

Usage of E-Polytetrafluoroethylene (E-PTFE) Membrane for Managing Trabeculectomy Flap-Related Over-Filtration due to Unavailability of Scleral Patch Graft during Nationwide Lockdown

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Abstract

Scleral flap tears during trabeculectomy are difficult to repair in a predictable fashion. Donor scleral flap reinforcements are commonly preferred for managing trabeculectomy flap-related over-filtration, leading to shallow anterior chamber (AC). Due to the advent of COVID-19 lockdown, especially in the initial phases, eye banking activities almost came to a standstill, with almost no corneal and/or scleral tissue retrievals. Hence, in this manuscript we have presented a mini case series with follow-up of two of our cases; where Gore-Tex (e-polytetrafluoroethylene) implant was used as an alternative to scleral patch graft, for managing trabeculectomy flap-related over-filtration, with their pros and cons. Though Gore-Tex implant stability in both cases were contentious, it still served the purpose of managing the flap-related over-filtration and subsequent shallow AC.

Index terms— Gore-Tex; Trabeculectomy flap tear; COVID-19 lockdown; Shallow anterior chamber; Over-filtration.

1 Introduction

While performing trabeculectomy, achieving an adequate scleral flap depth during dissection is mandatory to avoid tearing the flap in superficial dissections, or to avoid premature entry in deep dissections. [1] Scleral flaps are very difficult to repair in a predictable fashion and may need donor scleral flap reinforcement whenever necessary. After the COVID-19 outbreak, the eye banking activities almost came to a grinding halt. There were almost no corneal and/or scleral tissue retrievals from the hospitals and the community, especially during the first and second phase of nationwide lockdown. Hence, in this manuscript, we have presented two surgical scenarios, where Gore-Tex implant was used, instead of the traditional scleral patch graft. In both the trabeculectomy cases, the leak from trabeculectomy flap site was due to unexpected and atypical complications. Hence, to prevent aqueous fluid egress resulting in intra-operative shallow anterior chamber (AC) and post-operative shallow AC in Case 1 and Case 2 respectively, and due to unavailability of scleral patch graft, Gore-Tex implant was used as an alternative.

2 II.

Case Report W Case 1: An uncontrolled phakic primary open-angle glaucoma patient with bilateral glaucomatous optic atrophy, and on maximum tolerable medical therapy, with best corrected visual acuity (BCVA) of perception of light (PL) in right eye (OD) and no PL in left eye (OS), and intraocular pressure (IOP) of 24 mm Hg OD and 26 mm Hg OS, underwent trabeculectomy with Mitomycin -C for OD. Intra-operatively, the trabeculectomy surgery was uneventful till the flap suturing step, where suture track leak was noted after suturing, owing to the fragile nature of the scleral flap (Figure ?? a, b&c) in that patient, despite taking a good flap of adequate thickness, resulting in intra-operative shallow AC (Figure 2a) due to leakage from the flap. Though intra-operatively,

multiple sutures were anchored to secure the suture track leak, it was not successful in repairing the leakage. Hence, a 6mm x 3mm x 0.5mm Gore-Tex implant was sutured over the leakage area, by anchoring it with the adjacent underlying sclera, and the fornix-based conjunctival flap was closed (Figure ?? d, e&f). At the 1st week and 1st month post-operative follow-up, the Gore-Tex implant was stable with IOP in low teens, with a well-formed (Figure 2b, Figure ??a hence, only vigilant observation was advised. Between the 1st month and 3rd month, the patient was treated with tapering doses of topical steroids, antibiotics, and cycloplegics; and was on vigilant follow-up biweekly, with serial examinations of slit-lamp and Seidel test, for assessing the AC stability and integrity of the bleb. The patient has currently undergone 6 months of follow-up with good IOP control in low teens, BCVA of PL, good AC depth, good integrity of the bleb, and no extrusion of the implant.

3 III.

4 Discussion

In this manuscript, we have presented two of our cases with follow-up, where Gore-Tex implant was used as an alternative to scleral patch graft for managing trabeculectomy flap-related over-filtration. Both the flap leak complications were not iatrogenic and were inevitable; and the timing of the complication (i.e., during the initial phase of nationwide lockdown) didn't help either, as there were unavailability of cornea and/or scleral tissue retrievals, due to COVID-19. Hence, Gore-Tex implant was used to create a tamponade effect and manage the leaks, from the trabeculectomy flap tears. Both the surgeries were performed by the same surgeon with two years of experience in glaucoma surgery, post completion of his glaucoma surgical training.

The e-polytetrafluoroethylene (e-PTFE) membrane (Gore-Tex, W.L. Gore & Associates, Delaware, USA) has been widely used in preventing adhesion after cardiovascular and gynaecological surgeries. [1][2][3] In the ophthalmic field also, this membrane has been declared safe for usage in human eyes, almost two decades ago. But according to our knowledge, Gore-Tex has not been reported in the literature for the management of trabeculectomy flap tears. [4][5][6] Review of literature in PubMed revealed, e-PTFE implant can be used as an adjuvant for filtration modulation in trabeculectomy. [7,8] It also had good tolerability with lesser extrusion rates, when used as an adjuvant in trabeculectomy surgery and was advisable in reducing early hypotony-related complications. [7] It also contributed to attain medium-term IOP control, which is comparable to the low-dosage MMC. [7] Our study also reported good short-term IOP control with good AC formation, but unfortunately, there were signs of conjunctival thinning, adjacent to the implant in Case 1 and complete extrusion in Case 2. Nevertheless, despite signs of implant extrusion in Case 1 & extrusion of implant in Case 2, there were no signs of early or late-onset bleb leak and the conjunctiva was always intact throughout the post-operative period in both the cases. The possible reason for extrusion signs in Case 1 and extrusion of the implant in Case 2, could have been the thickness of the Gore-Tex implant used in this study, which was slightly higher than the ones reported in the literature.

