

Autologous fibrin glue versus suture for conjunctival autograft in primary pterygium: a randomized clinical trial

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Abstract

Purpose: To describe and compare the autologous fibrin glue versus traditional sutures for conjunctival graft attachment in patients undergoing primary pterygium excision surgery.

Method: Randomized clinical trial, including patients who underwent pterygium surgery with autologous conjunctival graft. According to randomization, a single-trained surgeon performed graft fixation with autologous glue or sutures. The glue was prepared immediately before the surgery, using the patient's blood components. Postoperative assessments were performed on days 1, 7, 21, 30 and 180. The study evaluated postoperative edema and pain, and complications. Mean surgical time was compared. Recurrence of the pterygium was assessed six months postoperatively.

Results: The study evaluated 61 eyes. Thirty-three eyes underwent pterygium surgery using the glue technique, and 28 underwent the traditional suture technique. Fifty-one patients (83.60%) had the graft successfully adhered to at the end of follow-up. Ten patients (10/33) lost their graft in the glue group, and only 69.70% of them had the graft present in the 4th week versus 100% of the patients in the suture group ($p = 0.001$). Pain scores were lower in the glue group, and clinical edema was significantly higher. There was no statistical difference in graft retraction. The presence of granuloma, necrosis and postoperative infection was not different.

Conclusion: Autologous fibrin glue is an available option for ACG fixation in particular contexts where fibrin glue is unavailable and it could offer advantages compared to sutures. Improvements in the autologous glue technique are necessary before widely applying it.

Introduction

Pterygium is an abnormal fibrovascular proliferation of the conjunctiva over the cornea in a triangular shape, varying local extension and depth [1, 2]. Its definitive treatment is the surgical excision [2, 3] and the autologous conjunctival graft (ACG) technique is the gold standard to reduce the rates of recurrence [1–4]. Commercially available fibrin glue has been used as a choice for fixation of the conjunctival graft due to its benefits such as shorter surgical time, less inflammation, minor discomfort, and a lower recurrence rate, maintaining the stability of the graft [4–6].

Fibrin glues are biological and biodegradable, produced through blood plasma derivatives that replicate the final stages of coagulation, in which the human fibrinogen solution is activated by thrombin (the two components of fibrin glue). [7–9] They are manufactured from human blood samples and bovine aprotinin. The processing of the plasma to produce these components can be done in a blood transfusion center - through the patient's own blood – or obtained from commercially available preparations [10–12]. Several studies show positive results in ocular surface surgeries with the commercially available fibrin glue [5, 13–17], however, few surgeons use autologous fibrin glue [18, 19]. Studies using pre-prepared autologous glue demonstrated graft adhesion and success rates comparable to groups that used conventional sutures, with lower recurrence rates, shorter operative time and similar

intra- and postoperative complication rates [19]. Other surgical specialties such as plastic surgery have routinely used a similar autologous fibrin glue (platelet-poor plasma) with satisfactory results associated with the prevention of hematomas and edema improvement in rhytidectomy [20]. The high cost, the risk of immune reaction to the product related to commercial glue, and the risk of infectious transmission are limiting factors for its use [2, 21, 22]. Therefore, the protocol for preparing the platelet-poor plasma solution is feasible to perform [23, 24] and the use of autologous biological glue would be an alternative with similar benefits.

Commercial fibrin glue is not available for all cases of pterygium surgery at Hospital de Clinicas de Porto Alegre and Santa Casa de Porto Alegre for monetary issues. With the use of glue from the patient's blood, in addition to the low cost of producing, patients could benefit from a postoperative period with minor discomfort when compared to sutures. The fibrin glue would cost R\$ 5 on average per patient *versus* the commercial fibrin glue (R\$ 490 per 2ml box).

Methods

Randomized clinical trial (RCT) included patients who underwent pterygium excision surgery with ACG from January 2019 to December 2019 at the Ophthalmology Service of the Santa Casa de Misericórdia Complex Porto Alegre/Brazil. Graft fixation was performed either with autologous glue or suture. The study included symptomatic patients with primary nasal pterygium aged 18 to 65, of both genders, whose surgical treatment was chosen. Exclusion criteria were: previous eye surgery, eye diseases that may interfere in the postoperative ocular inflammation evaluation (glaucoma or surface ocular disease), diabetic patients, and those who did not agree to collect blood for the preparation of autologous fibrin glue.

