade T1 (atrophic)- episcleral vessels under the body of pterygium are unobscured and totally distinguishable.
- Grade T2 (Intermediate)- episcleral vessel details are indistinct or partially obscured.
- Grade T3 (Fleshy)- Thick pterygium with vessels under the body totally obscured.

2. Based on the amount of encroachment on the cornea

- Grade 1- less than ¼ corneal diameter

- Grade 2- ¼ to ½ corneal diameter.
- Grade 3- more than ½ corneal diameter.

Risk factors favouring nasal site of pterygium

Various explanations are given for more common occurrence of pterygium on the nasal side

- It is more exposed to direct irritation than temporal conjunctiva.
- Light is reflected from the skin of nose back to the nasal limbus.
- Transcameral light focusing on the nasal limbus exposes limbal basal cells to raised amounts of UVR and may cause molecular genetic alterations to these cells. [32]
- The normal flow of tears is from temporal to nasal side towards the punctum which carries with it dust particles entering the conjunctival sac and accumulates in the lacus lacrimalis which might probably lead to more irritation of nasal conjunctiva.
- Greater exposure of nasal interpalpebral conjunctiva to ultraviolet radiation.
- Excess subconjuncival tissue on the nasal side.
- Pinguecula (which is shown in some studies to predispose to formation of pterygium) is found nasally.
- Greater curvature of nasal orbicularis oculi fibres causing squeezing effect on nasal subconjunctival tissue.
- Greater bowing of lateral two third of upper eyelid and consequent protection by longer lashes.

- Presence of two anterior ciliary arteries on the nasal side and only one on temporal side due to which any irritant can lead to more hyperemia on the nasal side.

Histology of pterygium

Pterygium is similar to pinguecula and actinic keratosis histologically.

It was described by Austin and co-workers as

- Hyalinisation of sub epithelial tissue of substantia propria.
- Diffuse or lobular collections of eosinophillic granular material with an associated increase in the number of fibroblasts and other inflammatory cells.
- Concretions with hyalinised and granular areas that may either show eosinophilia or basophilia.
- Increased number of thickened and tortuous fibres (elastotic material) which stain strongly with elastic stains. [48]

The body of pterygium has vascular and areolar tissue which is loose in early stages of growth and compact in old ones. In the neck of pterygium there are blood vessels and connective tissue. Also present include newly formed tubular glands and larger spaces lined with epithelium which might be the cause of cystic degeneration of the pterygium in certain cases.

Clinical features

Symptoms:

- Chronic irritative symptoms like discomfort, foreign body sensation, dryness, irritation.
- Congestion

- Diminution of vision due to growth across pupillary axis and induced astigmatism

  Mechanism to explain induced astigmatism- pooling of the tear film at the leading edge of the pterygium and mechanical traction exerted by the pterygium on the cornea.

- Lacrimation causing tearing
- Diplopia on lateral gaze due to limited horizontal eye movements, nasal movements restricted by fleshy mass and lateral movements by atrophic contracted pterygia.
- Cosmetic disfigurement.

Signs

- It appears as a fleshy triangular mass growing in the inter palpebral area towards the cornea with distinguishable three parts the cap, head and body; progressive pterygium appearing thich, fleshy and vascular with infiltration ahead of the advancing cap and atrophic/ regressive pterygium appearing as thin, flat, less vascular or avascular membrane.

Differential Diagnosis

- Pseudopterygium
- Pinguecula
- Limbal dermoid
- Epithelial hyperplasia
- Bowen's tumor
- Epithelioma
- Conjunctival intraepithelial neoplasia
- Corneal macropannus

Prophylaxis

Protection of eyes by dark glasses when exposed to sunlight and irritating environmental conditions. Cameron (1964) in Australia found that incidence reduced from 15% to 3% among those who had constantly used glasses since before the age of 15 years. Avoiding smoke and dust filled environment can also be helpful.

All these aim at reducing the incidence of pterygium occurrence.

Treatment

Indications for treatment of pterygium:

- Cosmetic disfigurement
- Vision impairment due to proximity to visual axis
- Visual impairment due to induced astigmatism
- Eye movement restriction leading to diplopia
- Atypical appearance such as dysplasia
- Symptoms of irritation, foreign body sensation, redness
- Observed growth by the ophthalmologists
- Reported growth by the patient
- Patients not satisfied with medical management [49]

Medical management

Irritative symptoms are treated with lubricating agents, vasoconstrictors or topical anti histamines. For moderate to severe vascular injection and irritation mild topical steroids can be indicated.

Beard and Dimitry in 1945 proposed use of application of sodium chloride for treatment of pterygium.

However medical management of pterygium was unsatisfactory as it just relieved symptoms for a while but was not a permanent solution and even could not prevent further growth of the tissue.

Role of Hyaluronidase in pterygium

Hyaluronidase is an enzyme which liquefies the tissue cementing substance hyaluronic acid. Rohathi and Trivedi in 1971 for the first time studied the beneficial effects of hyaluronidase in pterygium surgery. Meyer and Palmer were the first to isolate the main intercellular substance, Hyaluronic acid.

1 ml of hyalase is dissolved in 2cc of distilled water. A subconjunctival injection is given at the neck of the pterygium twice a week with a 25 guage needle pointing away from the limbus with subsequent ballooning of the pterygium away from the sclera. A maximum of 6 injections can be given (biweekly).

Surgical management

Always surgery is the mainstay of treatment for pterygium. Sushruta, the world's first ophthalmologist recorded the first pterygium removal. Many different methods of pterygium surgery have been advocated and used, some with unpredictable and poor results, due to the propensity to recur.

The surgical options available include the use of conjunctival autograft, limbal and limbal- conjunctival transplant, conjunctival flap and conjunctival rotation

autograft surgery, amniotic membrane transplant, cultivated conjunctival transplant, lamellar keratoplasty, use of fibrin glue and autologus blood in attaching the graft.

In 1850-74 Von Arlt described simple closure of the wound. In 1916 Magitol suggested a lamellar corneal graft applied to the denuded area of the cornea after excision of pterygium. In 1948 D'ombrain described bare sclera excision. It was in nineteenth century that proper reconstructive surgery began with Scarpa, Arlt, Desmarres and Knapp. Elsching in 1926 performed advanced conjunctival plastic surgery. Beta irradiation was begun to be used in 1950s and Mitomycin C as adjuvant therapy began to be used in 1960s for the first time in Japan. Amniotic membrane to substitute conjunctiva was used as early as 1946 but the idea was later developed and popularized by Tseng in 1990s.

The principles of surgical techniques for pterygium surgery are:

- Complete removal of pterygium tissue leaving a bare sclera.
- Ways to suppress regrowth of subconjunctival tissue.
- Ways to restore barrier function of limbus.
- Biological contact inhibition.

An ideal pterygium surgery should achieve three principal goals-

- Minimal to no recurrence
- Nil complications
- Satisfactory cosmesis

The different techniques are as enumerated

1. Avulsion technique:

In 17th century, Paluus and Aegeneta for the first time described avulsion technique. With a small hook the pterygium is seized, then a needle with horse hair and strong thread in its eye is transfixed through 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.

Zolli in 1979 refined this method. [50] Here 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 is used to grasp the perilimbal tissue 90 degrees away to give counter traction. Residual tissue is scrapped off from the corneal surface and the surface is polished with a diamond burr.

2. Excision of the pterygium

Scarpa in 1811 proposed the method of simple excision. Von Arlt proposed combining excision of pterygium with closure of the wound by undermining the normal conjunctiva and approximating the wound margins.

Arlt and Czemark described a simple method consisting of extirpation of all the fibrovascular proliferation and suturing the upper and lower edges of the conjunctiva. Czemark recommended passing suture through the superficial layers of cornea.

Bare sclera technique-

First described by D'Ombrain.

It is one of the most popular methods of removal of primary pterygium where pterygium is excised of all its 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 Castroveijo.The main goal in bare sclera technique is smoothness of the surface of the excision.

The rationale for the 'bare sclera' technique was that the area left uncovered would be epithelialised from the epithelial cells from the anchored conjunctival rim which would then act as a barrier against pterygium re-growth from pathological tissue remnants left in situ. [32] However with respect to recurrence rates it is least satisfactory with as high as 80% recurrence. This procedure is now considered unethical.

Procedure:

- Anaesthesia- Topical anaesthesia is instilled followed by 1.5ml of 2% lignocaine being injected under the body of pterygium by means of a 26 gauge needle.
- Partial superficial keratectomy- Universal eye speculum is put. A fine hook or crescent blade is passed through the neck of the pterygium at the limbus and the conjunctiva is lifted up. A sharp blade(Bard Parker knife, no. 15 or Desmarres knife) is used to make incision into the clear cornea approximately 0.75 mm infront of and parallel to the edges of the head of pterygium. The depth of penetration is maintained just below the Bowman's membrane.

- Transition at the limbus- There is either change in the transparency of the bed to a more opaque state and frequently even bleeding at the limbal plane. It is important to change over to Westcott's conjunctival scissors at this point to avoid dissection at a deeper plane.
- Excision of the pterygium- The body of pterygium is separated from the underlying sclera. Two horizontal incisions are made in normal conjunctica above and below the pterygium. The pterygium tissue 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 if any bleeding vessel is seen.

Recurrence rate with bare sclera technique is 25% to 85%.

3. Modified Mc Gavick's technique

It was advocated by D.K.Sen [51]. Here pterygium is seized with a plain forceps

About 4 mm 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 position and edges of the horizontal incisions are secured by two interrupted sutures.

4. Z plasty

This was described by Wilson and Bourne (1988) [52]. After removal of the pterygium, a flap of normal conjunctiva is interposed between the body of pterygium and corneal limbus. They said this served as barrier to the regrowth of pterygium and allowed preservation of superior bulbar conjunctiva for use in conjunctival autograft procedure in case of recurrences in future.

Recurrence rates with this procedure were 50%.

5. Spaeth's rotation

This technique was described by Raizada et al [53] Here a rectangular area containing the conjunctiva is shaped and then the direction is changed 90 degrees, either up or down.

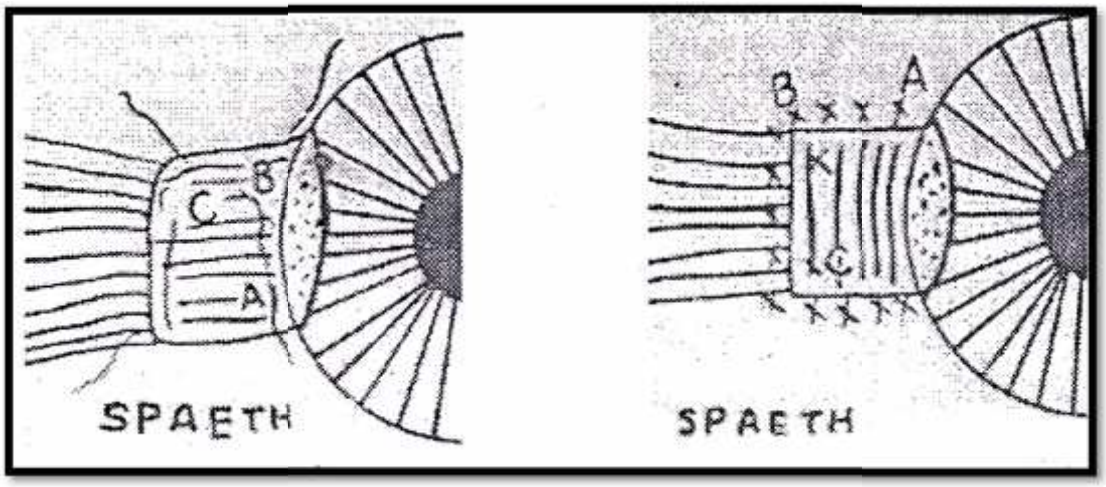


Figure 1: Spaeth's Rotation

The head of the pterygium is separated from cornea by a suture, three sides of the rectangle are outlined by incising the conjunctiva with sharp scissors. A suture is then 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 hence caused to rotate to the anchored corners.

6. Transplantation of the pterygium

Here head of the pterygium is dissected and transplanted under the conjunctiva away from the limbus so that any further growth is innocuous.

The pterygium was detatched from the cornea and fastened inferiorly making an opening in the conjunctiva by Desmarres (1851).

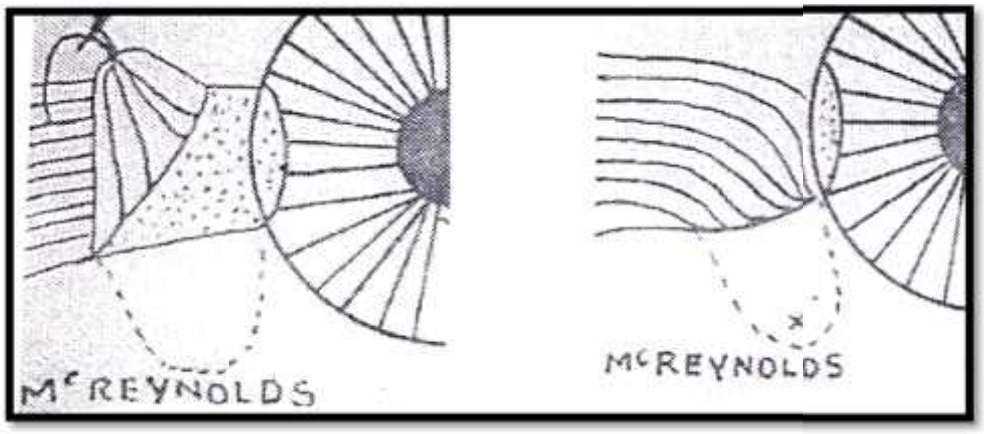


Figure 2: Mc Reynold technique

It was proposed by Mc Reynold to pass the head of the pterygium beneath the conjunctiva without cutting it and fastening it with suture near the insertion of the inferior rectus, beneath the lower bulbar conjunctiva.

Nehr on the other hand transplanted the loosened pterygium tissue beneath the upper bulbar conjunctiva.

The recurrence rate with this procedure was 60% - 70%.

7. Conjunctival autografts and flaps.

A] Sliding flaps- introduced by Mc Coombe and coworkers.

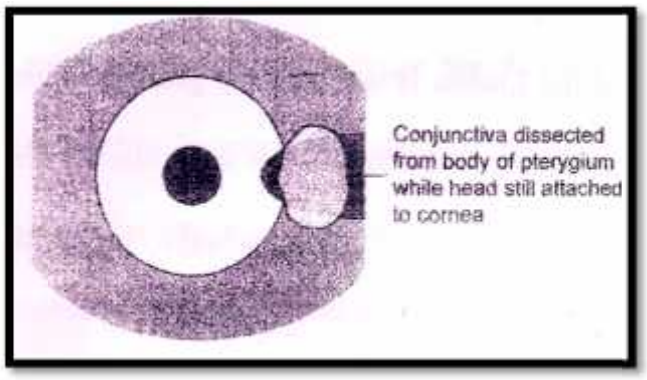
After pterygium is removed, conjunctiva is undermined with scissors. 10 mm vertical incision is made in the upper bulbar conjunctiva 3mm from the limbus. 7-0 vicryl suture is passed through the tip of the triangular flap of conjunctiva , through the superficial layer of sclera near the lower border of conjunctival defect 3 mm from the limbus and then through the free border of lower conjunctiva. Conjunctival flap is brought down by tying this suture. Second suture applied with 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 sliding conjunctival flap.

B] Free conjunctival autograft- introduced by Kenyon KR et al.(1985). It can be from same or opposite eye. This provides the best anatomical and physiological result. The aim here is to transplant the epithelium with its substantia propria but without Tenon's capsule. The graft is always limbus based.