This study highlights the fact that, the thickness of the Gore-Tex implant is very crucial in better stability and tolerability. In rabbit studies, 0.25 mm thickness implant was used and had fewer extrusions. [9] Similarly, Intra-operatively, there was an inadvertent flap tear, due to sudden jerky movement of the patient, during the AC entry step with the paracentesis blade, after the creation of the flap, causing a full-thickness flap tear near the limbus. The flap tear was managed effectively with sutures intra-operatively (Figure 5). Despite AC forming intra-operatively (Figure 5 d), the patient presented with BCVA of hand movements (HM), shallow AC, overfiltering large bleb, IOP of 4 mm Hg, and negative Seidel test (Figure 6) on post-operative day one; which was managed conservatively with aqueous suppressants, cycloplegics, and tight bandaging. Unfortunately, the AC didn't form until post-operative day 5, necessitating exploration of the flap area, once the other causes of shallow AC such as choroidal effusion, choroidal hemorrhage and malignant glaucoma were ruled out. Over-filtration was the primary suspect, owing to the intra-operative complication. Hence, exploration of the flap area was planned. On exploration, there was a leak noted from the flap tear area. Hence, Gore-Tex (Figure 7) implant was used to create a tamponade effect to seal the leak. A 6mm x 3mm x 0.5mm Gore-Tex implant was sutured over the leakage area, by anchoring it with the adjacent underlying sclera, and the fornix based conjunctival flap was closed. One week post repeat surgery, the Gore-Tex implant was stable with IOP in the low teens; BCVA improved to 20/60 OD with a wellformed AC. At the 2nd week follow-up, the implant was stable, but at the end of the 1st month follow-up, the implant extruded, exposing the site of the flap tear near the limbus, where there was a fistulous tract (Figure 8) formation between the AC and the sub-conjunctival region. However, the conjunctiva was intact with no bleb leak. The IOP control was within low teens with a wellformed AC throughout the post-operative period (Figure 9a). Between the 1st month and 3rd month, the patient was treated with tapering doses of topical steroids, antibiotics, and cycloplegics; with the patient being on vigilant follow-up biweekly, with serial examinations of slit-lamp and Seidel test for assessing the AC depth and the integrity of the bleb. The fistulous tract underwent subsequent fibrosis (Figure 9 b&c). The patient has currently undergone 12 months of follow-up with good IOP control in low teens, BCVA of 20/40, good AC depth, and good integrity of the bleb.

5 Medical Research

in another two-year randomised control trial in humans, 0.1 mm thick E-PTFE (Gore-Tex) implant was used, with or without low-dosage of mitomycin-C as an adjuvant in penetrating glaucoma surgery, with good stability and tolerability. [7] Whereas, 0.5 mm thickness implant was used in this study, which could have contributed to the weaker stability, migration, and extrusion. That is why in both cases, despite possibly an intact conjunctiva without bleb leak post-operatively, the Gore-Tex implant migrated in Case 1 and dislodged in Case 2.

a) Further modifications and suggestions for better stability and tolerability of Gore-Tex implant Gore-Tex implant can be placed by a technique (Figure 10) suggested by Cillino et al for better long term stability and follow-up, which is as follows; create two intra-scleral pockets with a bevel-up crescent knife, continue the scleral bed under the flap at its two vertical edges, with an extension of at least 0.5 mm and place the edges of the trimmed Gore-Tex into it. [7] Expanded e-PTFE membrane implant with multiple perforations are preferred compared to e-PTFE membrane implant without perforations, in view of augmenting fibrosis for better adhesion. [7,8] IV.

6 Conclusion

The advantages of using Gore-Tex implants are; it is safe and effective in creating a tamponade effect, in managing the over-filtration due to trabeculectomy flap-related complications. It can be considered as an alternative to scleral patch grafts, especially during COVID-19 times, when donor scleras may be unavailable, during the lockdown in certain areas. But in no way Gore-Tex can replace or substitute a scleral patch graft. We also suggest special modifications such as smaller thickness (< 0.25 mm) implants with multiple perforations in them, for better stability and tolerability. However, the long-term benefit of e-PTFE in managing these complications should be answered with larger randomised multi-centric clinical trials in a case-control format, with a longer follow-up period, with more number of cases.

7 Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

8 Financial support and sponsorship

9 Nil.

10 Conflicts of interest

There are no conflicts of interest.