The study was carried out following the principles of the Helsinki Declaration, and informed written consent was obtained. The study was approved by the Health Research and Ethics Committee of the Hospital de Clínicas de Porto Alegre (CAAE 74246017000005327-) and registered on ClinicalTrials.gov (20170467).

Patients were randomized using randomization.com into two groups to the technique for ACG fixation: Group 1: patients enrolled to have autologous fibrin glue, and Group 2: patients enrolled to receive 10-mono nylon suture. The patients and the surgeon were aware of the surgical technique minutes before the procedure, informed by a team member.

Surgical technique:

All surgeries were performed by the same trained surgeon (C.C.). Intraoperatively, topical anesthesia was performed with 5.0 mg/mL proxymetacaine hydrochloride eye drops (Anestalcon® - Alcon, Brazil) and 2% subconjunctival lidocaine. The pterygium was dissected from the apex using a 15-scalpel. The pterygium body and the underlying fibrovascular tissues were delineated from the conjunctiva and removed. The tenon-free ACG was obtained from the superior bulbar conjunctiva. The ACG was immediately transferred

to the bare sclera with limbus-limbus orientation and fixed according to the randomization. For those randomized to group 1, graft fixation occurred by applying 0.1ml of autologous glue to the bare sclera. All grafts were fixed with four 10.0-mono nylon sutures when randomized to the suture group.

Glue preparation

The glue was prepared according to a modified protocol described by Almeida *et al.*[24]: Before the procedure, the nursing technician collected a 5ml patient's blood sample through peripheral venipuncture, using 4.5 ml tubes loaded under vacuum, in glass or silicone polypropylene, colorless, sterile and resistant to centrifugation, with 3.2% sodium citrate. The tubes were taken for processing close to the operating room by the responsible professional (other than the surgeon). The blood was centrifuged at 1800 rpm for 15 minutes to acquire three phases in different shades from top to bottom:

1. A lighter upper portion, platelet-poor plasma (PPP)
2. A slightly darker intermediate portion with a strong yellow colour, the platelet-rich plasma (PRP).
3. Dark hemolyzed blood that was not used.

The supernatant plasma (PPP) was aspirated with a 10ml syringe and 10%-calcium-gluconate was added at a 1:10 ratio five minutes before using the preparation. The glue was aspirated in a sterile 3ml syringe, and 0.1ml was applied to the bare sclera before fixing the conjunctival graft. The graft was positioned with the aid of surgical tweezers (McPherson) and spread out to avoid areas of irregularity. Extra glue was applied if there were unstuck areas. After a 5-minutes drying period, the lid retractors were removed, and the patient was asked to blink to test graft adherence and mobility. No surgical step was performed during the 5-minutes waiting.

Post-operative care:

Patients were released with an eye patch, instructions to not rub their eyes and to use eye drops containing an association of tobramycin 3ml/ml and dexamethasone 1mg/ml topical (Tobradex® - Alcon, Brazil) every 4 hours in the first week, tapered gradually over one month.

Preoperative and Postoperative Evaluations

The primary outcome was the success rate of graft attachment. The secondary outcomes were the difference among edema, pain and complications between groups, and the pterygium recurrence rate. A comprehensive medical and ocular history was obtained. A detailed ocular examination was performed preoperatively, and nasal pterygium was classified according to the grade: 1 (up to 2 mm over the cornea), 2 (2 to 4mm) or 3 (more than 4 mm). Intraoperatively, surgical time was recorded in minutes from the lid retractor insertion to removal. A second notation removed the 5-minutes-waiting for the glue to dry for the glue group. Two observers performed the postoperative evaluation: the first, not masked, assessed the patients at the 1st, 7th, and 21st postoperative days. On the 21st day, the sutures were removed. The second ophthalmologist, masked-examiner, performed the evaluations on the 30th day and 6-month postoperative. The parameters obtained through slit lamp analysis were:

- Presence of the graft.
- Partial graft detachment, measured in quadrants.
- Graft edema (1–4).
- Graft necrosis, characterized by the pallor of the grafted conjunctival tissue.
- Graft retraction, characterized as the removal of the graft edges with bare sclera exposure.
- Conjunctival granuloma.
- Presence of infection on the graft donor or recipient area, characterized by purulent secretion and conjunctival hyperemia edema and pain.
- Pain assessment (Visual scale 0–5).
- Pterygium recurrence was assessed at the 6-month visit, as the formation of a fibrovascular tissue growing over the cornea at the position of a previously excised pterygium, after a period free of the lesion.