Procedure:

- Peribulbar block is given
- Universal wire speculum is used to separate the lids.
- Superior rectus bridle suture is inserted using 4-0 black silk.
- The pterygium along with the tenon's capsule is excised without damaging the underlying medial rectus and conjunctiva.
- The abnormal tissue at the limbal end is dissected.



Fgure 3: Pterygium Excision

- Graft harvesting: size of the conjunctival graft required to resurface the exposed sclera surface is determined using Castroviejo calipers in three 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 to expose the superior limbus and conjunctival surface. The measured dimensions are marked onto the superotemporal conjunctiva. Using a Pierse-Hoskins forceps and Westcott scissors, the graft is excised starting from the forniceal end. Care is taken to take the graft as thin as possible without including the tenon's capsule and without causing button holing. Once the limbus is reached the graft is flipped on the corneal surface 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 for stem cells.

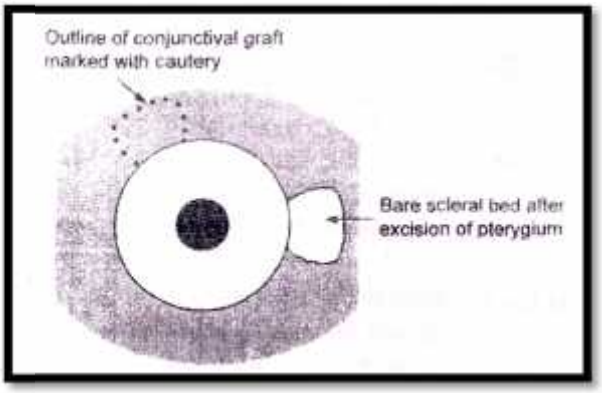


Figure 4: Harvesting of conjunctival autograft

- Placing the graft: After excising the graft it is slid onto the cornea. Without lifting the tissue of the cornea, it is rotated and moved on to 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/ 8-0 vicryl sutures. The graft is first anchored at the limbus and then on the nasal aspect

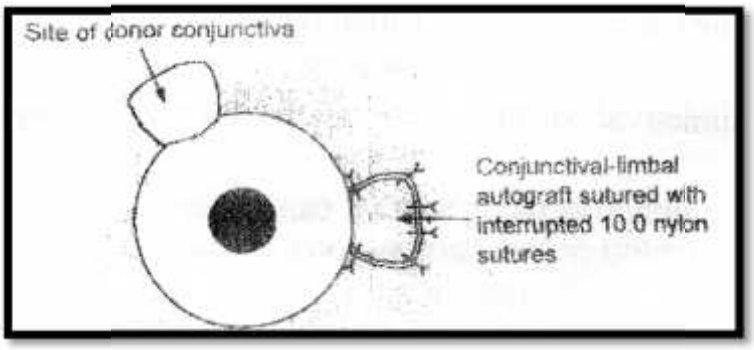


Figure 5: Placement of graft

There are different methods by which the graft can be secured to its recipient bed.

- Apart from sutures graft can be secured using the tissue adhesive that is the fibrin glue, which is applied to the dried surface of the bare sclera and the graft is placed over it. The graft adheres to the sclera with formation of fibrin clot. [54]
- The autograft can also be attached with electrocautery pen. The autograft is placed on the bare sclera after excision of the pterygium and the tissue junction is welded directly using electrocautery pen. The whole circumference of the graft is welded to the surrounding conjunctiva at appropriate intervals. Each weld takes approximately 0.5 seconds until coagulation is complete. A minimum of 8 welds and maximum of 10 welds are needed. [55]
- The latest method of securing the graft is with the use of autologus blood. After pterygium excision and fashioning of the autologus cojnuctival graft, the recipient bed is encouraged to achieve natural haemostasis. If no blood is available to provide autologus fibrin, small perforating veins and capillaries are purposely fractured to encourage a thin layer of blood to cover the bare sclera, [8] on which the graft is placed.

- Variations in conjunctival autograft surgery include the use of narrow strip conjunctival autograft, limbal conjunctival autografts, limbal epithelial autografts, conjunctival flaps or conjunctival rotation autografts.[56]

Limbal-conjunctival autografts: It has been proposed that including limbal cells in the conjunctival autograft may act as a barrier to conjunctival cells migrating to the corneal surface thus preventing chances of recurrence. This graft includes approximately 0.5 mm of the limbus and peripheral cornea. The recurrence rates after this graft (0-15%) are similar to conjunctival autograft surgery, while some authors state limbal conjunctival autografts as being superior to conjunctival autografts. [56]

The disadvantage of this graft is that it is time consuming and technically demanding. Till date even there is no conclusive report regarding the superiority of limbal-conjunctival autograft over conventional conjunctival autograft , and the added risk of limbal damage at the donor site remains.[56]

Conjunctival rotation autograft : It involves removal of the pterygium and reversal of the removed conjunctiva so that the most nasal aspect is sutured at the limbus and vice versa. This is useful in conditions where it is not desirable to use superior conjunctiva as a donor source, such as with excision of extensive pterygium, which leaves insufficient conjunctival tissue for autograft.[56]

Pterygium Extended Removal Followed by Extended Conjunctival Transplantation (P.E.R.F.E.C.T) has reported virtually no recurrences in a series of primary and recurrent pterygia removal. [57]

Amniotic membrane transplantation: In cases with very large conjunctival defects created following pterygium excision, or if proper autologus conjunctival graft

cannot be harvested, an alternative technique is the use of preserved amniotic membrane, which is readily commercially available and provides an excellent substrate for epithelial regrowth. [32]

Besides the conventional epithelised cryopreserved human amniotic membrane, the efficacy of membranes that are alternatively prepared such as the deepithelised or freeze dried sterilized ones have also been studied. An additional advantage of using amniotic membrane is that it removes the need of harvesting large autogrfats, thereby minimizing iatrogenic injury to the rest of the conjunctival surface.[56]

Amniotic membrane also possesses antiscarring, antiangiogenic and anti-inflammatory properties, which can be useful to treat pterygium and its recurrences. A study compared the excision of recurrent pterygia followed by amniotic membrane alone and amniotic graft combined with intraoperative mitomycin C and found no significant difference in the recurrence rates beween the two groups. [58]

Three prospective studies have compared amniotic membrane transplantation with other conventional treatment modalities. [58-60] In a randomized study, amniotic membrane transplant is associated with an unacceptably high recurrence rate compared with conjunctival autograft.[59] This report is also supported by another study. [60]

Cultivated conjunctival transplantation: This can be used to cover large epithelial defects following pterygium excision. It is a novel technique of closing the surgical defect with ex-vivo expanded conjunctival epithelial sheet on an amniotic membrane substrate. Although the preliminary study demonstrated no significant

difference in the recurrence rates compared with amniotic membrane transplantation, operated eyes achieved almost immediate re epithelisation of the ocular surface, reduced post operative inflammation and faster ocular rehabilitation. [61]

8. Lamellar / Penetrating keratoplasty

This is advocated mainly for recurrent pterygia. 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 the underlying sclera. There is often significant residual scarring and thinning of the cornea. Lamellar keratoplasty can be used to replace the damaged tissue.

9. Growth factor inhibitors

Anti vascular endothelial growth factor monoclonal antibodies have become widely available in ophthalmic practice mainly due to their property of suppressing various forms of intraocular neovascular growth, like exudative age related macular degeneration and subretinal neovascular membranes, proliferative diabetic retinopathy, neovascular glaucoma. [32] These factors include Pegaptanib, an oligonucleotide aptamer that binds exclusively to the 165 amino acid isoform of VEGF, and recombinant monoclonal antibody Bevacizumab as well as its fragment Ranibizumab, both directed against VEGF. [32]

Previous few studies have evaluated the potential use of Bevacizumab in pterygium management. [62,63] It is however associated with potential serious side effects, including significant cardiovascular toxicity. The study of VEGF expression in individual lesions may therefore allow for selective Bevacizumab or other anti-

VEGF administration, potentially reducing the risk of recurrence or aggressive behavior without taking unnecessary systemic risks. [32]

10. Adjunctive therapy

Beta irradiation as a treatment modality for pterygium was first developed by King in 1950. Mecham introduced use of antimitotics in 1962. Argon laser photocoagulation was used by Caldwell in 1985. Since the description of use of radon for the treatment of pterygium in 1940 by Burnam and Neil, adjuncts to surgery like radiotherapy, chemotherapy and argon laser have been advocated in the treatment of pterygium mainly to reduce recurrence .

Beta irradiation- It has been used effectively in the past mainly to reduce recurrence. The mechanism of action is inhibition of mitosis in rapidly dividing cells.

Strontium applicator was introduced for ophthalmogical use in 1950. Since then Strontium -90 has been the standard source of beta radiation. The Sr-90 plaque is a concave metal disc about 1-1.5 cm in diameter which is hollow and filled with an insoluble strontium salt. The side towards is very thin and has a delicate silver film that contains strontium and allows beta particles to escape. The dose of the radiation to the conjunctiva is controlled by the time the plaque is left in contact with the surface. The maximum radiation occurs within a 2 mm radius from the tip of the applicator. If a dose of 1800-2000 rad is given to the bed of pterygium , 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) used a modified Desmarres-Mac Reynolds transplantation bare sclera technique followed by irradiation with 2000 rad beta rays. After pterygium removal they cleaned the bare sclera area. Haemostasis

was achieved. The beta ray plaque was applied long enough to give a surface dose of 2000 rad, which equalizes to an application time of 3-3/4 minute with strontium 90 plaque.

Some of the complications with this procedure are

- Photophobia
- Pain
- Scleral necrosis
- Secondary cataract
- Scleral infectious ulceration and endophthalmitis

The recurrence rate with this procedure is 3-11%.

Argon Laser- Any early evidence of recurrent pterygium following surgical excision of pterygium is treated with 50 micrometer laser burns to the developing neovascular fronds. Spot size is kept to 50 micrometer and it is applied at the limbus in a pattern of 4 parallel rows. Conversion of laser light into heat energy produces a thermoablative effect. The power is kept minimum to prevent epithelial burning and shrinkage.

The complications associated include

- Secondary cataract
- Scleral necrosis
- Secondary iritis
- Scleromalacia

The recurrence rate is 12%.

Chemotherapy-

Thiotepa: The nitrogen mustard N, N', N' triethylene- thiophosphoramide (thiotepa or TEPA) is an alkalyting agent with anti mitotic properties. It acts by vascular endothelial proliferation. It was introduced by Mecham in 1962 as an adjunct to topical therapy. Concentration of 1:2000 (15mg in 30 ml of Ringer's solution) is given every three hours in day time for 6 weeks.

The complications include early and late onset poliosis and periorbital skin depigmentation that can remain permanent especially in dark individuals, irritation, prolonged conjunctival injection, epithelial toxicity leading to delayed epithelization of cornea, conjunctival deposition of black pigment, allergic reactions and scleral perforation.

Sun exposure during therapy was suggested as a contributing factor in skin and lash depigmentation. The periorbital skin depigmentation is the reason why thiotepa has not gained widespread acceptance in the post operative treatment of pterygium.

Mitomycin C: It is an antibiotic , a product of streptomyces caesiptosus, capable of alkylating DNA double helix and blocking both transcription and translation. It was first reported for the treatment of pterygium by Kunimoto and Mori in 1963. It is a potent antimetabolite used in suppressing tumor cells. [32]

This 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.

It is available as a blue violet crystalline powder form and is soluble in water.

Regimes used in treating pterygium include:

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

Other agents used include the alkylating agent 5- fluorouracil (5FU), a pyrimidine analogue used either intraoperatively or as postoperative subconjunctival injections. [32]

Gupta Ved P and Saxena T studied single drop Mitomycin C regime with other Mitomycin C regimes in pterygium surgery. [64] They compared recurrence rates in 4 groups. The recurrence was observed in 70% patients in group 1 (bare sclera group), 20% in group 2 (bare sclera excision with single drop instillation 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).

Although effective in reducing recurrence rates , antimetabolite use is associated with serious sight threatening complications, like delayed healing or even scleral melt , sometimes threatening vision or requiring further surgery for their management. The other complications are ocular pain, photophobia, lacrimation, lid edema, foreign body sensation (secondary to superficial punctate keratitis), scleral perforation, uveitis, cataract, glaucoma, symblepharon formation.

An avascularised sclera has been reported as the most common ocular complication following bare sclera excision with post operative Mitomycin C

0.02%.[65] The thin or necrotic sclera resulting from antimetabolites may be treated with the use of hyperbaric oxygen which induces hyperoxia, angiogenesis and episcleral fibroblast proliferation. [32]

Cano-para et al observed characteristic avascular sclera following intra operative Mitomycin C 0.01% for 5 min. [66]

Contraindications for topical use of Mitomycin C:

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

11. Fibrin Glue as a tissue adhesive

RelisealTM (Reliance life science) is a two component tissue adhesive which mimicks the natural fibrin formation. The glue does not stick to intact corneal or conjunctival epithelium.

The use of fibrin glue as a tissue adhesive was introduced in 1909.It was used by Tidrick et al in 1944 for skin graft fixation. [67] In early forties fibrin glue was introduced in ophthalmology to fixate penetrating corneal grafts in rabbits. [68]

Properties of an ideal tissue adhesive are : postoperative comfort, cost-effectiveness, rapid setting time, transparency, high tensile strength by forming strong bridge between wound edges, easy application, biodegradability and biocompatibility.

Synthetic tissue adhesives like cyanoacrylate, induce sufficient fibrin cross-linking kinetics but are limited by direct tissue toxicity and barrier effects. So, natural substances like fibrin may have significant advantages. [69]

In ophthalmology fibrin adhesive has been used successfully to close cataract incisions, attach soft tissue in oculoplasty surgeries, attach conjunctiva in strabismus surgeries and in glaucoma surgery, treat leaking blebs and close macular hole in retinal surgeries. [68]

The sealer protein has two major components, fibrinogen and thrombin, and two coagulating factors, aprotinin (fibrinolysis inhibitor) and calcium chloride. The setting time of this mixture is dependent on concentration of thrombin. A fast setting mixture sets within 30 seconds and a slow setting mixture within 1-2 minutes.

Mechanism of action- Fibrin glue adhesion mimicks the final common pathway between extrinsic and intrinsic pathway of coagulation in vivo. Fibrin clot formation starts with activation of Factor XIII by thrombin. The activated Factor XIII then hydrolyzes prothrombin to thrombin. Thrombin converts fibrinogen to fibrin. Fibrin self assembles into fibers to form a 3 dimensional matrix.

Thrombin also activates Factor XIIIa which is present in fibrinogen component of the glue, which stabilizes the clot by cross linking fibrin fibers as well as inducing polymerization of the fibers in the presence of calcium ions.

The main basis of adhesion being Factor XIII enzyme which causes the fibrin to cross link and form a coagulum with great cohesive strength.

Availability: The following components are present in separate vials

1. Freeze dried human fibrinogen (40mg/ml)
2. Freeze dried human thrombin (500IU/ml)
3. No antimicrobial preservative.
4. Aprotinin solution (Bovine) as a sterile solution in a composition of 3000 kiu/ml.
5. 5ml ampoule of sterile water for injection.
6. Applicator with two mixing chambers and one plunger guide.

Storage: The lyophilized powder to be stored between +2 degree Celsius and +8 degree celsius.