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1 2

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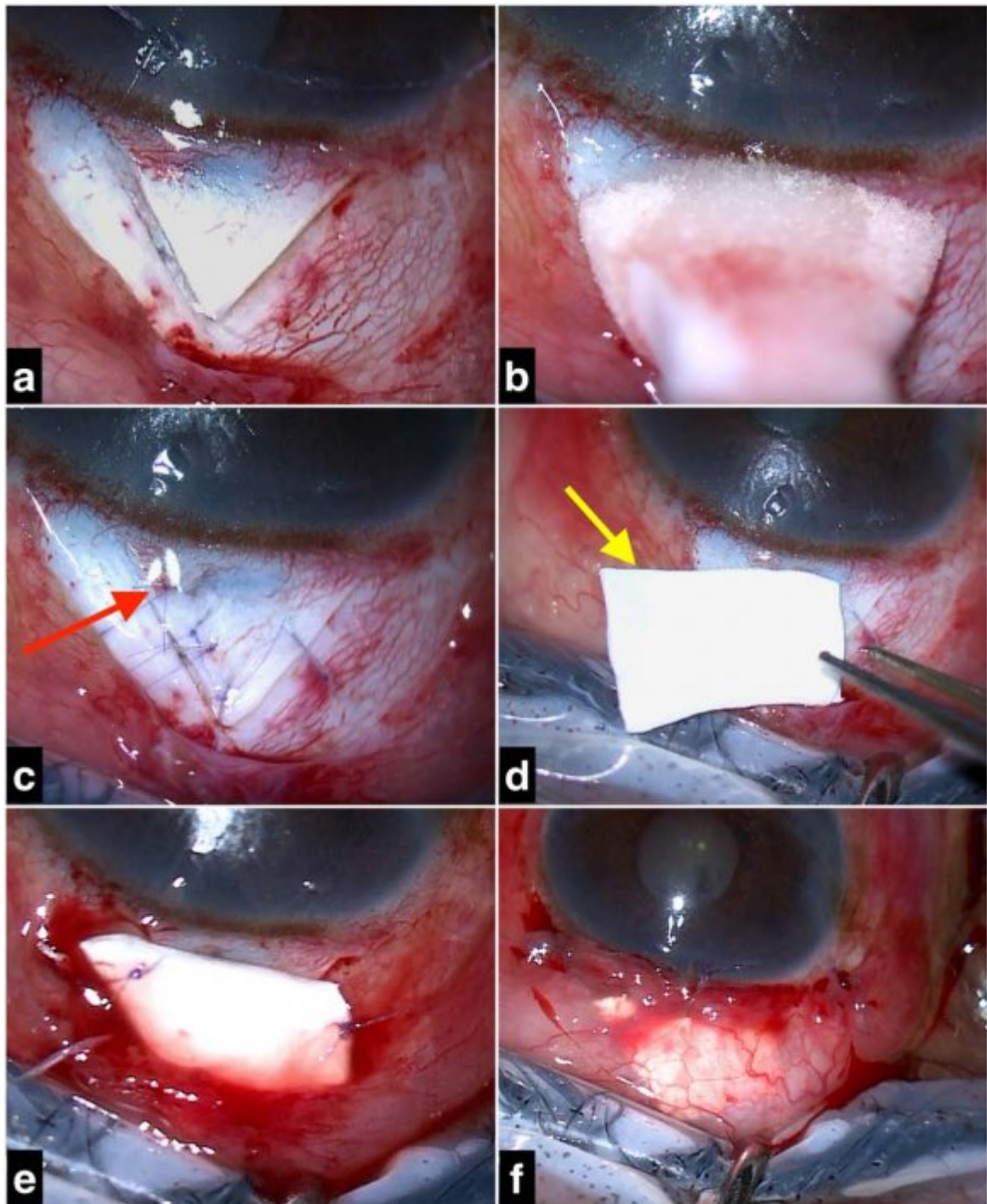


Figure 1:

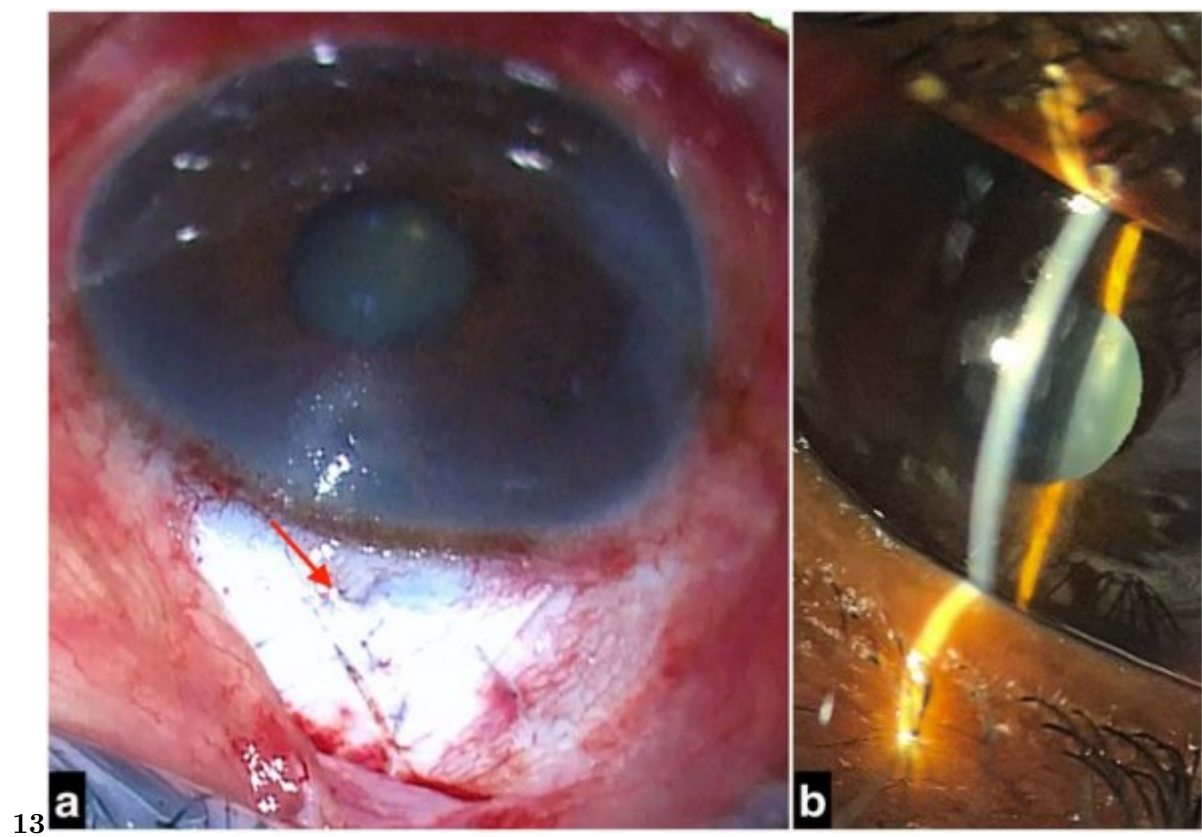


Figure 2: Figure 1 :Figure 3 :

