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"A Comparative Study Of The Surgical Outcome Of Pterygium Surgery By Conjunctival Autografting With Sutures Vs. With Fibrin Glue At A Tertiary Care Centre"

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ABSTRACT
Introduction: Conjunctival autografting after pterygium excision is associated with very low rates of recurrence and complications and hence a preferred technique worldwide. Grafts are commonly secured with fibrin glue or by suturing with 10-0 nylon based on the availability and preference of the surgeon.
Materials and Methods: A prospective study of 90 patients that undergo Pterygium surgery with conjunctival autografting in which graft is secured with the use of Fibrin glue (Group- A) or with 10-0 nylon sutures (Group-B) as per patient's choice and affordability were assessed. The study was IEC-approved and conducted at Vilasrao Deshmukh Govt Medical College, Latur. Patients were assessed on postoperative day 1, 7 and 40 and the results were analyzed after applying appropriate statistical tests.
Results: In present study most of the study participants were seen between 41-50 years of age group. Mean age of the study participants in group-A is 46.13±13.70 years and for group-B is 55.56±14.12 years. In both the groups equal number of males (42.22%) and females (57.78%) study participants were observed. In Group-A majority of the study participants (71.11%) were from Urban areas and in Group-B majority of the study participants (64.44%) were from rural areas. Left eye was more commonly involved. The difference between the median operative time shows statistical significance between Group A and Group B (p<0.0001). On Postoperative Day (POD) 1, in Group A 20% of cases were observed with 1 score on the watering scale and in Group B 53.33% of cases were observed having a score of 1 on watering scale, which was statistically significant difference.(p<0.001*) On POD 1, in Group A pain score 1 was present in 8.89% of cases whereas 35.56% of cases were seen having pain score 1 in Group B. Statistically difference was observed between the two groups (p=0.002*). On POD 7 in Group B 13.33% of cases were seen with 1 score on the Watering scale. On POD 7 in group B only 2.22% of cases were seen having pain. On POD 40, all the cases in both groups showed negative results on the Photophobia scale, Watering scale, and Pain scale.*
Conclusion: CAG secured with fibrin glue are safe, cost -effective, comfortable for the patients and time saving for surgeons in rural settings with high surgical burden of patients presenting with pterygium.
KEYWORDS: *Pterygium, Conjunctiva, Autografting, Surgical outcome, Operative time.*

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A pterygium (plural Pterygia) is elastotic degeneration followed by a triangular fibrovascular sub epithelial ingrowth of bulbar conjunctival tissue over the limbus onto the cornea. (1) Pterygia can develop on the nasal and/or temporal limbus and can affect either or both eyes. Pterygia can range from minor, atrophic quiescent lesions to big, aggressive, rapidly expanding fibrovascular lesions that can deform the corneal topography and, in advanced cases, obscure the cornea's optical centre.(2,3)

Pterygium is more prevalent in hot, dry, windy, dusty, and smoky conditions, as well as those with higher UV exposure. There are many theories that offer etiological details about pterygium. The currently acknowledged aetiology of this illness is ultraviolet light-induced disruption to the limbal stem cell barrier with subsequent conjunctivalization of the cornea.(3–5)

Conjunctival autografting after pterygium excision is associated with very low rates of recurrence and complications and hence a preferred technique. (6,7) Pterygium excision followed by grafting is shown to have lesser chances of recurrence and post-operative discomfort.(6–8) Grafts commonly used are conjunctival autograft harvested from superior or supero-temporal limbus and amniotic membrane grafts.