Advantages of fibrin glue:

- Reduces total surgical time as time required to place sutures is saved.
- Reduces risk of post operative infection compared to sutures which can be attributed to accumulation of mucous and debris in sutures which can act as nidus for infection.
- Non toxic
- Well tolerated
- Has some antimicrobial activity
- The wound edge will have higher tensile strength and less resistant to shearing stress.
- Helps in controlling bleeding
- Has low incidence of allergic reactions however anaphylactic reactions have been reported in certain cases and this is attributed to the presence of aprotinin in the glue. [68]

Disadvantages of fibrin glue:

- Risk of transmitted diseases from pooled and single donor blood donors

  This can be prevented or lessened by obtaining blood from screened healthy donors. The safest preparation would be by using patient's own blood to prepare fibrin glue but it is expensive and autologus donation to prepare glue requires at least 24 hours for processing and the resultant product will have variable concentrations thereby resulting in unpredictable performances. [68]

  Some of the methods used to inactivate viruses include solvent/ detergent method, gamma radiation, cryoprecipitation, adsorption, vapor heating, pasteurization and nanofiltration.

Use of Fibrin glue in pterygium surgery: Fibrin glue is being used as an alternative to sutures for securing conjunctival grafts. The use of the glue shortens operating time and also less postoperative discomfort. It also provides even attachment of the graft to the scleral bed. Most cases performed with fibrin glue healed with minimal inflammation and there were only sporadic cases of graft dislodgement or loss. [56]

Fibrin has two modes of action- sealing the wound and acting as a hemostatic agent.

A study showed that the use of fibrin glue was associated with a significantly shorter operative time and greater patient acceptance compared with using sutures. [69]

Another study in 2008 evaluated the efficacy and safety of fibrin glue in conjunctival autograft fixation in primary pterygium compared with that of suturing.[70] They found that fibrin glue application takes significantly shorter operating time and

is associated with fewer post operative symptoms than a sutured graft, indicating the safety of the procedure.

Studies have also demonstrated its efficacy for amniotic membrane graft fixation during pterygium surgery in terms of reduction of surgical time and post operative discomfort. A study reported that rubbing the eye can cause graft dehiscence following pterygium surgery with fibrin glue.

Autologus blood as a tissue adhesive:

Advantages- It is postulated in a study that it caused an even tension across the whole of the graft interface and no direct tension on the free graft edges and so there is reduced stimulus for subconjunctival tissue to form. [8]

The age old method of attaching the graft was sutures which had many complications like prolonged operating time, postoperative discomfort, suture abscess, buton holes and granuloma formation which actually require a second operation for removal [1,71]. Replacing sutures with tissue adhesive might shorten the operating time, improve post operative comfort, and avoid suture related complications. However, major concern of commercial fibrin glue is the cost (cost of 1 double syringe of Reliseal is equal to 5 vicryl sutures) and potential risk of transmitted infections. Autologus fibrin glue has been used as an alternative method for graft fixation. A recent study describes successful outcome with sutureless and glue-free conjunctival autograft. [8]

A study also suggested that apposition of the lids to the bulbar conjunctiva provides a natural biological dressing and confers a unique wound healing

environment. [8] The lids provide compression , a smooth frictionless surface, and a vascular bed with immune capability in close proximity to the injury site.

Human infection of parvovirus B19 (HPV B19) have been reported after use of fibrin glue by different manufacturers. [72,73] Prions are also of concern. The direct application of any of the apparently effective methods of prion decontamination to plasma products is inappropriate as the methods are harsh and denaturing. [74] So autologus blood in comparison with commercial products eliminates the potential risk of infection transmission and hypersensitivity reactions.

After the use of TISEEL fibrin sealant, three cases of anaphylactic reaction were reported, one of which resulted in death. The allergen was believed to be bovine protein aprotinin, which was induced in the product as an antifibrinolytic to slow the dissolution of the fibrin clot. [72,75]

Complications

Associated with pterygium:

1. Recurrent inflammation.
2. Recurrence following surgical removal.
3. Cystic degeneration- formed due to degenerative changes associated with destruction of part of its tissue.
4. Granuloma formation- occurs when tenon's layer is traumatized while excising the pterygium.
5. Symblepharon- occurs due to bare areas on cornea and conjunctiva after wide areas of excision and this might later interfere with normal ocular motility producing subjective sensation of diplopia in lateral gazes.

6. Neoplastic transformation- though rare benign transformations like benign melanoma, epithelioma, fibroblastic sarcoma are reported.
7. Astigmatism with the rule- 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.

Associated with the treatment procedure:

1. Excessive bleeding
2. Button holing of the conjunctival graft.
3. Perforation of the globe with the suture needle
4. Injury to medial rectus muscle tendon
5. Recurrence, dellen, pyogenic granuloma and persistent epithelial defects as postoperative complications.

Associated with the graft:

1. Graft edema- secondary to inadequate debridement of the graft which included tenon's capsule remnants.
2. Sclerocorneal dellen- due to over sized graft or persistent edema. Excessive use of diamond burr or blade to resect the head of the pterygium produces a rough surface with poor lubrication and subsequent dellen formation.
3. Graft necrosis- It is rare. It occurs when the graft is misplaced with epithelial side down or if the recipient bed is avascular.
4. Subconjunctival hematomas- subside spontaneously without consequence but can cause short term cosmetic deformity.

5. Epithelial inclusion cyst- are transparent and encapsulated. They appear 1-2 months post operatively and may be produced by inclusion of epithelial debris beneath the conjunctival graft. It is treated by excising the involved conjunctiva and marsupalizing the cyst.
6. Subconjunctival fibrosis- occurs usually at the donor site. It is triggered by abnormal exposure of the tenon's capsule and can cause problem that is cosmetic and involvement of extra ocular muscle in the scar tissue can cause diplopia.
7. Corneoscleral thinning- more common in recurrent pterygia. Tendencies to use deep keratectomies to remove the head of the pterygium are the main cause of exaggerated scraping.

METHODOLOGY

The present study is a randomized controlled trial to compare the efficacy of autologus blood (fibrin) versus sutures in attaching conjunctival autograft after pterygium surgery.

STUDY DESIGN

One year randomized controlled trial.

SOURCE OF DATA

Patients with primary pterygium attending Ophthalmology Out Patient Department at KLES Dr. Prabhakar Kore Hospital and MRC, Belgaum.

STUDY PERIOD

January 2013 to December 2013

SAMPLE SIZE

A total of 44 patients randomly divided into two groups of 22 each.

FOLLOW UP PERIOD

All patients were followed up for a minimum period of 3 months and a maximum period of 12 months.

INCLUSION CRITERIA

1. Patients with primary pterygium.
2. Patients who give consent for study.

EXCLUSION CRITERIA

1. h/o ocular surface infections.
2. h/o ocular trauma.
3. h/o any bleeding abnormalities.
4. h/o patients on anti-coagulant therapy.

SAMPLING PROCEDURE

According to sample size calculation formula.

$$n = \frac{2(z\alpha + z\beta)^2 \times p \times (100-p)}{(p_0 - p_1)^2}$$

Where,

$Z\alpha = 1.96$

$Z\beta = 0.84$

$$p = \frac{(p_0 - p_1)}{2}$$

p_0= efficacy in one group(sutures) i.e. 50% patients having foreign body sensation

p_1= efficacy in 2nd group (autologus fibrin-blood) i.e. 20% patients having foreign body sensation

$p_0 - p_1$ = effect size i.e. 30%

Group1 : Autologus fibrin: n=22 Group2 : Sutures: n= 22

RANDOMIZATION

Based on the computer generated randomization, patients were divided into two groups of 22 each.

ETHICAL CLEARANCE

Prior to the commencement of the study it was approved by the Ethical and Research Committee , Jawaharlal Nehru Medical College, Belgaum.

INFORMED CONSENT

All the patients fulfilling the inclusion criteria were explained about the nature of the study and its implications and a written informed consent was obtained before enrollment (Annexure I).

DATA COLLECTION

After enrollment, patients were interviewed for the demographic data such as age, sex, occupation. Patients were asked about the complaints and detailed history was taken regarding the presenting illness. All the findings were documented in a predesigned and pretested proforma (Annexure II).

Ocular examination

Ocular examination included recording visual acuity with Snellen's chart (in patients with visual acuity less than 6/60, acuity was recorded as counting fingers at particular distance or hand movements or perception of light or projection of rays).

Detailed anterior segment examination was done under slit lamp for the diagnosis of pterygium and characteristics such as grade, type and site were recorded. The grading of pterygium was done according to Tan et al classification as:

Grade 1(atrophic): episcleral vessels under the body of the pterygium not obscured and clearly distinguishable.

Grade 2 (intermediate): episcleral vessels under the body of the pterygium obscured partly and indistinguishable.

Grade 3(fleshy): episcleral vessels totally obscured.

Depending upon the progression, a thick fleshy and vascular pterygium with a few infiltrates in the cornea infront of the head of the pterygium were typed as progressive and thin, atrophic, attenuated with very little vascularity and no infiltrates in the cornea were typed as non-progressive. Based on the location, the pterygium was labeled as nasal or temporal.

Any patient with both nasal and temporal pterygium in the same eye were diagnosed as having 'Double Headed Pterygium' .

Investigations done included:

- Keratometry
- Intraocular measurement
- Lacrimal Sac Patency
- Bleeding time and Clotting time
- Random Blood sugar
- Blood Pressure

Surgical Procedure:

The surgical procedures were standardized and were performed by an experienced single surgeon.

Preoperative Prepararion-

- 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.

Intraoperative procedure:

- Under asceptic precautions a wire speculum was put to separate the lids. A superior rectus bridle suture was inserted using 4-0 black silk and was clipped to the drapes.
- The body of the pterygium with the involved tenon's capsule was excised, taking care to ensure 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 sclera surface was determined using Castroviejo calipers in three directions- extent across the limbus, maximum circumferential extent across the bed, and maximum distance from limbus.
- The bridle suture was then used to rotate the globe downwards exposing the superior limbus and conjunctival surface.

- Using a westcott's 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 on to 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.

Group 1:

- After excising the graft, 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.
- The graft was placed on the bare sclera (which contained blood, and if not limbal vessel was punctured using 26 guage needle to make blood available on the bare sclera) in such a way so as to maintain the original orientation of the juxtalimbal border towards the cornea.
- The sclera bed was viewed through the transparent conjunctiva to ensure that residual bleeding does not lift the graft.
- Small central hemorrhages were tamponaded with direct compression.
- The free graft was held in position for 8-10 minutes by application of gentle pressure over it.

Group 2:

- After excising the graft, 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 8-0 vicryl sutures.
- The superior rectus bridle suture was removed.
- Two drops of antibiotic drops were instilled in the conjunctival cul de sac and the eye was firmly patched.

Operating time was measured starting from insertion of lid speculum to its removal at the end of the surgery.

POSTOPERATIVE ADVICE:

In both the groups post operatively topical antibiotic- steroid eyedrops were used for six times a day for two weeks and then tapered over next 4-6 weeks. Lubricating drops were used for four times/ day for six weeks. The timing of suture fall off or absorption was noted.

POST OPERATIVE FOLLOW UP:

All patients were followed up regularly for a minimum period of 3 months (1^{st} day, 1^{st} week , 6^{th} week, 3^{rd} month). All eyes were examined on slit lamp for any complications and recurrence of pterygium.At every visit patients were assessed for the following outcome varialbles

Outcome variables:

- Pain
- Foreign body sensation
- Lacrimation

- Discomfort during blinking

The assessment of outcome variables was done using a questionnaire and the responses were graded on a scale of 0-3 as:

- Absent- no symptoms
- Mild- Patient had tolerable symptoms which were present occasionally
- Moderate- Tolerable symptoms present throughout the day or intolerable symptoms present occasionally
- Severe- Intolerable symptoms present throughout the day.

The operated eye was evaluated for the presence or absence of hemorrhage and displacement of graft. The overall appearance of the eye was assessed and graded as red or quiet. Further other complications such as graft edema, graft extrusion, graft dehiscence, graft contraction, granuloma formation were assessed and noted.

RESULTS

The present one year randomized controlled trial on 44 patients with primary pterygium attending Department of Ophthalmology, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum was conducted during the period of January 2013 to December 2013.

Based on the computer generated randomization, these patients were divided into two groups

Group 1: Autologus blood(fibrin) group: n=22;

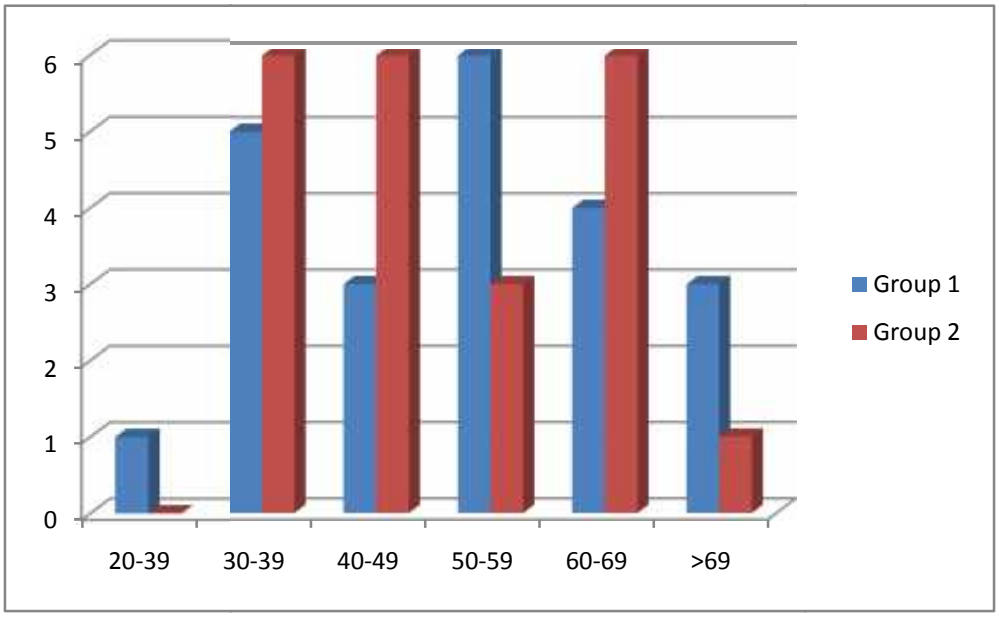
Group 2: Suture group: n=22.

The data was coded and compiled on Microsoft Excel spreadsheet. The data was analysed and results obtained are tabulated as below.

Table 1: Age distribution between the two groups

AGE (Years)	Group 1	Group2	Total	% age
20-29	1	-	1	2.27
30-39	5	6	11	25
40-49	3	6	9	20.45
50-59	6	3	9	20.45
60-69	4	6	10	22.72
>69	3	1	4	9.09
Total	22	22	44	100

Graph 1: Age Distribution between the two groups



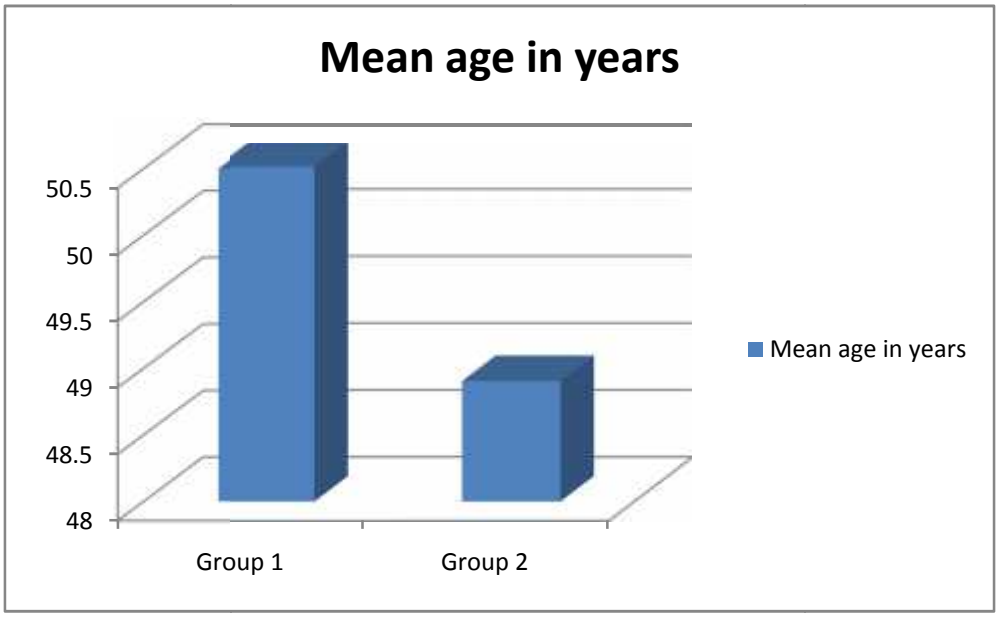
Out of the 44 eyes of 41 patients , 11 eyes (25%) belonged to the age group of 30-39 years of age, 10 eyes (22.72%) belonged to the age group of 60-69 years of age, 9 eyes (20.45%) each belonged to the age group of 40-49 years and 50-59 years of age, 4 (9.09%) belonged to the age group of > 69 years and 1 (2.27%) eye belonged to the age group of 20-29 years of age.