The data were entered into Excel and then exported into SPSS v. 20.0 (SPSS / IBM, Inc., Chicago, IL, USA). Categorical variables were described by frequencies and percentages, and quantitative variables were described by means and standard deviations. The Kolmogorov-Smirnov test was used to evaluate the normality of the variables. Independent t-test was used to compare the edema and pain scores between groups. The Spearman's rho Correlation Coefficient was used to study the correlation between pterygium recurrence and postoperative outcomes. The level of statistical significance was set at $P < 0.05$.

Results

Sixty-four patients were included (Glue = 33; Suture = 31). After excluding the ones that did not complete the 6-month follow-up, the study analyzed 61 eyes of 61 patients. The mean age was 51.10 years (range 28–69), and most patients were male (36/61, 59%). Thirty-three (33/61; 54%) eyes underwent pterygium surgery with the glue technique, and 28 (46%) eyes underwent surgery with sutures. There were no significant differences in the demographic characteristics of the groups (Table 1).

Table 1
Baseline characteristics of patients undergoing Pterygium surgery

	Glue N, %	Suture N, %	P value
Total	33 (100)	28 (100)	
Gender, male	21 (63.6)	15 (53.6)	0.426 ^a
Age (y)	49.94 ± 11.18	52.46 ± 10.21	0.509 ^b
Eye, right	18 (54.5)	12 (42.9)	0.363 ^a
Pterygium grade	10 (30.3)	4 (14.3)	0.233 ^a
1	17 (51.5)	17 (60.7)	
2	6 (18.2)	5 (17.9)	
3	0 (0)	2 (7.1)	
4			
^a Chi-square			
^b Mann-Whitney U test			

The total Operating Room (OR) timing did not differ between groups (glue = 26.64 ± 6.12 minutes *versus* suture = 25.54 ± 5.16; $p = 0.456$). However, when the 5-minutes-drying time was taken out, the hands-on surgical time differed, with a mean time of 21.63 ± 6.12 minutes in the glue group *versus* 25.54 ± 5.16 minutes in the suture group (95% IC 0.967–6.831; $p = 0.010$).

Fifty-one patients (51/61; 83.60%) had a successfully attached graft by the end of follow-up. Ten patients (10/33) lost their graft in the glue group, and only 69.70% of the glue patients (23/33) had a graft attached at day 30 versus 100% of the patients in the suture group (95% CI 0.557–0.873; $p = 0.001$). Five (15.2%) and 4 (14.3) patients from the glue group lost their graft within the first 24h postop and the first-week interval, respectively. One patient (4.2%) lost the graft between the day-7 and day-21 postop visit.

Partial graft detachment was present in 3 and 5 patients at postop day 01 in the glue and suture group ($p = 0.282$), respectively, and all of them ended up with a graft re-attached at day 30. In the glue group, the most frequent region of graft displacement was superior-temporal (3/5, 60%), and in the suture group was temporal (2/3, 66.66%)

Graft retraction was present in at least one visit in 4 and 7 eyes in the glue and suture group ($p = 0.420$), respectively, and a single one of them lost their graft during the follow-up (glue group). Graft retraction was present in two and three eyes in the glue group at the postop days 7 and 21, and the same was observed in 4 and 7 patients in the suture group. The overall presence of graft retraction was not

statistically different between groups (Glue 8.3% *versus* suture 14.3% at day 7, $p = 0.503$; Glue 13% *versus* suture 25% at day 21, $p = 0.285$). The most frequent location of graft retraction was nasal (2/4, 50%) in the glue group and superior temporal (3/7, 42.9%) in the suture group ($p = 0.145$). The presence of granuloma, graft necrosis and postoperative infection was not different between groups (Table 2).