The use of fibrin glue during pterygium surgery was first described by Cohen and McDonald in 1993. (9) Glue has two components: one consists of Fibrinogen mixed with Factor XIII and Aprotinin. The other component is a Thrombin-CaCl2 solution. All components are prepared from banked and well controlled human blood. Equal amounts of the components are mixed. Through the action of Thrombin, Fibrinopeptides are split to Fibrin monomers. These monomers aggregate by cross linking, resulting in a Fibrin clot. Thrombin concentration can be varied to regulate the speed of coagulation.(10)

The study aims at comparing the practical aspects of the two techniques i.e., conjunctival autografting secured with fibrin glue and sutures and to assess the two techniques on basis on operative time, post-operative redness, discomfort (pain) and graft health. Both techniques are comparable in terms of cost effectiveness, fibrin glue being a bit on the costlier side, and requires large number of cases to be operated in the same setting of day and time to cut costs.

I. Materials and method: -

It was a Prospective comparative study on 90 patients with clinically significant pterygium selected through simple random sampling undergoing pterygium surgery with conjunctival autografting in which graft was secured with 10-0 nylon sutures OR with use of fibrin glue as per patients' choice and affordability. The choice to opt for suture or glue was left to patient and they were allotted to group A (Fibrin glue) and B (10-0 nylon suture) accordingly. The patients in both groups were operated by the same surgeon under similar operating conditions. The study was approved by Institutional Ethical Committee. (Ref:146/2019)

Inclusion criteria:

1) Patients willing to be included in the study.
2) Age: 20-80.
3) Sex- male/female/unspecified.
4) All cases of pterygium (nasal/temporal).
5) All Pterygia encroaching on the cornea more than 1mm.
6) All Pterygia with complaints of foreign body sensation, watering

Exclusion criteria:

1) Inflamed Pterygia.
2) Recurrent Pterygia.
3) Pterygia with other ocular surface co morbidities like ankyloblepharon /Symblepharon.
4) Regressive pterygium.
5) Early/small pterygium which have not encroached the cornea.
6) History of hypersensitivity to human blood products.
7) Pterygium encroaching the pupillary area.
8) Individual not willing to be a part of the study.

Written informed consent was taken from all the patients and were examined pre -operatively thoroughly. Examination includes sociodemographic details, general and systemic examination and a detailed ophthalmic examination of lid, conjunctiva, cornea, anterior chamber, iris, pupil, lens, visual acuity and extraocular movements (EOM). All Pterygia encroaching on the cornea more than 1 mm was used as diagnostic criteria for the present study.(11) All the patients underwent baseline investigations required for pre anaesthesia fitness. Pre- anaesthesia clearance and physician fitness was taken as required.

Surgical Procedure: - All the procedure were performed under Peribulbar anaesthesia. Parts were painted and draped. The pterygium was cut at the neck and the head reflected to the cornea. The head was then peeled off the cornea, removed in pieces wherever possible. Remaining pterygium tissue tags if left on the cornea were peeled with the help of Lims' forceps and sharp dissection by Crescent blade was done only if needed. The pterygium tissue under the nasal or temporal conjunctiva was sharply and bluntly dissected off the conjunctiva above and sclera underneath. It was then pulled and cut boldly with Conjunctival scissors. Tenon's tissue was not cut beyond the pterygium tissue. Measurement of the defect left was taken and a conjunctival graft 1 mm larger than the defect was harvested. The graft was taken free from Tenon's and care was taken not to cause buttonholing of the graft. The defect bed was mopped free of any blood or remnant tissue. The graft was cut close to the limbus to include limbal stem cells in the graft tissue and the graft was oriented over defect with proper alignment of limbal side of the graft over the limbal edge of the defect. The different cases were then operated differently in both the groups. In GROUP A patients, a drop or two of the Component A of glue containing Fibrinogen, with Factor XIII and aprotinin was injected under the graft followed by another drop proximal to the previous of Component B which contains Fibrinogen and CaCl2. The formed mixtures were then lightly mixed after injecting component B with the cannula and excess of the mixture ironed out from