Table 2: Mean Age in the two groups

Variables	Group 1 (n=22)	Group 2 (n=22)
Mean	50.5	48.9
SD	14.81	13.23
Maximum	80	72
Minimum	30	30

T= 0.397 p= 0.693

Graph 2: Mean Age in the two groups



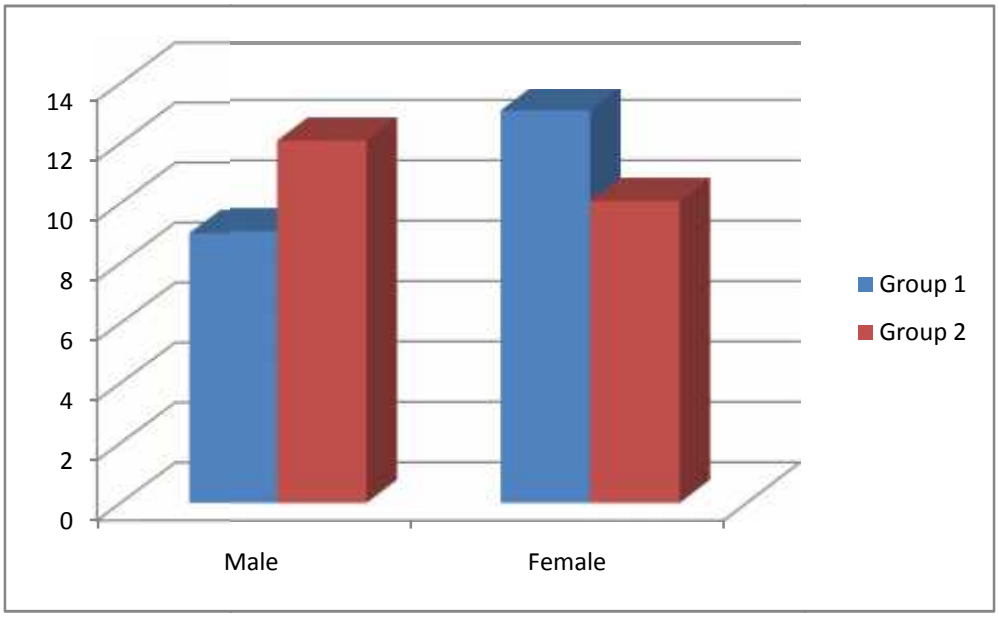
In the present study the mean age in Group 1 was 50.5 +/- 14.81 years with range being 30 to 80 years, and in Group 2 the mean age was 48.9 +/- 13.23 years with range being 30 to 72 years. Overall the mean age in the two groups was comparable.

Table 3: Sex Distribution between the two groups

Sex Distribution	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
Male	9	40.91	12	54.55
Female	13	59.09	10	45.45
Total	22	100	22	100

$x^2 = 0.820$ p= 0.365

Graph 3: Sex Distributionbetween the two groups

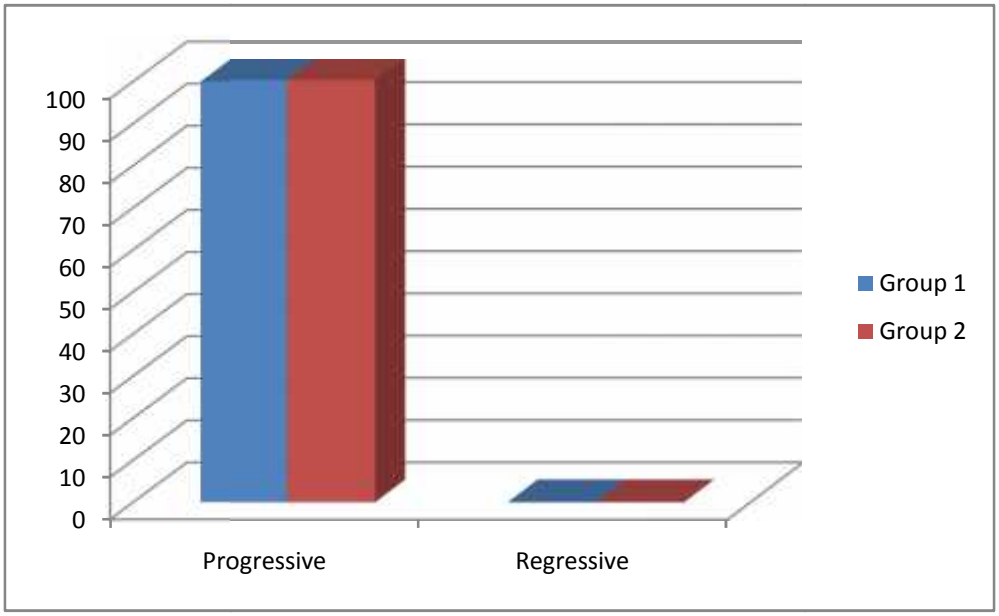


In this study there was a female preponderance in Group 1 with male to female ratio being 1:1.4, and male preponderance in Group 2 with male to female ratio being 1.2:1. However, sex distribution in both the groups was comparable.

Table 4: Type of Pterygium in the two groups

Type	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
Progressive	22	100	22	100
Non Progressive	0	0	0	0
Total	22	100	22	100

Graph 4: Type of Pterygium in the two groups

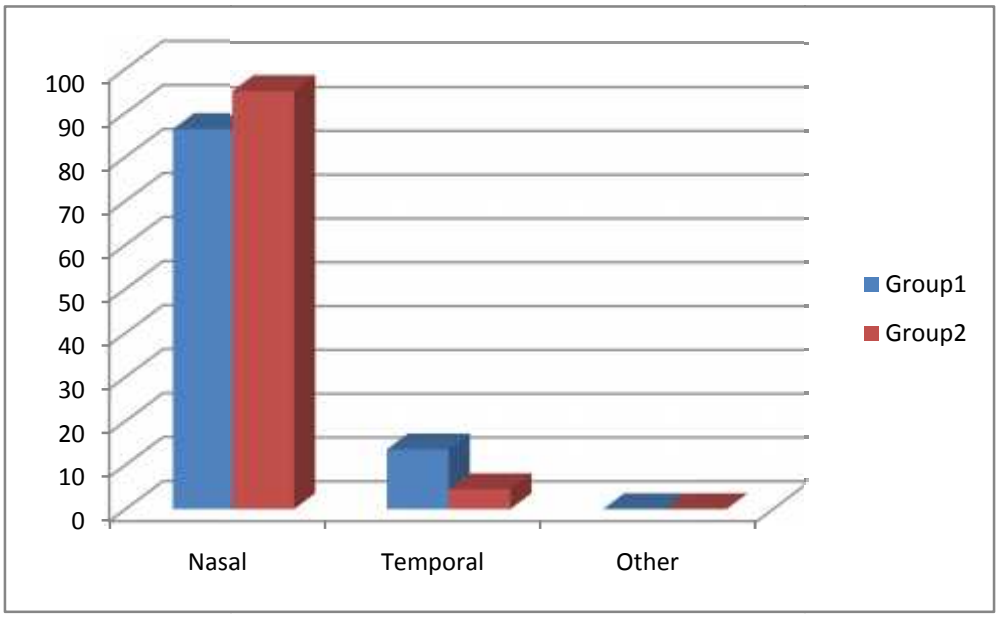


In this study it was found that all patients had progressive pterygium.

Table 5: Site of Pterygium in the two groups

Site	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
Nasal	19	86.36	21	95.45
Temporal	3	13.64	1	4.55
Other	0	0	0	0
Total	22	100	22	100

Graph 5: Site of Pterygium in the two groups



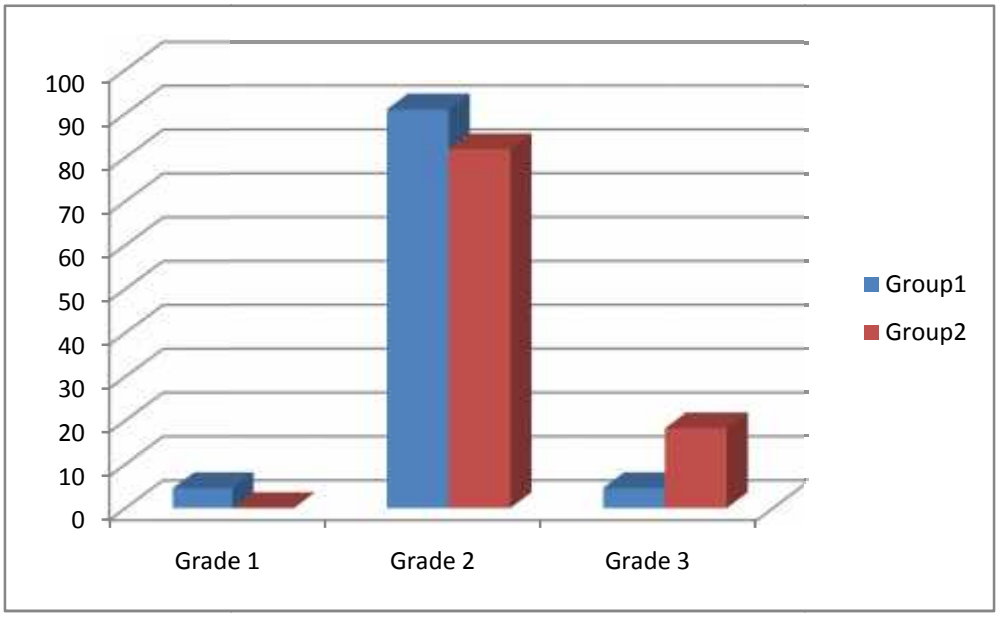
In this study majority of patients had pterygium on nasal side being 86.36 % in Group 1 and 95.45% in Group 2. Of the 22 eyes in Group 1, 3 eyes (13.64%) had pterygium on both nasal and temporal side ‘ Double Headed Pterygium’ in the same eye

Table 6: Grade of Pterygium in the two groups

Grade	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
Grade 1	1	4.55	0	0
Grade 2	20	90.91	18	81.82
Grade 3	1	4.55	4	18.18
Total	22	100	22	100

Fischer Exact Test: p= 0.345

Graph 6: Grade of Pterygium in the two groups

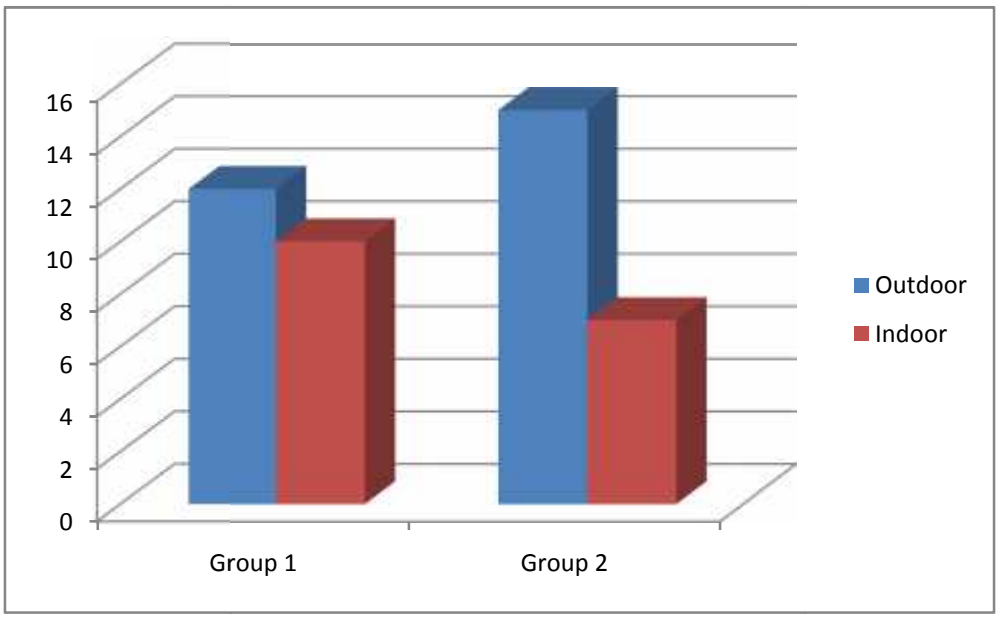


In this study most of the patients in both the groups had Grade 2 Pterygium being 90.91 % in Group 1 and 81.82% in Group 2. In Group 1, 4.55% of patients each had Grade 1 and Grade 3 Pterygium. In Group 2, 18.18% patients had Grade 3 pterygium, where as none of them had Grade 1 pterygium. However this difference was not statistically significant and both the groups were comparable.

Table 7: Occupation in the two groups

Activity	Group 1	Group 2	Total	Percentage
Outdoor	12	15	27	61.36
Indoor	10	7	17	38.64
Total	22	22	44	100

Graph 7: Occupation in the two groups

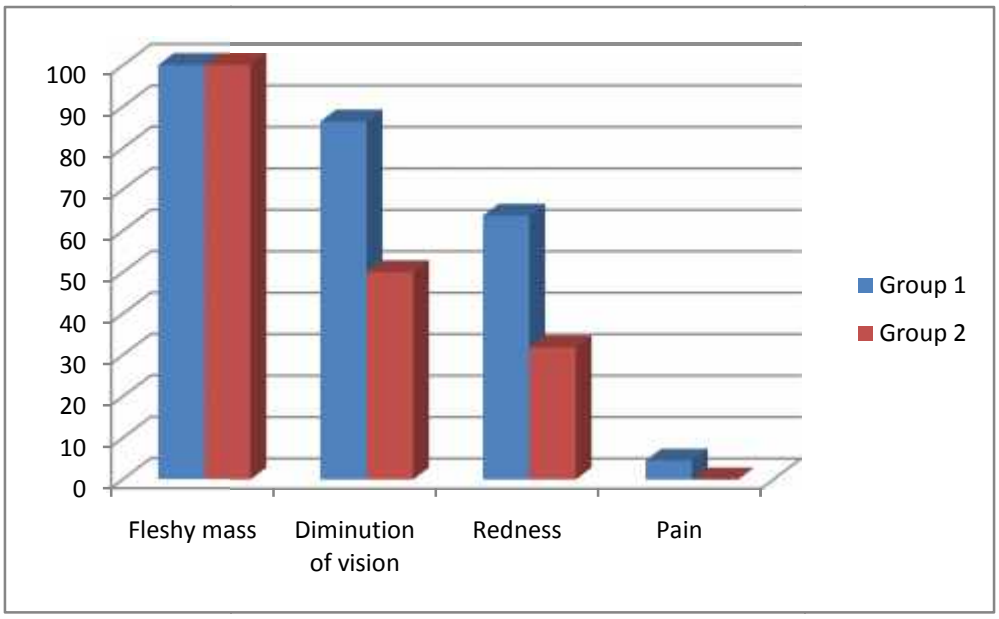


Out of the 44 eyes involved in the study, 27 (61.36%) were exposed to the external environment of dust, wind and smoke as they were mainly outdoor workers. 17 (38.64%) were of those who worked indoors.