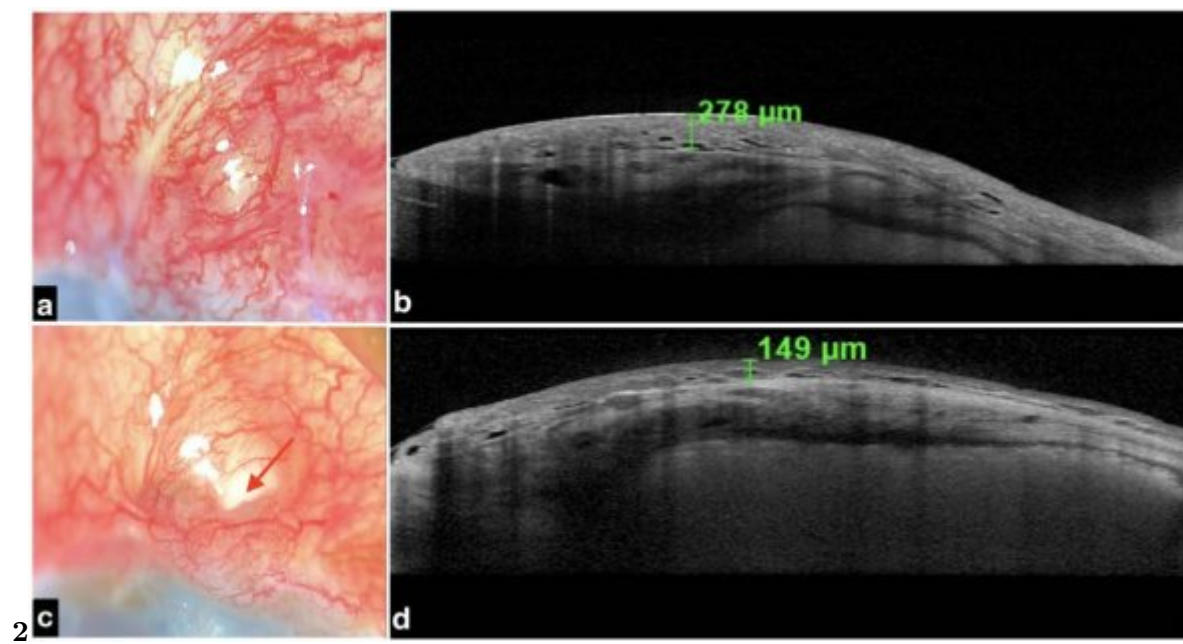


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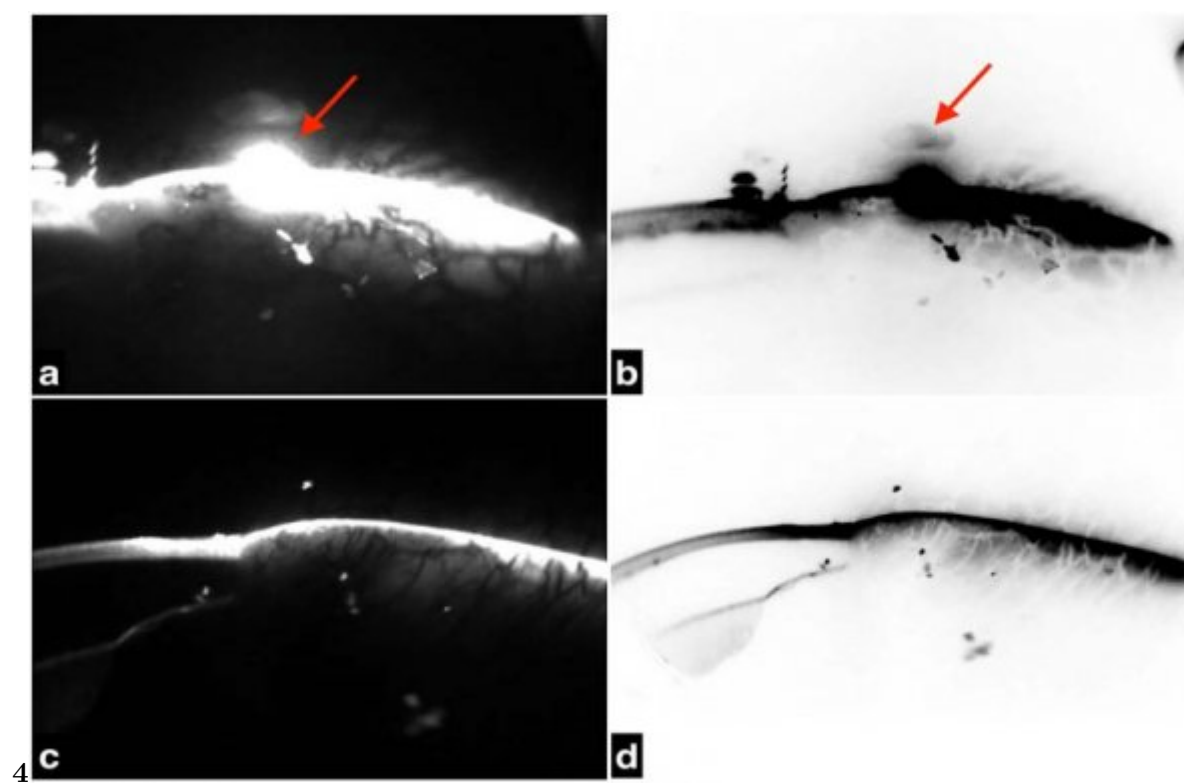