under the graft. The graft was also ironed by use of two arms of the McPherson's forceps and was made to lie flat over the defect with proper alignment of the limbal edge to the limbus. The excess graft tissue was tucked under the free conjunctiva edge and ironed well enabling adhesion/attachment. In GROUP B two sutures were taken initially at both ends of the graft along the limbus and then 4 to 5 sutures were taken on the edge distal to limbus. The sutures used were 10-0 Nylon interrupted sutures. The below procedures were followed similarly in both the groups. No bare area was left. No glue was used, nor any sutures taken over the donor site. The conjunctiva was just pulled and ironed trying to press it against the defect superiorly i.e., over the donor site. No adjunctive therapy was used after pterygium excision. Eye padding was done after instilling antibiotic + steroid eye ointment and was kept overnight. Total time required for the procedure was recorded from the first nick over the pterygium neck till securing the eye bandage. Any deviation in the usual course intra operatively was noted and those cases were excluded to ensure comparability.

Patients underwent detailed ophthalmic examination along with assessment on Pain scale, Photophobia scale, Watering scale and the graft health were assessed on Post-Operative Day 1 (POD-1). Findings were noted and then patients were discharged. All the patients were discharged postoperatively on Moxifloxacin + dexamethasone eye drops 6 times a day tapered over 1 week, Carboxymethylcellulose 0.5% eye drop 6 times a day till POD 40. Dark goggles were given, and patients instructed to wear them till POD 40. Patients were followed up on POD -7 and 40; detailed ophthalmic examination along with assessment on Pain scale, Photophobia scale, Watering scale and the graft health were assessed.

Following grading system were used during the follow up period for analysing the outcomes.
A) Grading of inflammation- Grade 0: No dilated corkscrew vessel in graft, Grade 1: 1 bright red, dilated corkscrew vessel crossing the graft bed margin, Grade 2: 2 bright red dilated corkscrew vessels crossing the graft bed margin, Grade 3: 3 bright red dilated corkscrew vessels crossing the graft bed margin, Grade 4: ≥3 bright red dilated corkscrew vessels crossing the graft bed margin. (9,12)
B) Grading of subconjunctival haemorrhage: Grade 0- none, Grade 1- ≤25% of size of the graft, Grade 2 - ≤50% of size of the graft, Grade 3- ≤75 of size of graft, Grade 4- Haemorrhage involving the entire graft.(9,12)
C) Grading their symptoms (pain, photophobia, and watering) on a scale
(Pain grade 0: no pain grade 1: pain on movement grade 2: pain at rest)
(Photophobia grade 0: no photophobia grade 1: mild grade 2: severe)
(Watering grade 0: no watering grade 1: outdoors in wind grade 2: indoors).(13)

Statistical Analysis

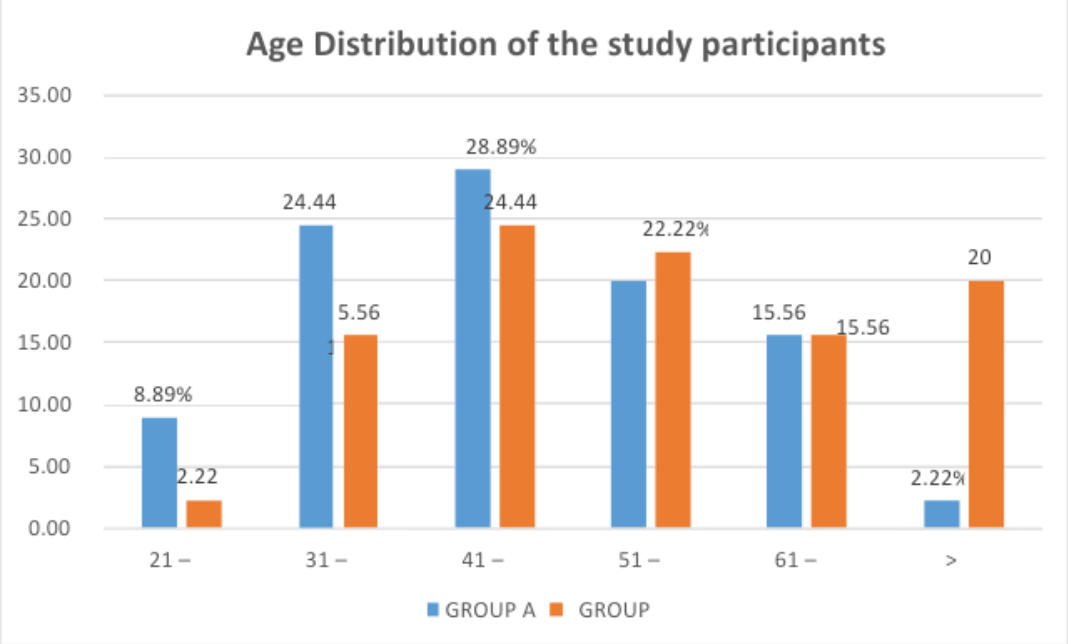
Data was entered in Microsoft Excel 2016. Data analysis was conducted with both Microsoft Office and Statistical Package for Social Sciences (SPSS) version 23. For Quantitative data, the normality of data was checked. If found normally distributed, data was described by using mean and standard deviation. For data not found normally distributed, median and interquartile range were used.