Table 8: Presenting Complaints in the two groups

Complaints	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
Fleshy mass	22	100	22	100
Diminution of vision	19	86.36	11	50
Redness	14	63.64	7	31.82
Pain	1	4.55	0	0

Graph 8: Presenting Complaints in the two groups



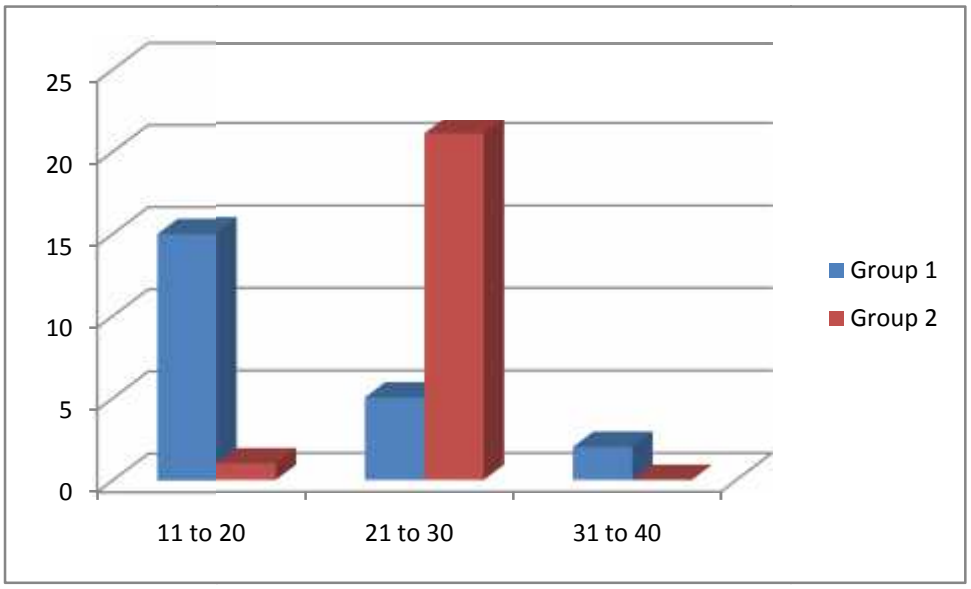
In this study all the patients in both the groups presented with fleshy mass. Diminished vision was noted in 86.36% in Group 1 and 50% in Group 2, Redness was noted in 63.64% in Group 1and 31.82% in Group 2, Pain was noted only in one patient in Group 1 where as none of the patients in Group 2 had pain.

Table 9: Operative time in the two groups

Time (minutes)	Group 1 (n=22)		Group 2 (n=22)	
	Number	Percentage	Number	Percentage
11-20	15	68.18	1	4.55
21-30	5	22.73	21	95.45
31-40	2	9.09	0	0
Total	22	100	22	100

P=0.004

Graph 9: Operative time in the two groups



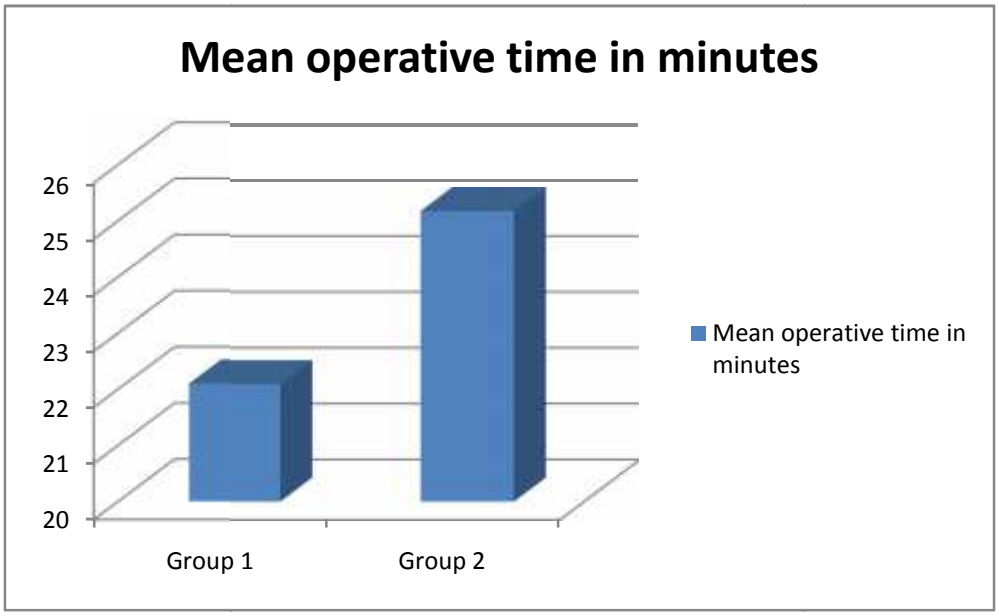
In this study 11-20 minutes was required for a good number of patients in group 1 (68.18%) compared to only 4.55% in group 2 which was statistically significant. In 2 patients (9.09%) in group 1 > 31 minutes was needed as they had 'double headed pterygium' and both were operated in the same sitting.

Table 10: Mean Operative Time in the two groups

Variables	Group 1(n=22)	Group 2(n=22)
Mean	22.1	25.2
SD	5.43	2.61
Minimum	15	18
Maximum	33	30

T= 3.126 p= 0.004

Graph 10: Mean Operative Time in the two groups

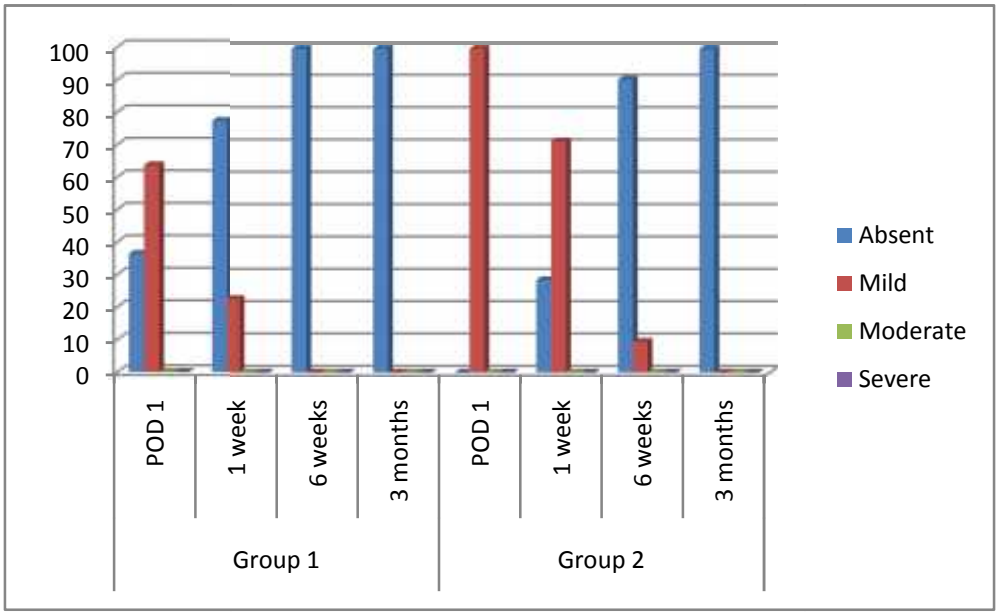


The mean operative time in group 1 was less compared to group 2 (22.1+/- 5.43 vs 25.2 +/- 2.61 minutes) with range in group 1 being 15 to 33 minutes and in group 2 being 18 to 30 minutes.

Table 11: Assessment of pain in the two groups from Post operative day 1 to 3 months.

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Absent	8	36.36	0	0
	Mild	14	63.64	22	100
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	22	100
x^2= 7·486		p= 0.006			
1 week	Absent	17	77.27	6	28.57
	Mild	5	22.73	15	71.43
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
		Fischer Exact p= 0.004			
6 weeks	Absent	22	100	19	90.47
	Mild	0	0	2	9.52
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
		Fischer Exact p= 0.223			
3 months	Absent	22	100	20	100
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	20	100

Graph 11: Assessement of pain from Post operative day 1 to 3 months between the two groups.

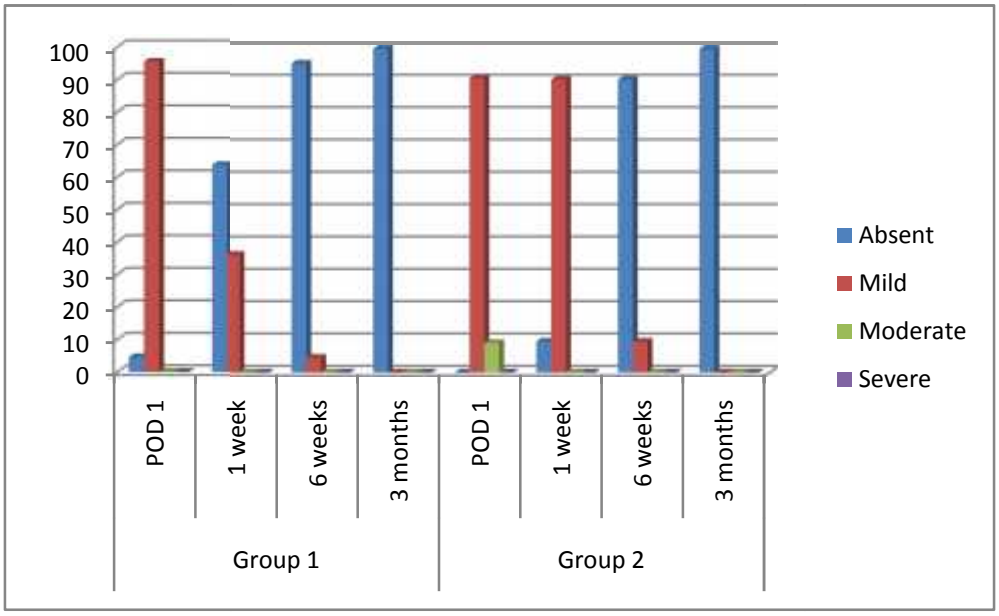


In this study on post operative day one 63.64% patients in group 1 experienced mild pain and 36.36% had no pain, while all patients in group 2 experienced mild pain on Post op. day 1. At 1 week 22.73% patients had mild pain in Group 1 and 71.43 % in group 2 had mild pain which was statistically significant. During further follow up at 6 weeks and 3 months none of the patients in both groups reported pain. 2 patients in group 2 were lost to follow up 1 at 1 week and other at 3 months.

Table 12: Assessment of foreign body sensation in the two groups from post op. day 1 to 3 months

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Absent	1	4.55	0	0
	Mild	21	95.45	20	90.91
	Moderate	0	0	2	9.09
	Severe	0	0	0	0
	Total	22	100	22	100
		Fischer exact p= 0.488			
1 week	Absent	14	63.64	2	9.52
	Mild	8	36.36	19	90.48
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
x^2= 13.466		P< 0.001			
6 weeks	Absent	21	95.45	19	90.48
	Mild	1	4.55	2	9.52
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
		Fischer exact p= 0.607			
3 months	Absent	22	100	20	100
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	20	100

Graph 12: Assessment of foreign body sensation from post op. day 1 to 3 months in the two groups

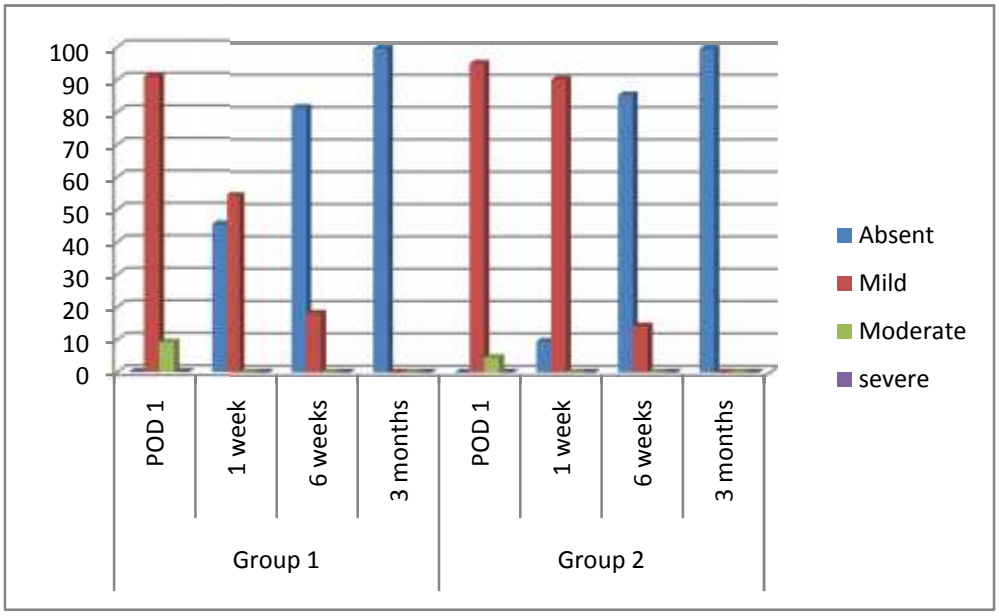


In this study it was found that 95.45 % patients in Group 1 had mild foreign body sensation on post op. day 1 where as 90.91 % had mild foreign body sensation and 9.09% had moderate foreign body sensation in group 2 on post op. day 1. On follow up at week 1, 36.36% patients reported mild foreign body sensation and 63.64% had no foreign body sensation in Group 1, while 90.48% had mild foreign body sensation and 9.42% had no foreign body sensation in group 2. At 6 weeks follow up 4.55% in Group 1 and 9.52% in Group 2 had mild foreign body sensation. Further at 3 months follow up none of the patients in both the groups had foreign body sensation. The foreign body sensation was statistically significant between the two groups at 1 week and comparable at other follow ups. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months.