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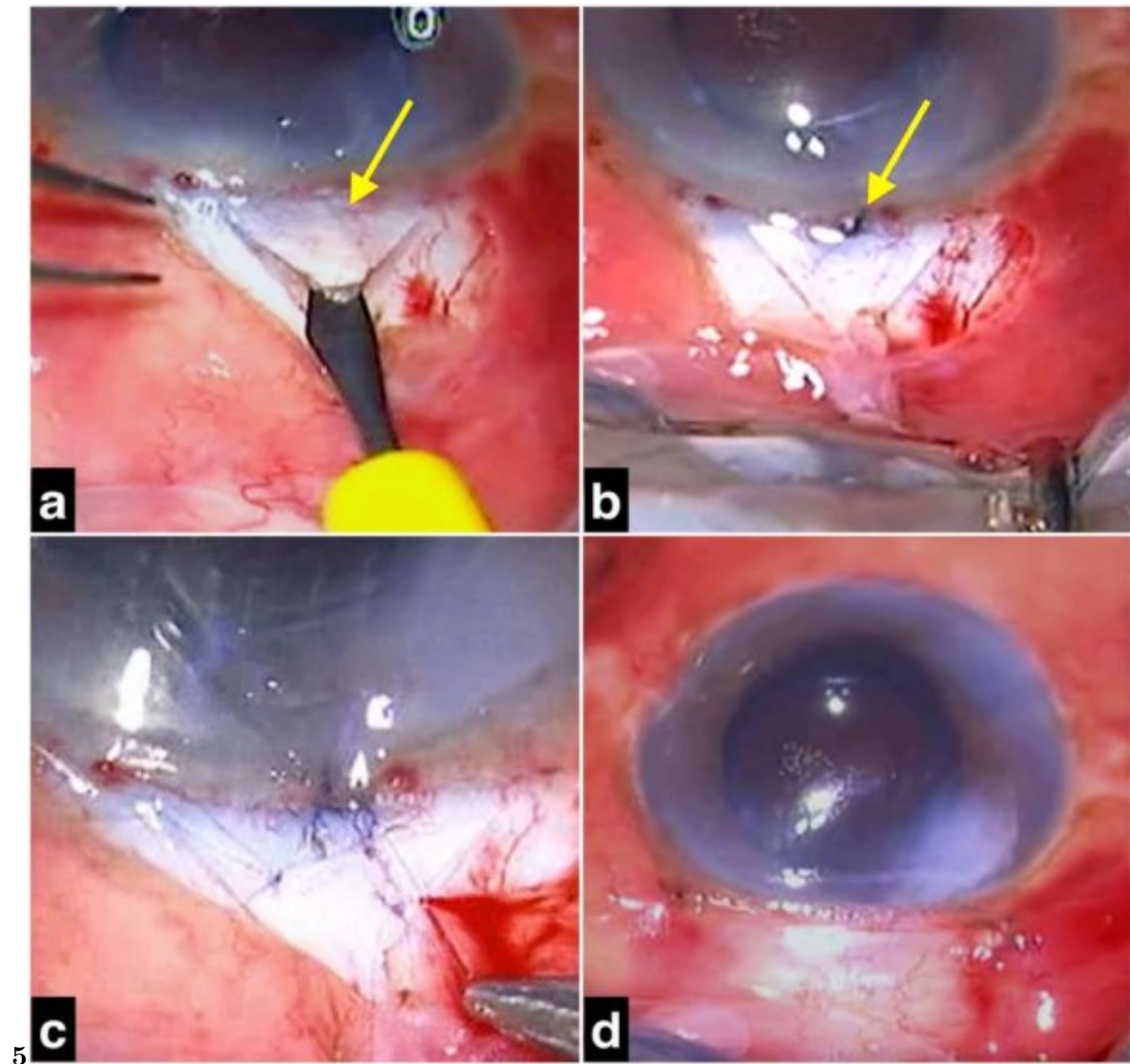