All the categorical variables have been described using frequencies and percentages. Tests of significance were applied at a 95% confidence interval. Chi-square test and Fisher Exact test, as applicable, have been used for comparisons of categorical variables and the *Mann-Whitney U Test* was used for comparison of median. A p-value of less than 0.05 has been considered significant.

II. Results:

In present study most of the study participants were seen between 41-50 years of age group. Mean age of the study participants in group-A is 46.13±13.70 years and for group-B is 55.56±14.12 years. In both the groups equal number of males (42.22%) and females (57.78%) study participants were observed. In Group-A majority of the study participants (71.11%) were from Urban areas and in Group-B majority of the study participants (64.44%) were from rural areas. Left eye was more commonly involved organ. In Group A 53.33% of study participants were seen with the left eye affected and 46.67% of study participants have seen with the Right eye affected whereas in group-B 60% of study participants were seen with left eye affected and 40% study participants had Right eye affected. (Table:1)

Figure:1- Age Distribution of the study participants.



In the present study in Group A 35.56% of each study participant were diagnosed as Be N Pterygium, Le N Pterygium respectively, 28.89% of study participants were diagnosed as Re N Pterygium whereas in Group B 40% of study participants were diagnosed as Be N Pterygium, 31.11% study participants with Re N Pterygium, 24.44% study participants of Le N Pterygium and 2.22% each study participants were diagnosed as Re N Le T Pterygium and Re T Pterygium respectively. The operative time in the present study does not follow normal distribution so median operative time with inter-quartile range (IQR) was calculated. Median operative time (IQR) was 14 (3) minutes and 26(4) minutes respectively in Group-A and Group-B. Median operative time was compared by using the *Mann-Whitney U Test* for both groups. A statistically significant difference was observed in the median operative time between both groups. ($p<0.0001$*) (Table-2)

Table :1- Demographic data of patients in the fibrin glue and suture group:

Parameters		Group-A (n=45)		Group -B (n=45)	
		Number	Percentage (%)	Number	Percentage (%)
Age (Mean ± S.D)		46.13±13.70		55.56±14.12	
Gender	Male	19	42.2	19	42.2
	Female	26	57.8	26	57.8
Residential area	Urban	32	71.1	16	35.5
	Rural	13	28.9	29	64.5
Eye Affected	Left	24	53.3	27	60.0
	Right	21	46.7	18	40.0
Diagnosis	Be N Pterygium	16	35.6	18	40.0
	Le N Pterygium	16	35.6	11	24.4
	Re N Pterygium	13	28.8	14	31.2
	Re N Le T Pterygium	0	0.0	1	2.2
	Re T Pterygium	0	0.0	1	2.2