Table 13: Assessment of Lacrimation at post op. day 1 and 3 months between the two groups

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Absent	0	0	0	0
	Mild	20	90.91	21	95.45
	Moderate	2	9.09	1	4.55
	Severe	0	0	0	0
	Total	22	100	22	100
		Fischer exact p=1			
1 week	Absent	10	45.45	2	9.52
	Mild	12	54.55	19	90.48
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
x^2= 6.894		P=0.009			
6 weeks	Absent	18	81.82	18	85.71
	Mild	4	18.18	3	14.29
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
x^2= 0		P=1			
3 months	Absent	22	100	20	100
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	20	100

Graph 13: Assessment of lacrimation from post op. day 1 to 3 months in the two groups

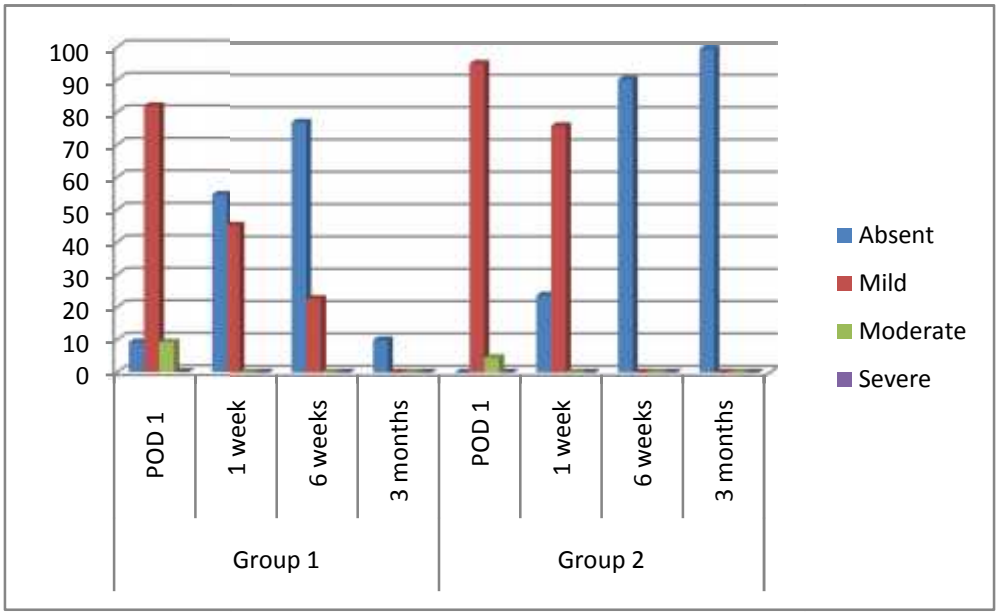


In this study it was found that on post op. day 1 90.09% patients had mild lacrimation and 9.91% had moderate lacrimation in group 1, where as 95.45% had mild lacrimation and 4.55% had moderate lacrimation in group 2. On follow up at week 1 45.45% had mild lacrimation in group 1 and rest 55.45% had no lacrimation, where as 90.48% had mild lacrimation and 9.52% had no lacrimation. At 6 weeks 18.18% had mild lacrimation in group 1 and 14.29% had mild lacrimation in group 2. At 3 months none of the patients had lacrimation in both the groups. The results were statistically significant between the two groups at week 1 of follow up where as they were comparable at other follow up periods. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months.

Table 14: Assessment of discomfort from post op. day 1 to 3 months between the two groups

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Absent	2	9.09	0	0
	Mild	18	81.82	21	95.45
	Moderate	2	9.09	1	4.55
	Severe	0	0	0	0
	Total	22	100	22	100
		Fischer exact test p= 0.410			
1 week	Absent	12	54.55	5	23.81
	Mild	10	45.45	16	76.19
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
x^2= 4.246		P= 0.039			
6 weeks	Absent	17	77.27	19	90.48
	Mild	5	22.73	2	9.52
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	21	100
x^2= 0.576		P= 0.44			
3 months	Absent	22	100	20	100
	Mild	0	0	0	0
	Moderate	0	0	0	0
	Severe	0	0	0	0
	Total	22	100	20	100

Graph 14: Assessment of discomfort from post op. day 1 to 3 months between the two groups

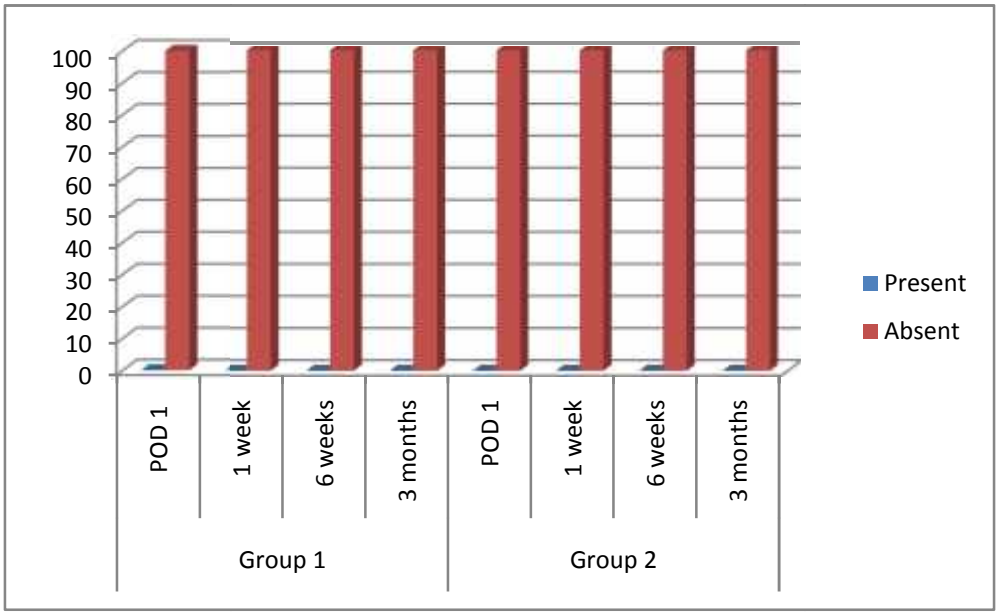


In this study on post op. day 1 81.82% patients had mild discomfort and 9.09% had moderate discomfort in Group 1, where as 95.45% had mild discomfort and 4.55% had moderate discomfort in Group 2. At 1 week follow up 45.45% had mild discomfort and 54.55% had no discomfort in Group 1, where as 76.19% had mild discomfort and 23.18% had no discomfort in Group 2. At 6 weeks 22.73% had mild discomfort and 77.27% had no discomfort in group 1, where as 9.52% had mild discomfort and 90.48% had no discomfort in Group 2. At 3 months none of the patients in both the groups had any discomfort. The results between the two groups were statistically significant at week 1 and comparable at other periods of follow up. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months.

Table 15: Assessment of displacement of graft from post op. day 1 to 3 months between the two groups

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Present	0	0	0	0
	Absent	22	100	22	100
	Total	22	100	22	100
x^2= 3.220		P= 0.073			
1 week	Present	0	0	0	0
	Absent	22	100	21	100
	Total	22	100	21	100
6 weeks	Present	0	0	0	0
	Absent	22	100	21	100
	Total	22	100	21	100
3 months	Present	0	0	0	0
	Absent	22	100	20	100
	Total	22	100	20	100

Graph 15: Assessment of displacement of graft from post op. day 1 to 3 months between the two groups

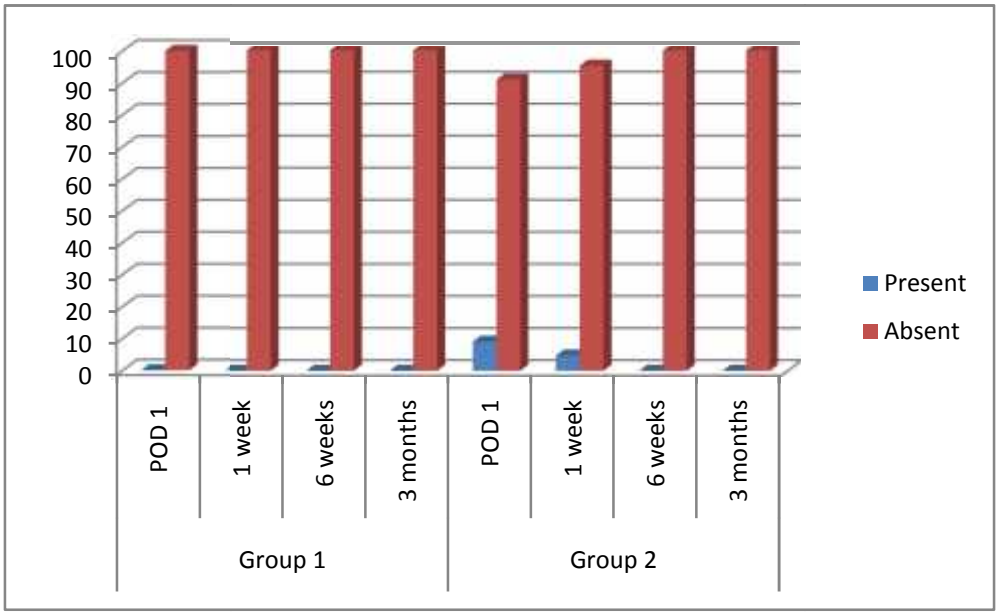


It was never noted that the graft got displaced in either of the two groups at any follow up visit which showed that both the groups were comparable.

Table 16: Assessment of graft retraction from post op. day 1 to 3 months in the two groups

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Present	0	0	2	9.09
	Absent	22	100	20	90.91
	Total	22	100	22	100
		P= 0.488			
1 week	Present	0	0	1	4.76
	Absent	22	100	20	95.23
	Total	22	100	21	100
		P=0.488			
6 weeks	Present	0	0	0	0
	Absent	22	100	21	100
	Total	22	100	21	100
		P= 0.073			
3 months	Present	0	0	0	0
	Absent	22	100	20	100
	Total	22	100	20	100
		P= 0.073			

Graph 16: Assessment of graft retraction from post op. day 1 to 3 months in the two groups

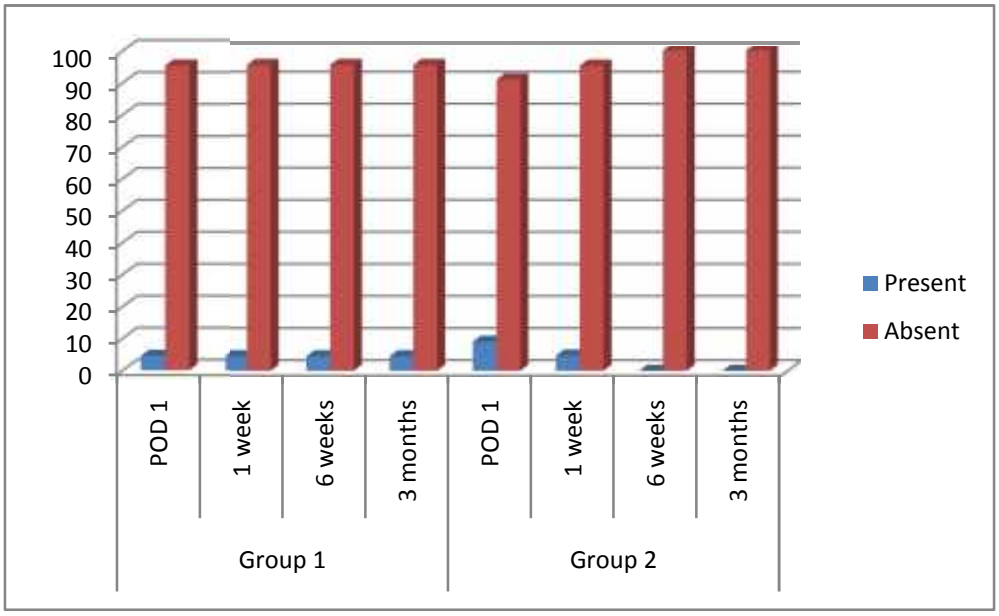


In this study none of the patients in group 1 had retraction of graft at any time of follow up , where as 9.09% of group 2 had graft retraction on post op. day 1, 4.76% had graft retraction in first week follow up and none had in further follow ups. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months.

Table 17: Assessment of subgraft hemorrhage from post op. day 1 to 3 months in the two groups

Follow up	Findings	Group 1 (n=22)		Group 2 (n=22)	
		Number	Percentage	Number	Percentage
POD 1	Present	1	4.55	2	9.09
	Absent	21	95.45	20	90.91
	Total	22	100	22	100
		P=1			
1 week	Present	1	4.55	1	4.76
	Absent	21	95.45	20	95.24
	Total	22	100	21	100
		P=1			
6 weeks	Present	1	4.55	0	0
	Absent	21	95.45	21	100
	Total	22	100	21	100
		P=1			
3 months	Present	1	4.55	0	0
	Absent	21	95.45	20	100
	Total	22	100	20	100
		P=1			

Graph 17: Assessment of Sub graft hemorrhage from post op. day 1 to 3 months in the two groups

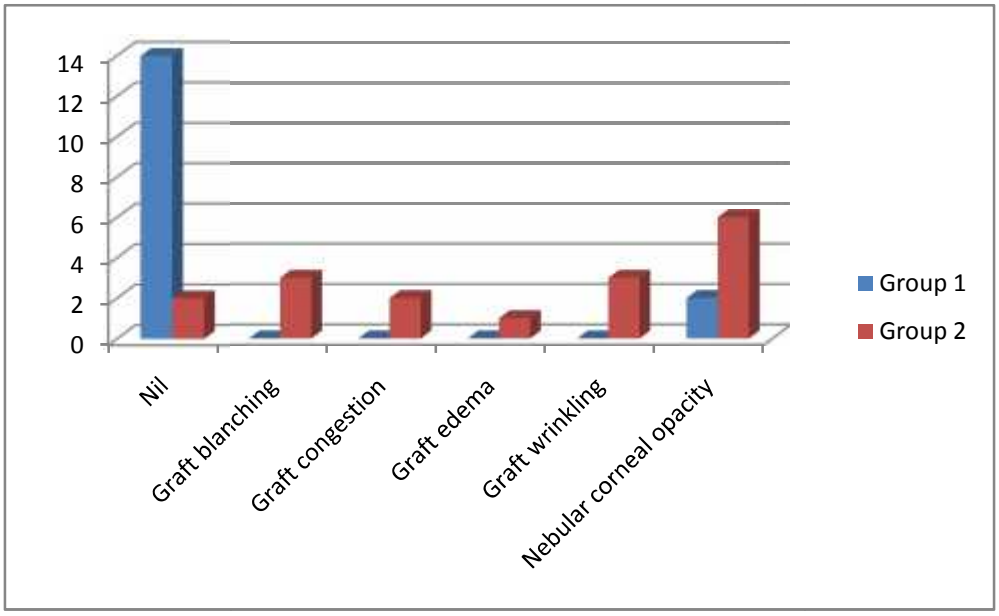


In this study in Group 1, 1 patient (4.55%) had sub graft hemorrhage on all the follow up visits beginning from post op. day 1, where as in Group 2, 2 patients (9.09%) had subgraft hemorrhage on post op. day 1, 1 patient (4,76%) had sub graft hemorrhage in the first week and none had in the next follow ups.

Table 18: Assessment of other complications from post op. day 1 to 3 months in the two groups

Complications	Group 1	Group 2	Total	Percentage
Nil	14	2	16	36.36
Graft Blanching	0	3	3	6.82
Graft congestion	0	2	2	4.55
Graft edema	0	1	1	2.27
Graft wrinkling	0	3	3	6.82
Nebular corneal opacity	2	6	8	18.18

Graph 18: Assessment of other complications from post op. day 1 to 3 months between the two groups



In this study 14 patients in group 1 had no complications at any time during the postoperative period against 2 patients in Group 2 which was statistically significant with a probability value of <0.001. 3 patients in Group 2 had Graft blanching, 2 patients had Graft congestion, 1 patient had Graft edema, 3 patients had Graft wrinkiling. Nebular corneal opacity as a consequence to separating head of pterygium from corneal surface was noted in 2 patients in Group1 and 6 patients in. Group 2.

Table 19: Assessment of Recurrence of pterygium in the two Groups

Groups	Group 1	Group 2
No. of recurrence	0	0
Percentage	0	0

The patients in both the groups were followed for a minimum period of 3 months to a maximum period of 1 year and no recurrence was noted in any of the eyes.

DISCUSSION

Many surgical adjunct therapies have been explained for managing pterygium. But, an ideal procedure is still not established for catering to the common complications of post operative inflammation and recurrence. Conjunctival autograft is simple and safe modality for management of pterygium.

Graft suturing has its own hindrances of long operating time , additional trauma to the graft tissue and suture granuloma. Sutures may also act as nidus to infection along the suture tract.