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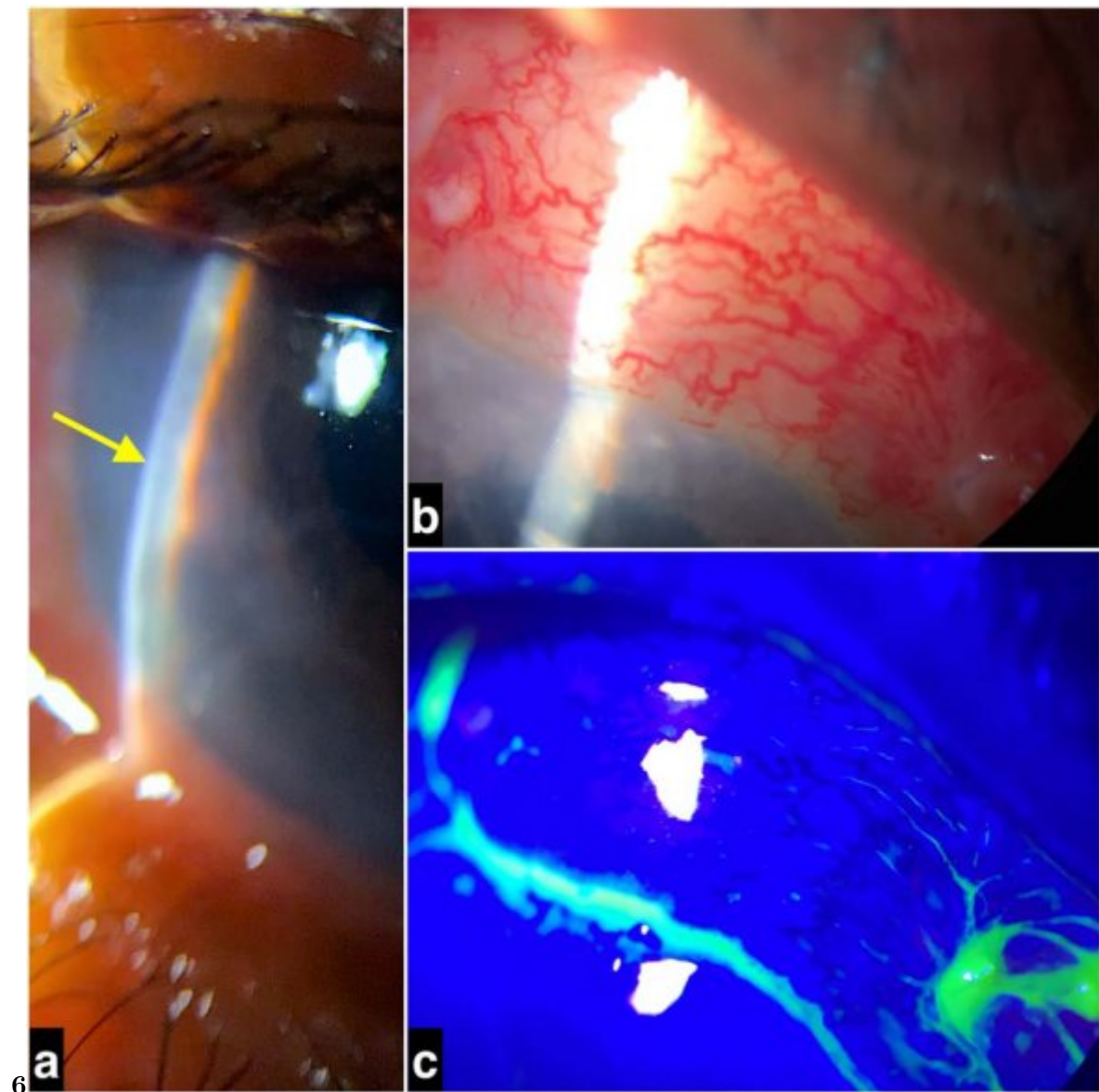


Figure 6: Figure 6 :