Table 2
 Postoperative evaluation following pterygium surgery during the first month and recurrence rate at 6-month post-op

	Glue 33 eyes	Suture 28 eyes	<i>P value</i>
Surgical total time (minutes)	26.64 ± 6.12	25.54 ± 5.16	0.456 ^c
Surgical adjusted time (min)	21.63 ± 6.12	25.54 ± 5.16	0.010 ^c
Presence of graft at day 30	23 (69.7)	28 (100)	0.001 ^a
Loss of graft	5 (15.2)	0	0.032 ^a
Day 1	4 (14.3)	0	0.038 ^a
Day 07	1 (4.2)	0	0.275 ^a
Day 21			
Partial graft displacement	3 (12)	5 (17.9)	0.552 ^a
Day 01	3 (11.1)	1 (3.6)	0.282 ^a
Day 07	0	4 (14.3)	0.054 ^a
Day 21	0	0	
Day 30	0	0	
Granuloma	3 (9.1)	2 (7.1)	0.782 ^a
Day 01	0	0	0.906
Day 07	0	0	0.782
Day 21	1 (3)	1 (3.6)	
Day 30	3 (9.1)	2 (7.1)	
Graft retraction	4 (16.0)	7 (25)	0.420 ^a
Day 01	0	0	0.503
Day 07	2 (8.3)	4 (14.3)	0.285
Day 21	3 (13)	7 (25)	0.898
Day 30	3 (13)	4 (14.3)	
Postoperative infection	0	0	
Necrosis	0	0	

^a Chi-square ^c Independent t-test

	Glue 33 eyes	Suture 28 eyes	<i>P value</i>
Recurrence	4 (12.1)	0	0.057 ^a
^a Chi-square ^c Independent t-test			

Graft edema was present in both groups, and it was very similar on postoperative day 1. Clinical edema grade was higher in the glue group at day 7 [2.29 + 0.80 in the glue group *versus* 1.75 + 0.645 in the suture group (95% CI 0.137–0.946; $p = 0.010$)] and it did not show significant differences later in the postop day 21 and 30 (graph 1).

Pain scores were lower in the glue group at all the follow-up visits. At day one, glue group scored 2.48 + 1.41 *versus* 2.71 + 0.897 in the suture group (95% CI -0.850 to 0.391; $p = 0.447$). The pain score showed a significant difference at postoperative day 07 and day 21 [day 07: 0.61 + 0.60 in the glue group *versus* 1.61 + 0.68 in the suture group (95% CI 0.669–1.33; $p < 0.001$); and day 21: 0.15 + 0.36 in the glue group and 0.43 + 0.57 in the suture group (95% CI 0.024–0.530; $p = 0.032$)]. The pain scores are shown on graph 2.

Figures one, two and three illustrate the usual aspect of attached ACG with autologous fibrin glue (AFG).

The recurrence rate was 6.6% (4/61). Four patients in the glue group presented pterygium recurrence and none of the patients in the suture group. Although the absence of recurrence in the suture group, this difference was not statistically significant. (95% CI 0.774–0.998; $p = 0.057$). The patients with recurrence were all male (95% CI 0.792–0.998; $p = 0.085$). Spearman's rho bivariate correlation showed a moderate correlation between recurrence and the absence of the graft at day-1 ($r = 0.404$; $p = 0.001$). The surgical technique ($r = 0.244$; $p = 0.058$) and the pterygium grade ($r = 0.098$; $p = 0.451$) were not statistically associated with the recurrence.

None of the patients with recurrence had displacement or retraction of the graft anytime. See Table 3 and 4 for the characteristics of eyes with recurrence.

Table 3
Factors associated to pterygium recurrence

	Recurrence N = 4	No recurrence N = 58	P value ^a
Technique, glue	4 (12.12)	29 (87.9)	<i>0.057</i>
Pterygium grade	2 (50)	12 (21.1)	<i>0.504</i>
1	1 (25)	33 (57.9)	
2	1 (25)	10 (17.5)	
3	0	2 (3.5)	
4			
Absence of graft at day 01	2 (50)	3 (5.3)	<i>0.002</i>
Absence of graft at day 7	2 (50)	7 (12.06)	<i>0.690</i>
Absence of graft at day 30	2 (50)	8 (14)	<i>0.060</i>
Graft displacement (<i>anytime</i>)	0	8 (15.7)	<i>0.543</i>
Retraction (<i>anytime</i>)	0	11 (21.9)	<i>0.466</i>
Granuloma (<i>anytime</i>)	0	5 (8.8)	<i>0.536</i>
^a Chi-square			

Table 4
Bivariate correlation on pterygium recurrence

	Correlation ^d	<i>p</i>
Surgical technique	0.244	<i>0.058</i>
Pterygium grade	0.098	<i>0.451</i>
Presence of graft at day 01	0.404	<i>0.001</i>
Presence of graft at day 30	0.240	<i>0.062</i>
Graft displacement	0.083	<i>0.552</i>
Graft retraction	0.101	<i>0.470</i>
^d Spearman's rho Correlation Coefficient		

Discussion

Pterygium is a prevalent condition in tropical countries. Although it is clear to diagnose and treat, recurrence is a persistent problem and can cause vision impairment complications, such as cornea opacity, astigmatism and high order aberrations. The aim for a perfect surgery technique encourages ophthalmologists to keep developing new strategies that could set the surgery into a less painful, more effective and feasible treatment.