Recently use of conjunctival autograft with fibrin glue application is gaining poularity with varied outcomes. Fibrin glue is safe and effective method for conjunctival autografting in primary pterygium excision. The glue provides not only stability as provided with sutures but also produces significantly less inflammation, better patient comfort, less operating time.

Autologus fibrin further reduces complications of using fibrin glue like high cost and risk of transmitted viral infections as fibrin glue is prepared from pooled serum. Hence the present study was undertaken to evaluate the efficacy of autologus fibrin versus suture in patients undergoing conjunctival autografting and also to compare operative time and post operative complications.

Forty four eyes were included in our study. They were randomly assigned to Group 1 or Group 2. Those in Group 1 underwent Conjunctival autografting with Autologus blood following pterygium excision and those in Group 2 underwent conjunctival autografting with 8-0 vicryl sutures following pterygium excision.

1. **Age**:

We found a mean age of 50.5 years in group 1 (range 30-80 years) and 48.9 years in Group 2 (range 30-72 years). Our study showed maximum incidence of pterygium between 30-39 years (25%).

Ebrahim Mikanki, et al in their study on pterygium patients found mean age of 49 years and 47 years in their study groups.[77] This was comparable to our study.

2. **Sex**:

In this study there was a female preponderance in Group 1 with male to female ratio being 1:1.4, and male preponderance in Group 2 with male to female ratio being 1.2:1.

A prospective, randomized, hospital based, comparative study from India reported 22 females and 25 males out of 47 patients. [78] Though the literature like above documents male preponderance, our study showed female preponderance in one group which may be due to the fact that quite majority of patients come with cosmetic disfigurement for treatment. Also as most women in our study were from rural background more exposure to 'chullah' smoke might point towards etiological factors in development of pterygium.

3. **Type of pterygium**:

In this study it was found that all patients had progressive pterygium that is 100% in both the groups.

4. **Site of pterygium**:

In this study majority of patients had pterygium on nasal side being 86.36 % in Group 1 and 95.45% in Group 2. 3 patients (13,64%) in Group 1 and 1 patient (4.55%) in Group 2 had temporal pterygium.Of the 22 eyes in Group 1, 3 eyes (13.64%) had pterygium on both nasal and temporal side ' Double Headed Pterygium' in the same eye.

Srinivas K Rao in a study on 51 patients found, that pterygium was nasal in 46(86.8%), temporal in 4(7,5%) and both nasal and temporal in 3 (5.7%) eyes.[79] Our study correlates well with this study.

Doloezalovo [80] in his study on 1388 patients found only 1 case of unilateral temporal pterygium.

Sevel and Sealy's study on 100 temporal pterygia has cautioned ophthalmologists about an underlying malignancy in patients with temporal pterygium. [81] Malignant change should be considered if there is unusual evidence of invasion, extension and if it becomes vascular.

B Ramasamy et al reported a case of temporal pterygium which on biopsy turned out to be conjunctival intra epithelial neoplasia. [82]

Hence 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.

5. **Grade of pterygium**:

In this study most of the patients in both the groups had Grade 2 Pterygium being 90.91 % in Group 1 and 81.82% in Group 2. In Group 1, 4.55% of patients each had Grade 1 and Grade 3 Pterygium. In Group 2, 18.18% patients had Grade 3 pterygium, where as none of them had Grade 1 pterygium.

In a study from Malaysia done on 137 eyes of 113 patients, 68% reported with grade 2 pterygium. [83] Another study from Turkey reported 48% with Grade 2 pterygium in fibrin glue group compared to 52% in suture group.

6. **Occupation**:

In our study out of the 44 eyes involved in the study, 27 (61.36%) were exposed to the external environment of dust, wind and smoke as they were mainly outdoor workers. 17 (38.64%) were of those who worked indoors.

Catherine A McCarty et al, in his study found that 6.7 % of the rural population had pterygium and found 43.6% attributable risk of sunlight and pterygium. [84] His study suggests that pterygium is a significant public health problem in rural areas,primarily due to sun exposure.

S R Dukin et al found a statistically significant relationship between the risk of developing pterygium and outdoor occupation. [85]

D J Moran in examination of more than 100 000 Arborigines and non-arborigines in rural Australia, found a strong positive correalation between climatic UV radiation and pterygium prevalence providing further evidence of a causal relationship.

Ichiro et al in a study on welders who are occupationally exposed to excess UV light found out that 8% of the welders had pterygium in comparison to control in which the prevalence was 0.4%. [87] . Hence through our study it was proved that sunlight and Ultra violet light exposure made a major contribution towards pathogenesis of pterygium.

7. **Presenting complaints**:

In this study all the patients in both the groups presented with fleshy mass. Diminished vision was noted in 86.36% in Group 1 and 50% in Group 2, Redness was noted in 63.64% in Group 1and 31.82% in Group 2, Pain was noted only in one patient in Group 1 where as none of the patients in Group 2 had pain.

The commonest signs and symptoms of pterygium include discomfort, foreign body sensation, redness, irritation, dryness, lacrimation and decreased visual acuity. [88]

In our study cosmetic reason became the leading cause to drive the patients to the hospital as all the patients in both the groups of our study came with complaints of fleshy mass in the eye.

8. **Operative time in the two groups**:

In this study 11-20 minutes was required for a good number of patients in group 1 (68.18%) compared to only 4.55% in group 2 which was statistically significant. In 2 patients (9.09%) in group 1 > 31 minutes was needed as they had ‘double headed pterygium’ and both were operated in the same sitting. The mean operative time in group 1 was less compared to group 2 (22.1+/- 5.43 vs 25.2 +/- 2.61 minutes) with range in group 1 being 15 to 33 minutes in range in group 2 being 18 to 30 minutes. Longer operating time is considered to be closely associated with

enhanced post operative reaction and increased risk of infection and thus, reduction of operating time has important implications. A meta analysis of 7 trials analysed the duration of operation. [89] All the randomized control trials in this meta analysis study revealed statistically significant longer operating time for suture. A similar Indian study reported average surgical time as 21 minutes in the fibrin glue group as compared to 38 minutes in the suture group. [90]

9. **Patient Outcome**:

Pain

In this study on post operative day one 63.64% patients in group 1 experienced mild pain and 36.36% had no pain, while all patients in group 2 experienced mild pain on Post op. day 1. At 1 week 22.73% patients had mild pain in Group 1 and 71.43 % in group 2 had mild pain which was statistically significant. During further follow up at 6 weeks and 3 months none of the patients in both groups reported pain. 2 patients in group 2 were lost to follow up 1 at 1 week and other at 3 months. A similar study noted that on a 10- point numerical rating scale, both the fibrin adhesive and suture group had low median pain scores. [83] However, the pain scores immediately post surgery and at 1 week post surgery were significantally lower in the fibrin adhesive group ($p > 0.05$). A study from Sweden, reported that the medians of the visual analogue score values at each measurement after adjusting for individual pain sensitivity found significantly lower pain values in the fibrin adhesive group both on Day 0, and at each point of time during the first post operative week and concluded that the use of fibrin tissue adhesive when securing the autologus conjunctival graft in pterygium surgery causes significantly less pain than using sutures.[91]

Foreign Body Sensation

In this study it was found that 95.45 % patients in Group 1 had mild foreign body sensation on post op. day 1 where as 90.91 % had mild foreign body sensation and 9.09% had moderate foreign body sensation in group 2 on post op. day 1. On follow up at week 1, 36.36% patients reported mild foreign body sensation and 63.64% had no foreign body sensation in Group 1, while 90.48% had mild foreign body sensation and 9.42% had no foreign body sensation in group 2. At 6 weeks follow up 4.55% in Group 1 and 9.52% in Group 2 had mild foreign body sensation. Further at 3 months follow none of the patients in both the groups had foreign body sensation. The foreign body sensation was statistically significant between the two groups at 1 week and comparable at other follow ups. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months.

Similar study in India, reported that, in Fibrin adhesive patients, post operative foreign body sensation of mild and moderate grade was seen in 54.54% and 36.36% of eyes respectively. [83] At the end of 1 month, 90.91% patients had no foreign body sensation and 9.09% had mild sensation. Compared to this in suture group, 100% patients had severe foreign body sensation on day 1 ($p<0.001$). Similar results were reported in a study from Israel which observed foreign body sensation in 20% fibrin adhesive patients while in suture group 60% patients felt foreign body sensation on 1st post operative day ($p<0.001$). [69] A study from Turkey found that the intensity of post operative complaints including foreign-body sensation was significantly lower in patients treated with fibrin adhesive than in those treated with sutures at both post operative days 1 and 10 ($p< 0.001$). [92] Also the intensity of itchy sensation at the

first two postoperative visits was lower among patients in the fibrin adhesive group than in suture group. ($p<0.05$).

Lacrimation

In this study it was found that on post op. day 1 90.09% patients had mild lacrimation and 9.91% had moderate lacrimation in group 1, where as 95.45% had mild lacrimation and 4.55% had moderate lacrimation in group 2. On follow up at week 1 45.45% had mild lacrimation in group 1 and rest 55.45% had no lacrimation, where as 90.48% had mild lacrimation and 9.52% had no lacrimation. At 6 weeks 18.18% had mild lacrimation in group 1 and 14.29% had mild lacrimation in group 2. At 3 months none of the patients had lacrimation in both the groups. The results were statistically significant between the two groups at week 1 of follow up where as they were comparable at other follow up periods. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months. A study from Phillipines concluded that subjective symptoms of lacrimation were fewer and disappeared more rapidly in the fibrin adhesive group than the suture group. [93] An Indian study reported significant symptomatic relief in lacrimation amongst the patients in fibrin adhesive group compared to suture group. [83] Another study from Turkey also observed a lower score in post operative patient's complaints of stinging, watering and pain. [94]

Discomfort

In this study on post op. day 1 81.82% patients had mild discomfort and 9.09% had moderate discomfort in Group 1, where as 95.45% had mild discomfort and 4.55% had moderate discomfort in Group 2. At 1 week follow up 45.45% had mild discomfort and 54.55% had no discomfort in Group 1, where as 76.19% had mild discomfort and 23.18% had no discomfort in Group 2. At 6 weeks 22.73% had

mild discomfort and 77.27% had no discomfort in group 1, where as 9.52% had mild discomfort and 90.48% had no discomfort in Group 2. At 3 months none of the patients in both the groups had any discomfort. The results between the two groups were statistically significant at week 1 and comparable at other periods of follow up. 2 patients in group 2 were lost to follow up, 1 at 1 week and other at 3 months. In a study done in Phillipines, fibrin adhesive was used for attaching conjunctival autografts and resulted in less patient discomfort than did Nylon sutures. [93] A study from Turkey observed that patient satisfaction with regard to subjective symptoms was significantly higher in fibrin adhesive group than the suture group at all follow up visits, and the patients in the glue group experienced a more comfortable post operative period. [95] In a meta- analysis performed , it showed that total discomfort was considerably less in fibrin adhesive group than in suture group. [89]

Graft Displacement

It was never noted that the graft got displaced in either of the two groups at any follow up visit which showed that both the groups were comparable. An Indian study reported, in suture group all the patients had well placed graft on immediate post operative day. [83] Another study observed 8.33% , 1 out of 12 patients in the fibrin adhesive group had dislocation of graft which then had to be sutured. [90] Another study from Sweden reported transplant loss as 1% patient out of 362 from fibrin adhesive group, 2% out of 156 from vicryl suture group. [7]

Graft Retraction

In this study none of the patients in group 1 had retraction of graft at any time of follow up , where as 9.09% of group 2 had graft retraction around 1.5 – 2 mm on

nasal side on post op. day 1, 4.76% had graft retraction in first week follow up and none had in further follow ups. The patients were closely followed, and re epithelialization of the conjunctival defect occurred within 2 weeks. A study from Spain also repored mild graft retraction which required no intervention for a complete secondary reepithelialization.[96]

10. **Complications**:

In the present study we did not encounter any serious intra operative or post operative complications.

Intra operative complications-Two patients in Group 1, Six patients in Group 2 developed nebular grade corneal opacity due to deep keratectomy being done during excision of head of pterygium. In none of the patients button holing of the graft occurred during harvesting the graft.

Postoperative complications- In this study 14 patients in group 1 had no complications at any time during the postoperative period against 2 patients in Group 2 .

Graft edema was noted in 1 patient (2.27%) in Group 2 and none in Group 1. The edema gradually subsided over a period of 10 days. Starck et al [97] in their study pointed out towards 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.

Graft blanching was noted in 3 patients (6.82%) in Group 2 on the post operative day 1 which subsided by first week and remained healthy thereafter. While none of the patients in Group 1 had graft blanching. Graft congestion was noted in 2 (4.55%)

patients in Group2 while none in Group 1 had graft congestion. Graft wrinkling was noted in 3 (6.82%) patients in Group 2 and none in Group 1 had grfat wrinkling.

In this study in Group 1, 1 patient (4.55%) had sub graft hemorrhage on all the follow up visits beginning from post op. day 1, where as in Group 2, 2 patients (9.09%) had subgraft hemorrhage on post op. day 1, 1 patient (4,76%) had sub graft hemorrhage in the first week and none had in the next follow ups.A study done in Canada found no significant difference in the degree of subconjunctival hemorrhage between the two groups at any point during the follow up period. [54] Another study noticed hemorrhage under the graft in one case of one group on the second post operative day. [94] A meta analysis recorded no complications in both the groups in 2 studies.[89]

11. **Recurrence**:

All eyes were followed up for a minimum period of 3 months and maximum period of 1 year. None of the eyes in our study showed any recurrence.

Chen at al reported the mean time to recurrence from 3 to 4.8 months and only 6% are noted after the sixth post operative month. [98]

O Gris et al in their study on 7 patients with recurrent pterygium found that there was no recurrence after a follow up period of 14 months. [99]

The limitation of this study was smaller sample size and a short follow up period to assess the recurrence rate of the pterygium. Hence long term studies are needed to determine whether the recurrence rate of pterygium is affected by autologus fibrin adhesive instead of sutures.

CONCLUSION

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

The present study showed better efficacy of autologus fibrin adhesive in conjunctival autografting among the patients undergoing pterygium excision, in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Also, it significantly reduced the surgical time with fewer post operative complications.

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

Through our study we would conclude that both the techniques of attaching conjunctival autograft after pterygium excision are equally efficacious in terms of post operative complications and recurrence, but the decision of selecting the technique vests with the surgeon after considering the time available and meticulous skill required.

SUMMARY

- Fibrin glue as an adhesive is used in many ophthalmic procedures like conjunctival closure in strabismus, vitreoretinal surgery and glaucoma surgeries. Because of its biological and biodegradable properties, fibrin based adhesives may be used to attach the conjunctival autograft without inducing inflammation. The present study was undertaken to assess the efficacy of autologus blood versus sutures in attaching the graft in patients undergoing conjunctival autgrafting and also to compare operative time and post operative complications.
- This one year randomized controlled trial on 44 eyes with primary pterygium was conducted at the Department of Ophthalmology, KLE S Dr. Prabhakar Kore Hospital and Medical Research centre, Belgaum during the period of January 2013 to December 2013. Based on computer generated randomization, these patients were divided into two groups namely, Group 1 (Autologus blood group: n=22) and Group 2 (Suture group: n=22).
- In this study 11 eyes (25%) belonged to the age group of 30-39 years of age, 10 eyes (22.72%) belonged to the age group of 60-69 years of age, 9 eyes (20.45%) each belonged to the age group of 40-49 years and 50-59 years of age, 4 (9.09%) belonged to the age group of > 69 years and 1 (2.27%) eye belonged to the age group of 20-29 years of age.
- In this study the mean age in Group 1 was 50.5 +/- 14.81 years with range being 30 to 80 years, and in Group 2 the mean age was 48.9 +/- 13.23 years with range being 30 to 72 years.