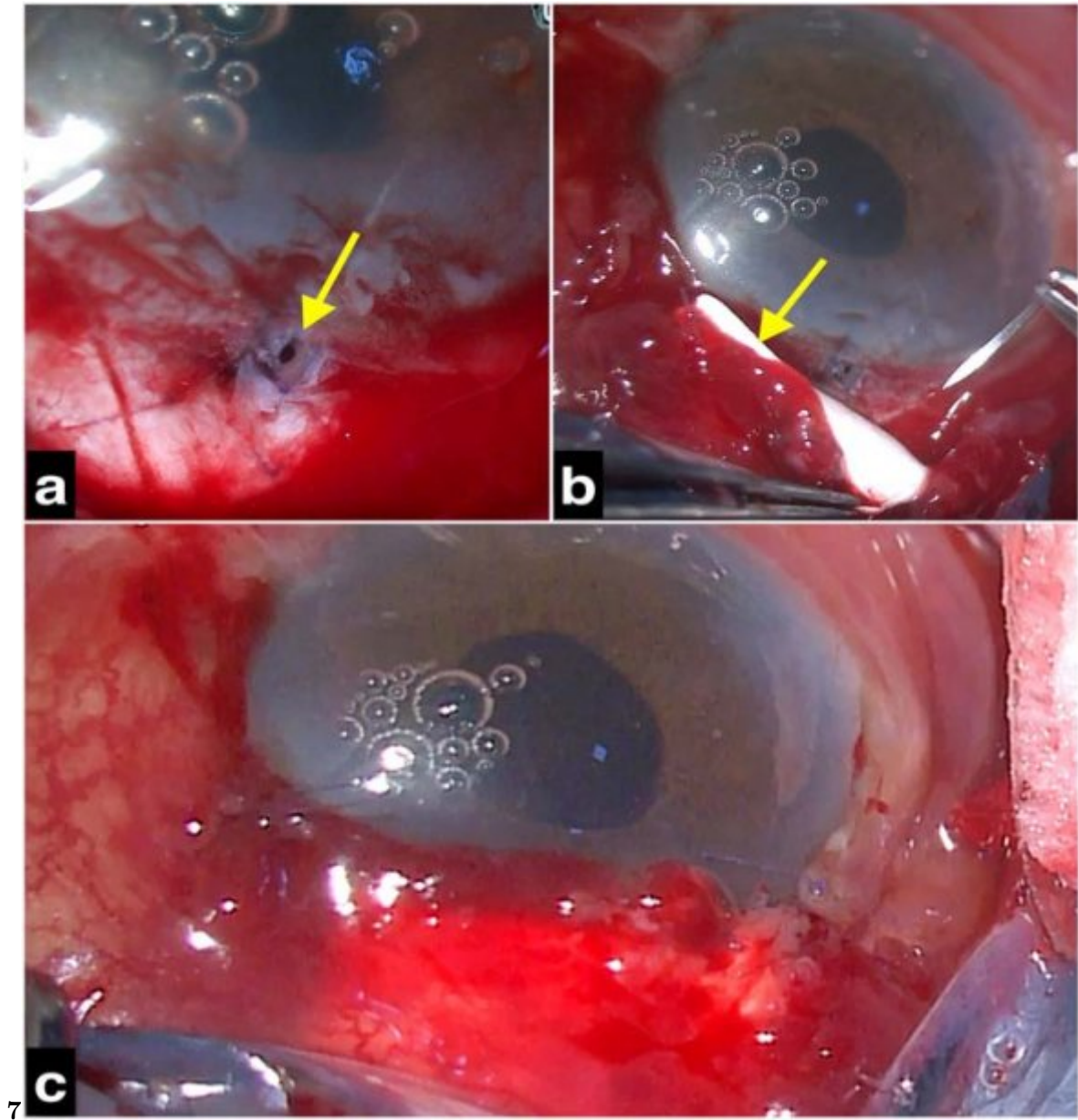


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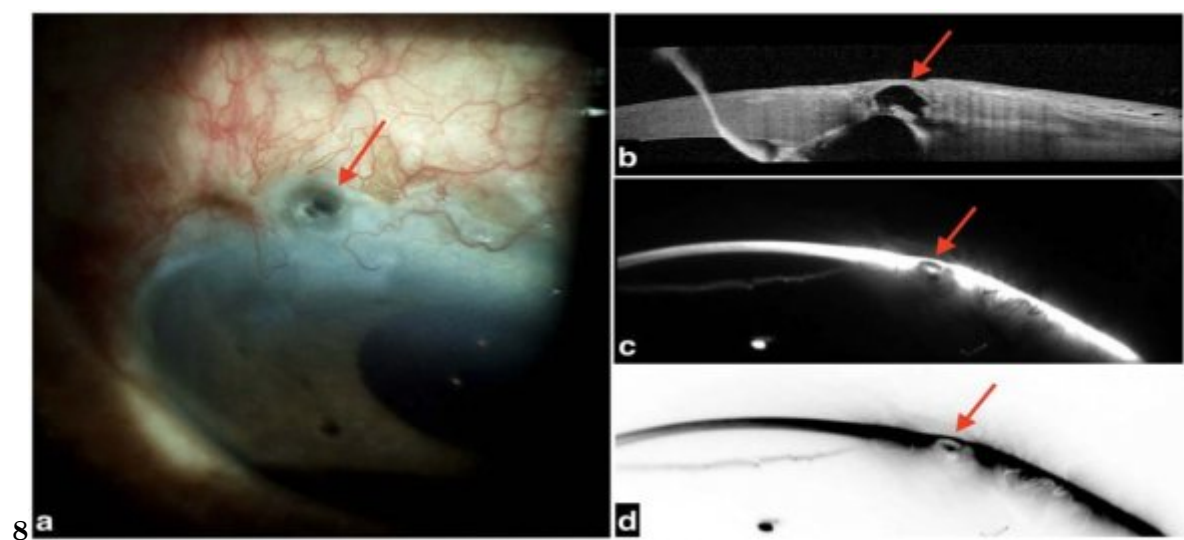


Figure 8: Figure 8 :