Placing the graft with commercial fibrin glue has benefits already shown. Moreover, Rubin *et al.*[13] demonstrated a significant reduction in the surgical time when the fibrin glue was used (19.05 minutes) compared to the suture group (48.15 minutes), in addition to less discomfort and less ocular hyperemia in all post-operative visits. Although the total time would not differ between techniques, the hands-on surgical time was shorter, and the graft attachment maneuvers were faster and probably caused less graft touching with the glue technique. Moreover, surgery was performed by a single experienced surgeon in our study, and if we consider surgeons in training, sutures would probably take a significantly longer time.

We found lower rates of postoperative pain scores in the glue group, similar to the literature.[17, 19] Pain was lower and might be associated with lower manipulation and the absence of suture. Edema, however, was higher in the glue group. This might be related to the uniform edge sealing achieved with fibrin glue, preventing blood and fluid drainage underneath the graft. The findings are similar to the ones previous reported, with the glue group presenting significant lower rates of pain, discomfort, inflammation and subconjunctival hemorrhage.[18]

There was no statistical difference between the groups concerning the graft attachment rates, although we found greater numerical losses in the autologous glue group. Mahdy and Wagieh[18] prepared the autologous glue in a pathology laboratory, through centrifugation (similar to the one used in the present study), to adhesion the amniotic membrane and conjunctival graft, and they also had a numerically not significantly higher rate of graft loss. Despite those numbers, they considered the autologous glue safe. Similarly, the study by Boucher *et al.*[25] found higher rates of graft loss in the autologous glue (30%; $p = 0.020$), and they suggested that graft size and postoperative patch duration could be associated factors. In opposition to those, Alamdari *et al.*[19] performed an RCT comparing suture versus autologous fibrin glue (AFG) and found that the conjunctival autografts in both groups were successfully attached. There were, however, two differences reported by the Alamdari study compared to ours: surgeries were performed by two surgeons and the patients underwent peribulbar blockage anesthesia. Analogous, Kurian *et al.*[26], found no difference in the groups in terms of graft displacement. When comparing those two last studies, the autologous glue preparation may differ.[19, 26]

Regarding pterygium recurrence, the presence of the conjunctival autograft technique has been associated with lower recurrence rates, ranging from 9.2–13% [1, 5, 27–29]. Among the techniques of GAC fixation, the one associated with the least amount of recurrence is a matter of debate.[30] We did not find a statistically significant difference between groups. Still, it tends to occur more frequently in patients

whose graft was lost, mainly when the graft loss happened within the first week. One hypothesis is that eye movement might have played a role in early graft detachment and, consequently, pterygium recurrence. In the present study, we performed the surgery without peribulbar anesthesia, with might have allowed eye movements under the patch during the first 24 hours.

Another fact that must be considered is glue preparation, because there is no global consensus on the best way to provide it. Some use only the patient's autologous blood and place the graft on the bare sclera, with minimal cautery.[26, 31, 32] Other studies prepare an autologous fibrin glue: Almadari *et al.* [19] drew up the glue one week before the procedure through the peripheral blood centrifuging for 30 min and PPP separation, and the fibrinogen concentrate was prepared by the method of cryoprecipitate. Our study did not use the cryoprecipitate, and the patient's blood was collected right before the surgery. The time before surgery for handling and preparing the autologous fibrin glue could have negative implications for the practice of this technique. There was neither graft loss nor recurrence in the AFG group in the Alamdari study, and those are the main differences we found, besides more prolonged topical corticosteroids for their patients.

Even though the study is an RCT, we recognize the limitations involving the number of patients and the absence of different glue techniques. Topical anesthesia might also impact, but it represents the daily clinical practice in our service. Autologous fibrin glue is an available option for ACG fixation in particular contexts where fibrin glue is unavailable and it could offer advantages compared to suture, as the reduction of pain, necessity of suture removal and potentially less risk of infection or suture related granulomas. We recognize that larger studies are warranted to confirm these findings.