- There was a female preponderance in Group 1 with male to female ratio being 1:1.4, and male preponderance in Group 2 with male to female ratio being 1.2:1.
- All the patients in both the groups presented with fleshy mass. All patients had progressive pterygium.
- In this study majority of patients had pterygium on nasal side being 86.36 % in Group 1 and 95.45% in Group 2. 3 patients (13,64%) in Group 1 and 1 patient (4.55%) in Group 2 had temporal pterygium.Of the 22 eyes in Group 1, 3 eyes (13.64%) had pterygium on both nasal and temporal side ‘ Double Headed Pterygium’ in the same eye.
- Most of the patients in both the groups had Grade 2 Pterygium being 90.91 % in Group 1 and 81.82% in Group 2. In Group 1, 4.55% of patients each had Grade 1 and Grade 3 Pterygium. In Group 2, 18.18% patients had Grade 3 pterygium, where as none of them had Grade 1 pterygium.
- The mean operative time in group 1 was less compared to group 2 (22.1+/- 5.43 vs 25.2 +/- 2.61 minutes) with range in group 1 being 15 to 33 minutes and in group 2 being 18 to 30 minutes.
- The present study showed better efficacy of autologus fibrin adhesive in conjunctival autografting among the patients undergoing pterygium excision, in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Also, it reduced significantly the surgical time with fewer post operative complications.

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ANNEXURE-II

DATA COLLECTION INSTRUMENT

☐☐☐ I D No.

Name (in capital letters)

(First name) (Middle name) (Last name)

Age (in ☐☐☐ yrs)

Sex : ☐ (1=Male; 2=Female)

☐☐☐☐☐☐☐☐ OP/I.P.No.

Address:

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Telephone ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ No.

Date of admission : ☐☐ ☐☐ ☐☐☐☐

Date of surgery : ☐☐ ☐☐ ☐☐☐☐

Date of discharge : ☐☐ ☐☐ ☐☐☐☐

Provisional Diagnosis: Eye-

Pterygium grade (1=1;2=2;3=3;4=4)

Pterygium type (1= progressive; 2= non progressive) ☐

Pterygium site(1= nasal; 2= temporal;3= other) ☐

Inclusion Criteria: ☐ (1=Met; 2=Not met)

Informed consent: ☐ (1=Taken; 2=Not taken)

Chief Complaints (1=Yes; 2=No)

	RE	LE
Fleshy mass over cornea	☐	☐
Diminution of vision	☐	☐
Redness	☐	☐
Pain	☐	☐

History of present illness: (1= yes;2=no)

	RE	LE
History of fleshy mass over cornea:	☐	☐
History of pain : Mild	☐	☐
Moderate	☐	☐
Severe	☐	☐
History of redness:	☐	☐
History of watering:	☐	☐
History of discharge:	☐	☐
History of itching:	☐	☐
History of ocular irritation:	☐	☐
History of photophobia:	☐	☐
History of diplopia:	☐	☐
History of coloured halos:	☐	☐

Other complaints: (if present):

Past History (1=Yes; 2=No)

	RE	LE
Intra-ocular Surgery		
Trauma		
Other		

Other past history (if present):

Medical History (1=Yes; 2=No)

Diabetes	
Hypertension	
Bleeding disorders	
Others	

Other medical history (if present):

Family History ☐ (1=Significant; 2=Insignificant)

If 1, specify:

Personal History ☐ (1=Significant; 2=Insignificant)

If 1, specify:

General Physical Examination

Vitals

- Pulse (per min) ☐☐☐
- Blood Pressure (systolic/diastolic)(mm of hg) ☐☐☐/☐☐☐
- Temperature ☐ (1=Febrile; 2=Afebrile)
- Respiratory Rate (per min) ☐☐☐

(1=Yes; 2=No)

Pallor		Clubbing	
Icterus		Lymphadenopathy	
Cyanosis		Oedema	

Systemic Examination (1=Normal; 2=Abnormal)

C V S If 2, specify	
R S If 2, specify	
C N S If 2, specify	
P / A If 2, specify	

Ocular Examination

- Head posture ☐ (1=Erect; 2=Tilted)
- Facial symmetry ☐ (1=Symmetrical; 2=Asymmetrical)
- Visual axes (1=Parallel; 2=Deviated)
- Extra-ocular movements (1=Normal; 2=Restricted)
  - Uniocular RE ☐ LE ☐
  - Binocular ☐ ☐

- Vision (1=6/6 - 6/12; 2=6/18 - 6/36; 3=< 6/36)

	RE	LE
Unaided		
Pin-hole		
Spectacles		

- Refraction

	RE				LE			
	Sphere	Cylinder	Axis	Vision	Sphere	Cylinder	Axis	Vision
Distance								
Near								

- Anterior segment examination

	RE	LE
Adnexa (1=Normal; 2=Abnormal) If 2, specify		
Conjunctiva Pterygium Present=1 Absent=2 If 1 Grade (1=i; 2=ii;3=iii)		
Location Nasal=1 Temporal=2 Other=3		
Type (1=Progressive;2= non progressive)		
Cornea [1=Clear(other than conj. Mass); 2=edematous; 3=other] If 3, specify		
Sclera (1=Normal; 2=Abnormal) If 2, specify		
Anterior chamber (1=Normal depth; 2=shallow; 3=deep)		
Iris (1=Normal; 2=Atrophic patches; 3=other) If 3, specify		
Pupil • Size (1=normal; 2=constricted; 3=dilated) • Reactions: o Direct o Indirect (1=present; 2=absent; 3=sluggish)		
Lens (1=Clear; 2=Cataract) (If 2: 1=immature; 2=mature; 3=hypermature)		

Fundus

	RE	LE
Glow (1=Good; 2=Faint; 3=Absent)		
Media (1=Clear; 2=Hazy)		
Disc • Size (1=Normal; 2=small; 3=large) • Margins (1=Normal; 2=Abnormal) • VCDR (1=0.2; 2=0.3; 3=0.4; 4=0.5; 5=0.6; 6=0.7; 7=0.8; 8=0.9; 9=1.0) • NRR (1=Normal; 2=Thin)		
Blood vessels (1=Normal; 2=Abnormal)		
Background (1=Normal; 2=Tessellated; 3=Other)		
Macula (1=Normal; 2=Abnormal)		

Investigations

- Tonometry

	RE	LE
IOP (mm Hg)		

- Random blood sugar | | | |

DIAGNOSIS:

SURGERY:

Autograft attached with[1=Autologus fibrin(blood); 2= sutures]

Operating time (1= <20mins;2= 21-30mins;3=31-40mins; 4= 41-50mins;5=51-60mins; 6>60mins)

Graft size:

FOLLOW UP

Vision (1=6/6 - 6/12; 2=6/18 - 6/36; 3=< 6/36)

	RE	LE
Unaided		
Pin-hole		
Spectacles		

Refraction at 6 weeks

	RE				LE			
	Sphere	Cylinder	Axis	Vision	Sphere	Cylinder	Axis	Vision
Distance								
Near								

	1st op. day	**1st week**	**6th week**	**3rd month**
• Pain 1=absent; 2=mild; 3=moderate; 4=severe	☐	☐	☐	☐
• Foreign body sensation 1=absent; 2=mild; 3=moderate; 4=severe	☐	☐	☐	☐
• Lacrimation 1=absent; 2=mild; 3=moderate; 4=severe	☐	☐	☐	☐
• Discomfort during blinking 1=absent; 2=mild; 3=moderate; 4=severe	☐	☐	☐	☐
• Haemorrhage 1= present; 2=absent	☐	☐	☐	☐
• Displacement of graft 1=present; 2=absent	☐	☐	☐	☐
• Overall appearance of the eye 1=red; 2=quiet	☐	☐	☐	☐

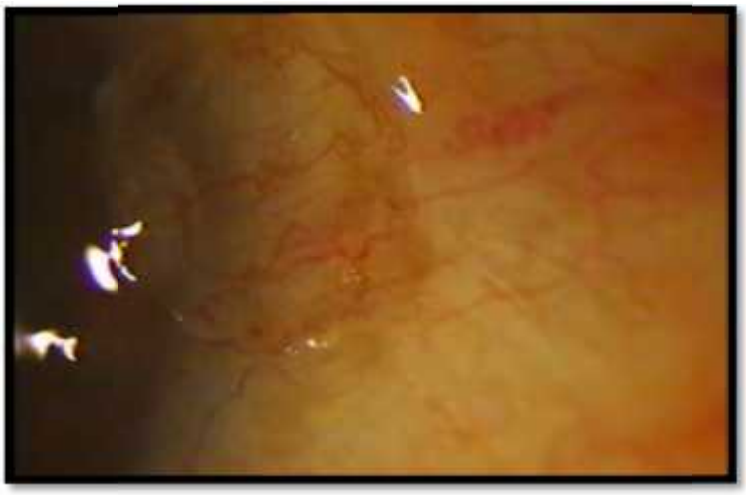
Other findings(if any):

ANNEXURE III – PHOTOGRAPHS

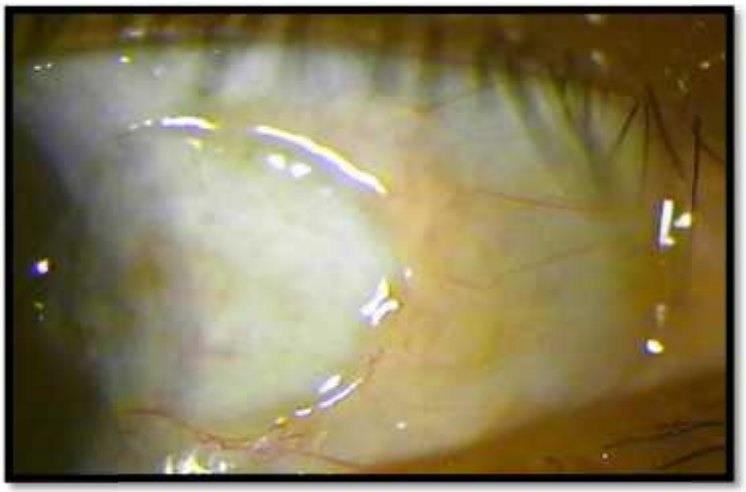
Instruments for conjunctival autograft with suture

Instruments for conjunctival autograft with autologus blood

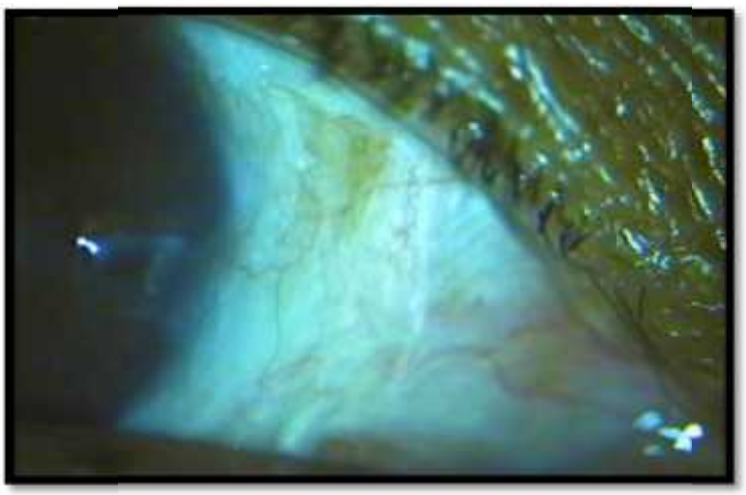
POST OPERATIVE PHOTOGRAPHS (1ST DAY, 6 WEEKS, 3 MONTHS) OF CONJUNCTIVAL AUTOGRAFT WITH AUTOLOGUS BLOOD



Post op. day 1



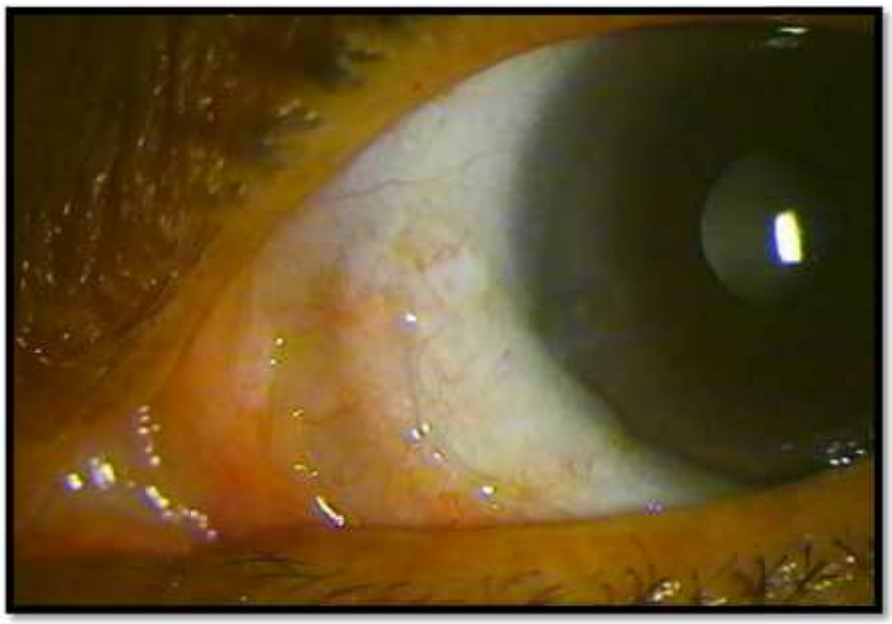
Post op. day 6 weeks



Post op. day 3 months

POST OPERATIVE PHOTOGRAPHS (1ST DAY, 3 MONTHS) OF CONJUNCTIVAL AUTOGRAFT WITH 8-0 VICRYL SUTURE.

Post op day 1



Post op day 3 months

"DOUBLE HEADED PTERYGIUM" PRE OPERATIVE AND POST OPERATIVE PHOTOGRAPHS.

Pre op

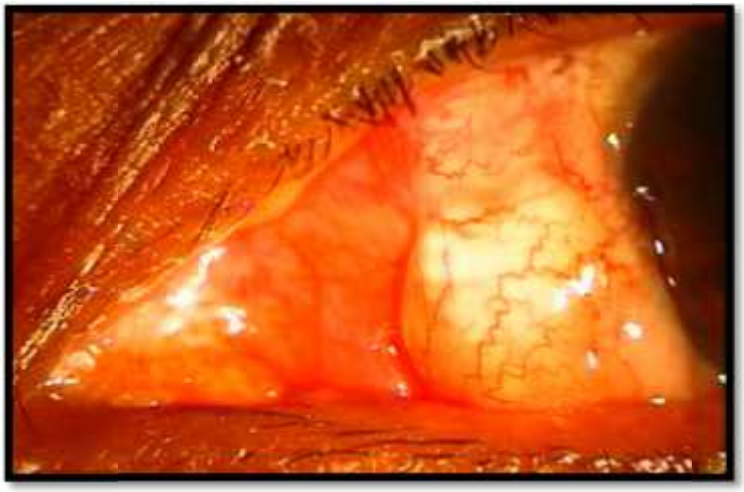
Post op. day 1

Post op. day 6 weeks

Complications

Conjunctival cyst at donor site

Sub graft hemorrhage



Graft edema

ANNEXURE-V

KEY TO MASTER CHART

M - Male

F - Female

L - Left

R - Right

NO - Nebular Opacity

MO - Macular Opacity

SCH - Subconjunctival hemorrhage

GE - Graft edema

GB - Graft Blanching

GC - Graft congestion

GR - Graft Retraction

GW - Graft wrinkling

SGH - Sub graft hemorrhage