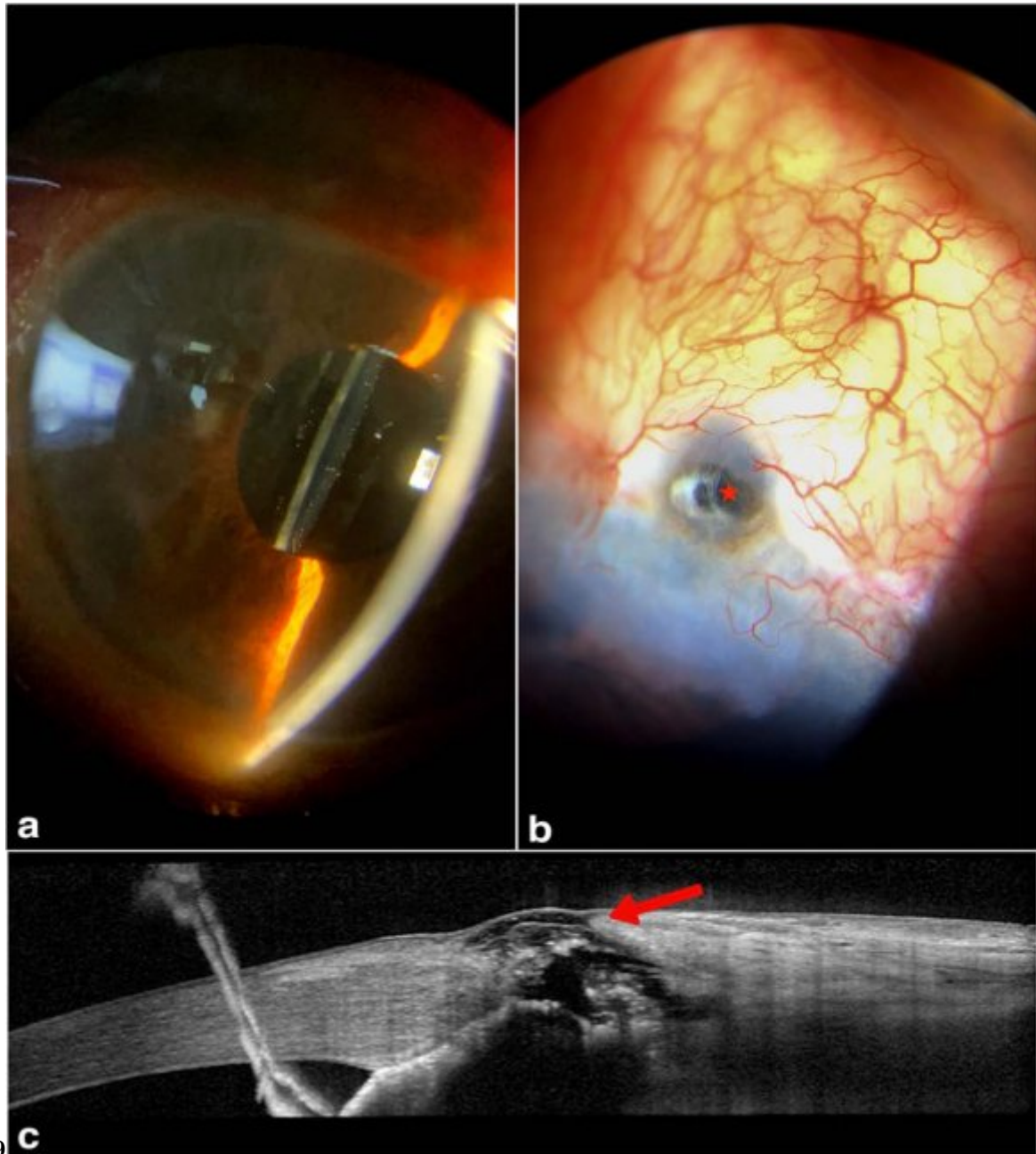


Figure 9: Figure 9 :

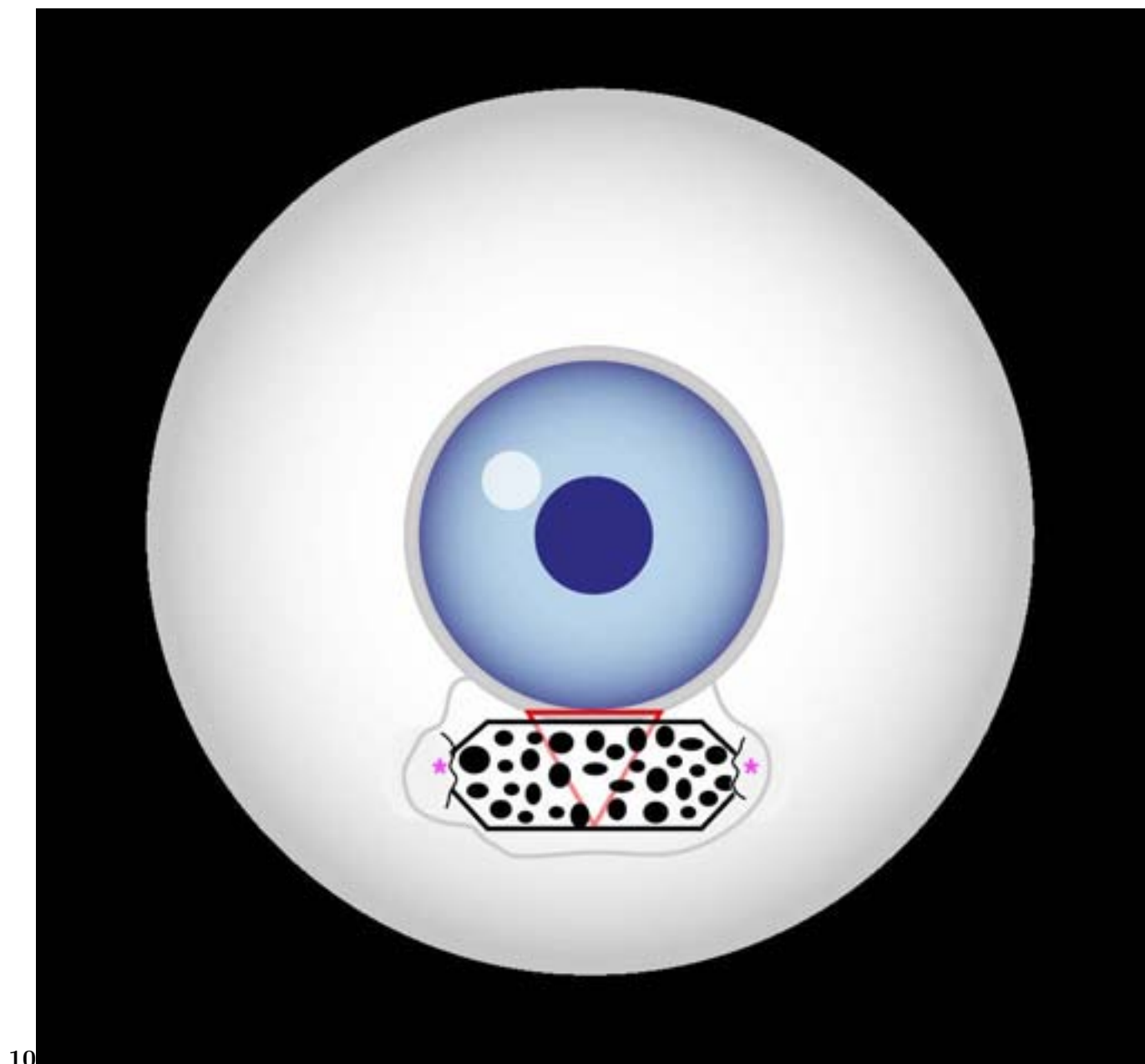


Figure 10: Figure 10 :

Case 2: An uncontrolled primary angle-closure glaucoma patient with bilateral cataract and glaucomatous cupping of 0.7 in both eyes (OU), and on maximum tolerable medical therapy, with the BCVA of 20/400 OD and 20/40 OS, and IOP 25 mm Hg OD and 22 mm Hg OS, underwent combined cataract and trabeculectomy surgery with Mitomycin -C for OD.

Figure 11:

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