On Post-op Day 1, in Group A 8.9% of study participants were seen having graft hemorrhage whereas in Group B 11.1% of study participants were seen with graft hemorrhage. Statistically, no significant difference was observed between the two groups. On post-op day 7, 2.22% of study participants developed graft edema whereas in Group B 4.44% of study participants were seen with graft edema, and 2.225% of study participants were observed with donor site granuloma. (Table-3)

On Day 1 in present study in Group B 2.22% study participants were seen on Photophobia scale with score 1. On Day 1, in Group A 20% study participants were observed with watering scale score 1 and in Group B 53.33% study participants were observed having watering scale score 1. On comparing at watering scale on Day-1, a statistically significant difference was observed between the two groups (p=0.001). (Table-3)

Table2: Operative time

Parameter	Group A (n=45)	Group B (n=45)	p-Value*
Operative time Median (IQR)	14 (3)	26 (4)	<0.0001*

***p-value calculated by Mann Whitney U test.**

Table:3- Ocular manifestation associated with pterygium excision in the fibrin glue and suture group:

Parameters		Group A (n=45)	Percentage (%)	Group B (n=45)	Percentage (%)	p-value*
Post op Day-1	Graft hemorrhage	4	8.9	5	11.1	0.73
	Nil	41	91.1	40	88.9	
Post-op Day 7	Graft Edema	1	2.2	2	4.4	……..
	Donor site Granuloma	0	0.0	1	2.3	
	Nil	44	97.8	42	93.3	
Photophobia scale Day 1	Photophobia score 1	0	0	1	2.2	……
	No Photophobia	45	100	44	97.8	
Watering scale Day 1	Watering score 1	9	20.0	24	53.4	0.001*
	No watering	36	80.0	21	46.6	
Pain scale Day 1	Pain score 1	4	8.9	16	35.6	0.002*
	No Pain	41	91.1	29	64.4	
Watering scale Day 7	Watering score 1	0	0	6	13.3	……..
	No watering	45	100	39	86.7	
Pain Scale Day7	Pain score 1	0	0	1	2.2	…….
	No Pain	45	100	44	97.8	

On day 1, in Group A pain (score 1) was present in 8.9% of study participants whereas 35.6% of study participants were seen having pain (score 1) in Group B. On comparing at pain scale score on Day-1, a statistically significant difference was observed between the two groups (p=0.002*). On day 7 in Group B 13.3% of study participants were seen with score 1 on Watering scale. On Day 7 in group B only 2.2% of study participants were seen having pain score 1. On Day 40, all the study participants in both groups showed negative results on the Photophobia scale, Watering scale, and Pain scale. (Table-3)

III. Discussion:

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, lamellar keratoplasty and the use of fibrin glue.(6,14,15) All of these techniques involve the use of sutures or fibrin glue and are therefore vulnerable to associated complications. The presence of sutures may lead to prolonged wound healing and fibrosis.(16)

Complications such as pyogenic granuloma formation are easily treated; whereas others such as symblepharon formation, forniceal contracture, ocular motility restriction, diplopia, scleral necrosis and infection are much more difficult to manage and may be sight threatening.(16)

Uy et al (2005)(17) in their study concluded that out of 22 patients 59% were male and mean age of the study population was 45±20 years (range , 23-67 years). Moizuddin M.D (2018) (18) in their study they observed 52 females (74.2%) and 18 males (25.7%) with mean age (38.83±9.2 years and 38.88±6.5 years, respectively, age range from 20–60 years. Wadgaonkar, et al. (2017) (13)in their study 47.4 mean age was seen in Group A and 42.8years mean age was seen in group B. In Group A 48% were male cases and 52% were female cases where in Group B 52% were male cases and 48% were female cases.