Therefore, the fibrin adhesive remains the mainstay for pterygium surgery until a more comprehensive recommendation on the use of autologous blood emerges. Improvements in the autologous glue technique are necessary before consistently applying it.

Declarations

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The authors declare that there is no conflict of interests.

Ethical issue: The study was conducted in accordance with the principles of Declaration of Helsinki 1996 version and Good Clinical Practice standards. The study protocol was approved by the ethical committee from both hospitals involved: Hospital de Clinicas de Porto Alegre and Santa Casa de Misericórdia de Porto Alegre. *Informed consent was obtained from all individual participants included in the study.*

The authors affirm that human research participants provided informed consent for publication of the images in Figures 1a, 2 and 3.

Author Contributions: Christine Cioba, Samara Barbara Marafon, Gabriela Maria Zambon, Alexandre Marcon and Diane Ruschel Marinho contributed to the study's conception and design. Material preparation and data collection were performed by Christine Cioba, Barbara Gastal Borges Fortes, Marcelo Fabris and Gustavo Michel. Data analysis were performed by Christine Cioba, Samara Barbara Marafon and Diane Ruschel Marinho. The first draft of the manuscript was written by Christine Cioba, Samara Barbara Marafon and Diane Marinho and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Graph

Graphs 1 and 2 are available in the Supplementary Files section

Figures

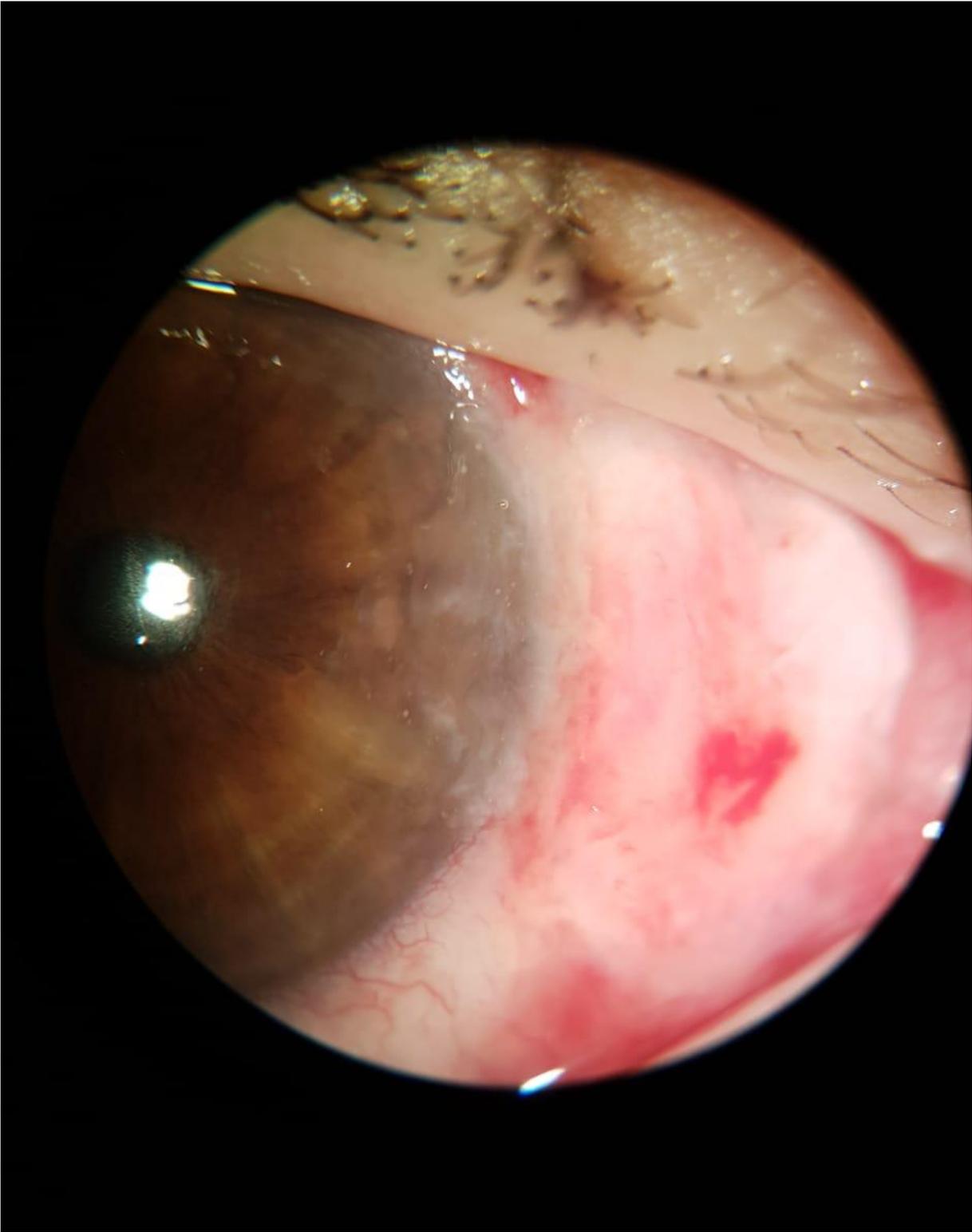


Figure 1

Postoperative day one after pterygium excision with ACG and autologous glue.

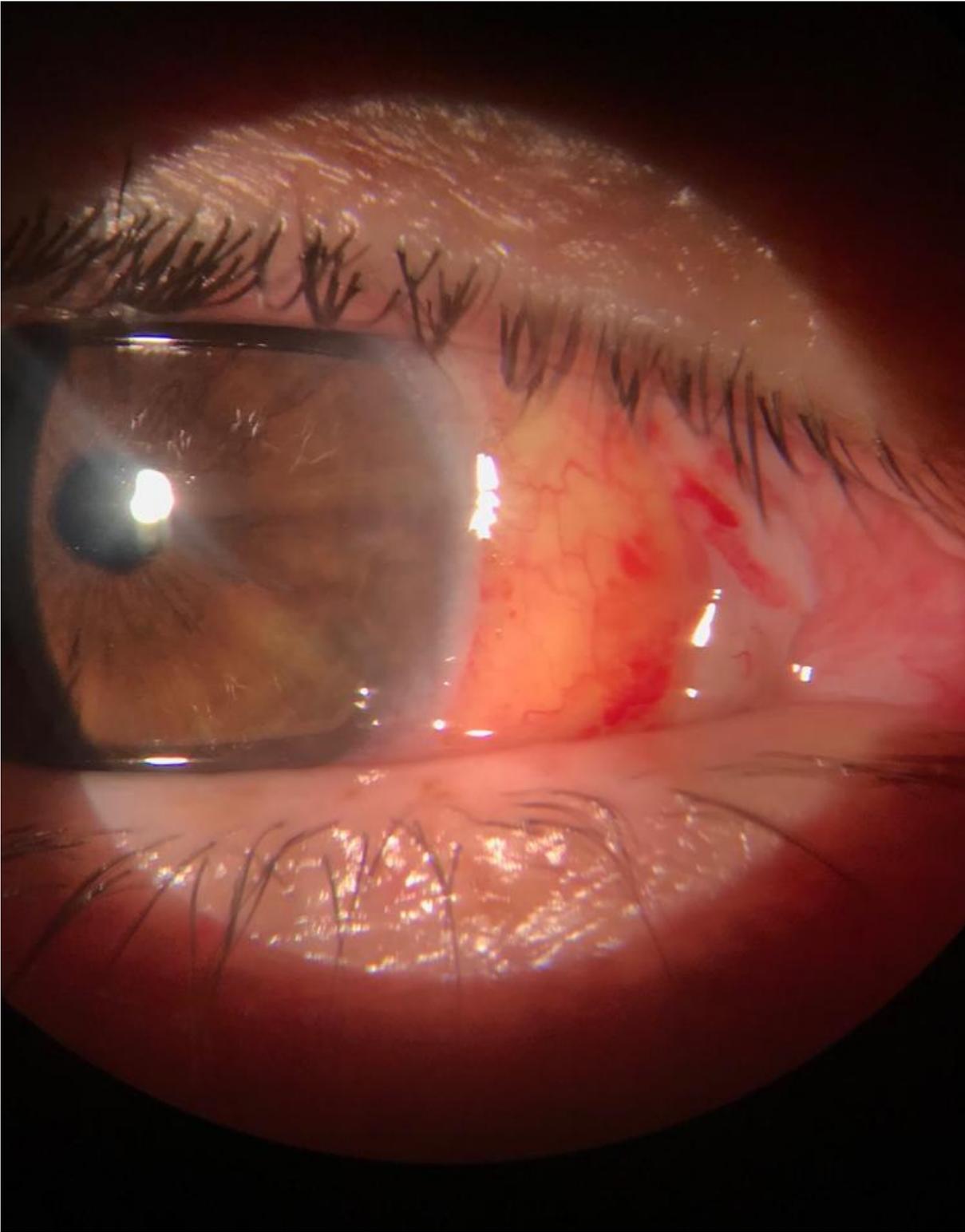


Figure 2

Postoperative day seven after pterygium excision with ACG and autologous glue.