In present study most of the cases were seen between 41-50 years of age group. Mean age of the study participants in group-A is 46.13±13.70 years and for group-B is 55.56±14.12 years. This was comparable with findings by Uy et al (2005) and Wadgaonkar et al (2017). In both the groups equal number of males (42.22%) and females (57.78%) study participants were observed. In Group A 28.89% cases had age between 41-50 years of age followed by 24.44% cases had age between 31-40 years, 20% cases had between 51-60, 15.56% cases had between 61-70, 8.89% cases had between 21-30 and 2.22% cases had age more than 70 years of age. In Group B 24.44% cases had age between 41-50 years of age, 22.22% cases had age between 51-60, 15.56% of cases each were seen having age between 31-40 and 61-70 years of age group, 20% cases had age more than 70 years and 2.22% cases were seen having age between 21-30 years of age. (Figure-1)

In the study by Wadgaonkar, et al. (2017)(13) in Group A 84% cases were seen from Rural area and 16% cases from Urban area where in group B 60% cases were from Rural area and 40% cases from Urban area. In present study in Group A 71.11% cases were Urban residence and 28.89% cases were from rural area where in Group B 64.44% cases were from rural area and 35.56% cases were from Urban area. In present study Left eye was most common involved. In Group A 53.33% cases were seen with left eye affected where 46.67% cases were seen with Right eye affected where in group B 60% cases were seen with left eye affected and 40% cases had Right eye affected. In present study in Group A 35.56% each case were diagnosed as Be N Pterygium, Le N Pterygium respectively, 28.89% cases were diagnosed as Re N Pterygium. In Group B 40% cases were diagnosed as Be N Pterygium, 31.11% cases with Re N Pterygium, 24.44% cases of Le N Pterygium and 2.22% each case were diagnosed as Re N Le T Pterygium and Re T Pterygium respectively. Similar findings were observed in the study by Uy et al (2005)(17) in which all the pterygia were nasally located.

In study conducted by Wadgaonkar, et al. (2017),(13) average operative time was 15.76 min (range, 12–20 min) in the group B and 33.56 min (range, 30–45 min) in the group A. The operating time was significantly less in the glue group versus suture group (P = 0). The operative time in the present study does not follow normal distribution so median operative time with inter-quartile range (IQR) was calculated. Median operative time (IQR) was 14 (3) minutes and 26(4) minutes respectively in Group-A and Group-B. Difference between the mean operative time shows statistically significance between the Group A and Group B. These results were comparable with the findings by Cha et al (2011)(19) in which the operation duration was 27.71 (5.22) minutes in the fibrin glue group ,which was remarkably shorter than that in suture group i.e. 43.30 (8.18) minutes, p =0.000.

In present study at Post op Day 1, in Group A 8.89% cases were seen having graft haemorrhage where in Group B 11.11% cases were seen with graft haemorrhage. Statistically no significant was observed between two groups. At post op day 7, 2.22% cases developed graft edema where in Group B 4.44% cases were seen with graft edema, 2.225 cases were observed with donor site granuloma. Statistically no significant was observed between two groups. (Table-3)

In study conducted by Moizuddin M.D. (2018),(18) 5.71% cases were seen with graft dehiscence, 2.85% cases with granuloma and 2.85% cases with Graft edema which is comparable with our study. Wadgaonkar, et al. (2017) (13) observed all the four complaint scores at the 1st and 7th days were significantly lower in fibrin group for chemosis and photophobia (P = 0.001) for pain and watering (P < 0.001). There were 2 episodes of subconjunctival haemorrhage in the group A (8%) and none in group B. On day 1 in Group A 18 cases were seen having 1 and 2 score respectively on Watering scale, 10 cases were seen having 1 score at Photophobia scale and 24 cases were observed having pain score 1 and 2 on pain scale where in Group B only 3 cases were seen with 1 score on Photophobia scale. On Day 14 no case was observed having watering scale, photophobia scale and pain scale.

Similarly in the study by Uy et al (2005)(17) they observed that the subjective symptoms of pain, foreign body sensation, tearing and discomfort were fewer and disappeared more rapidly in the glue group than the suture group. The intensity of these symptoms was significantly lower in the glue group than suture groups on all follow up days (p<0.001). All the patients treated with glue were asymptomatic after 2 weeks.

In present study, in Group A 11.11% cases were seen with graft haemorrhage, 2.22% cases with Graft edema where in Group B 11.11% cases were seen with graft haemorrhage, 4.44% cases with graft edema and 2.22% cases with donor site granuloma. Statistically no significant was observed between two groups. On Day 1 in present study in Group B 2.22% cases were seen on Photophobia scale with score 1. Statistically no significant was observed between two groups. On Day 1, in Group A 20% cases were observed with watering scale score 1 and in Group B 53.33% cases were observed having watering scale with score 1. Statistically difference was observed between two groups (p=0.001). On day 1, in Group A pain was present in 8.89% cases where 35.56% cases were seen having pain in Group B. Statistically difference was observed between two groups (p=0.002*). On day 7 in Group B 13.33% cases were seen on Watering scale with score-1. On Day 7 in group B only 2.22% cases were seen having pain. Statistically no difference was observed between two groups.

On Day 40, all the cases in both groups showed negative results on Photophobia scale, Watering scale and Pain scale.

IV. Conclusion:

Pterygium is a very common eye disorder in rural parts of India owing to prolonged sun exposure and outdoor farming activities. Pterygium excision and Conjunctival autografting (CAG) is a safe, time tested and reliable surgical technique from ages with least chances of recurrence.

CAG is secured with sutures in rural poor resource settings due to its cost-effectiveness. In this study it is proven that CAG secured with fibrin glue are safe, cost -effective, comfortable for the patients and time saving for surgeons in rural settings with high surgical burden of patients presenting with pterygium.

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Conflict of interest: None declared.

Ethical approval: The study was approved by the Institutional Ethics Committee. (Ref:146/2019)

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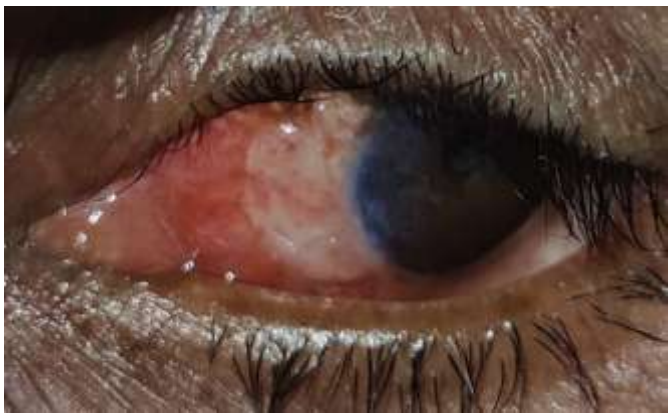
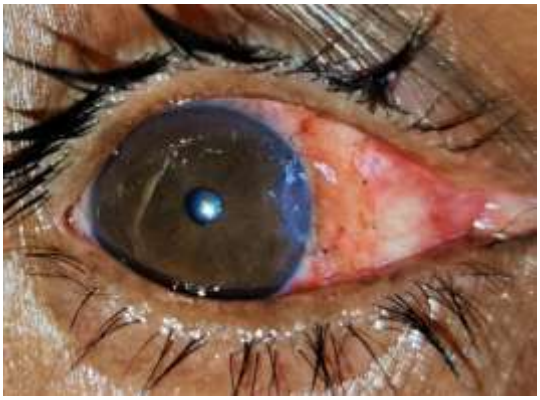
PHOTOGRAPH -1: BILATERAL NASAL PTERYGIUM

PHOTOGRAPH -2: SUPERO - TEMPORAL CAG HARVESTING



PHOTOGRAPH -3: CAG WITH FIBRIN GLUE POST-OPERATIVELY AT DAY 1



PHOTOGRAPH -4: CAG WITH SUTURES POST-OPERATIVELY AT DAY 1