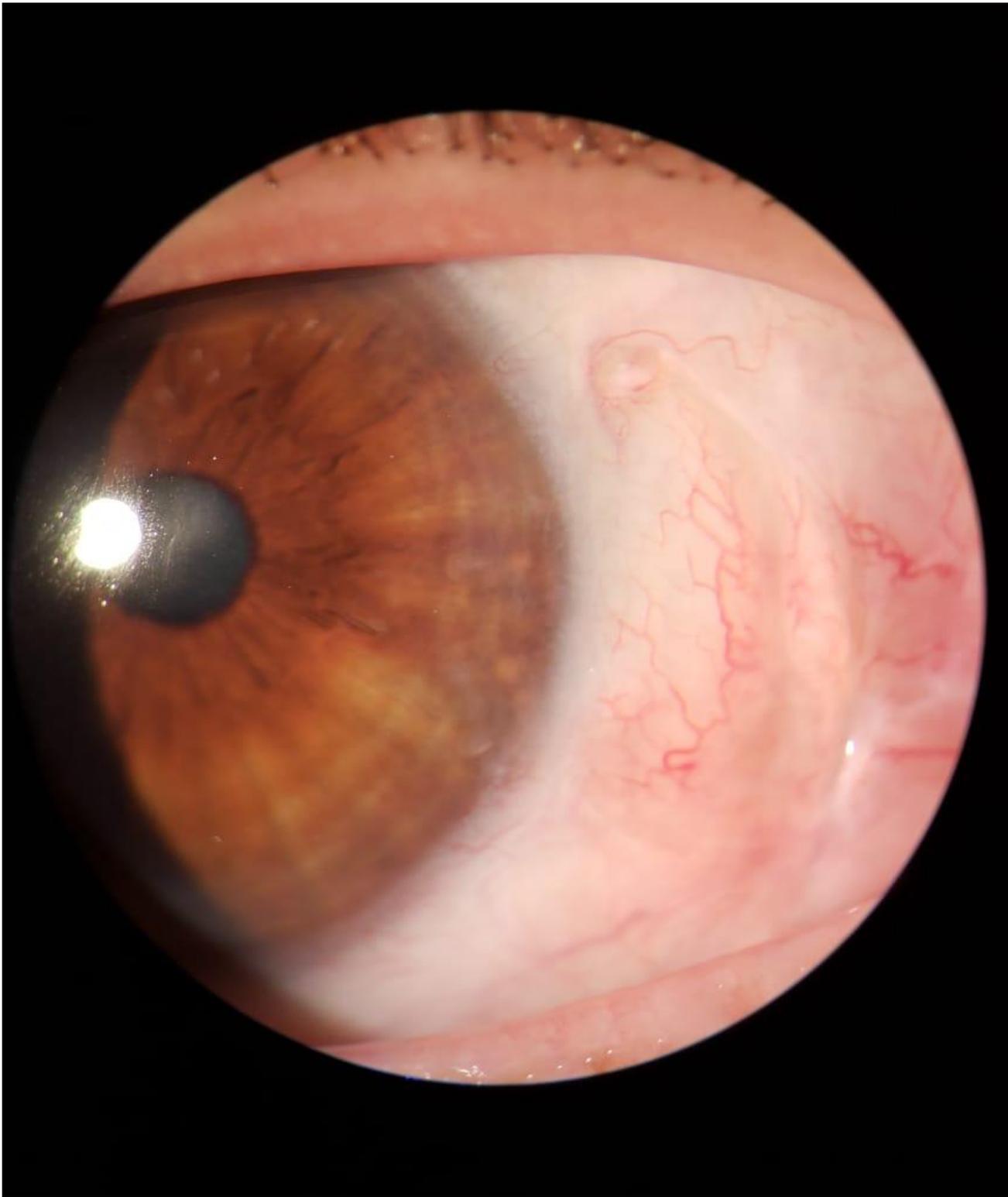


Figure 3

Thirty days postoperative after pterygium excision with ACG and autologous glue.

Supplementary Files

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- 1.png
- 2.png