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Conjunctival erosion following a PRESERFLO® MicroShunt procedure

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ABSTRACT

Purpose: We describe a case of conjunctival erosion following a PRESERFLO® MicroShunt procedure, and the subsequent revision surgery.

Observations: Conjunctival erosion was noted overlying the MicroShunt implant at postoperative week 11, 8 weeks following a bleb needling procedure for bleb encapsulation. A brisk leak was observed at the site of erosion. The patient underwent a subsequent revision procedure with repositioning of the MicroShunt implant and mitomycin C (MMC) application.

Conclusion and importance: Conjunctival erosion may be a relatively rare but important complication following MicroShunt surgery and may arise from a variety of risk factors. Extra care should be taken during bleb needling in the context of MicroShunt, and needling should be directed posteriorly, beyond the distal tip of the MicroShunt.

1. Introduction

The PRESERFLO® MicroShunt (Santen, Miami, Florida, USA) is a microincisional filtration surgical device. It is an ab externo poly(poly (styrene-*block*-isobutylene-*block*-styrene) or 'SIBS' MicroShunt, composed of an inert biocompatible material. We performed our first MicroShunt procedure in May 2019, and have since implanted over 60 MicroShunts.

The MicroShunt is presented as an alternative to trabeculectomy and a primary surgical intervention in patients with open angle glaucoma.[1] The theoretical advantages include easier surgery, shorter operating time and potentially less frequent postoperative visits. It is arguably less invasive than trabeculectomy, without the need for the creation of a scleral flap or ostium. The flow resistance imparted by the small tube diameter of the MicroShunt theoretically confers minimal risk of hypotony. The first prospective randomized study comparing MicroShunt (395 patients) versus trabeculectomy (131 patients) demonstrated reductions in intraocular pressure (IOP) and glaucoma medications in both groups, albeit with a lower mean IOP in the trabeculectomy group (11.1 mmHg versus 14.3 mmHg) at 1 year.[2] The MicroShunt group had significantly fewer postoperative interventions and a lower incidence of hypotony compared to trabeculectomy.

Conjunctival erosion following MicroShunt surgery may be relatively rare, but has been described following an inferiorly placed MicroShunt[3] and in the context of surgical revision.[4] Conjunctival erosion and exposure is well described following conventional tube shunt surgery and is a risk factor for endophthalmitis, evidence for which has been demonstrated in large retrospective studies.[5,6]

We describe a case of conjunctival erosion over a MicroShunt implant. Erosion was noted following a bleb needling procedure and suggests that extra care should be taken with needling in the context of the MicroShunt. The patient underwent revision surgery to reposition the MicroShunt through a superotemporally positioned scleral tunnel.

2. Case report

We report the case of a 76-year-old man of Jamaican origin with bilateral advanced primary open angle glaucoma (POAG) and a previous MicroShunt in the right eye. The patient had a medical history of hypertension controlled with one medication.

Preoperatively, the best corrected visual acuity (BCVA) was 6/7.5 in both eyes. IOP in the right eye was 17 on topical dexamethasone only (following previous MicroShunt), while the left eye IOP was 38 mmHg on four different IOP lowering medications. The mean deviation in the left eye on Humphrey visual field 24-2 SITA Standard was −8.91dB with evidence of progression in the preceding 12 months. The conjunctiva was white and uninflamed. He had no prior surgery in the left eye. We discussed surgical options with the patient including MicroShunt and trabeculectomy and following discussion of the risks and benefits the patient opted for a MicroShunt procedure for the left eye and provided

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informed consent.

The patient underwent a left eye MicroShunt procedure, performed as per local protocol. A corneal stay suture was placed, followed by a superior fornix-based conjunctival peritomy with posterior dissection. MMC 0.4 mg/mL soaked sponges were applied subconjunctivally for 5 minutes. The conjunctival edge was elevated in order to minimize MMC contact at the limbus. Sponges were removed and the subconjunctival space was washed out with 50 mL of balanced salt solution (BSS). Limited cautery was applied to bleeding vessels and a Tookes knife used to smooth the scleral surface. The sclera was marked 3 mm posterior to the limbus using the marking instrument provided and a scleral pocket was created at this location using the Mani angled 1 mm wide blade. A 25G needle, bent with the bevel facing upwards, was inserted into the scleral pocket and advanced a short distance. The eye was rotated into primary position and the needle was angled along the iris plane and advanced to enter the anterior chamber (AC), following which the needle was removed. A corneal paracentesis was created at 3 o'clock with a 15° blade and the AC was inflated with BSS. The MicroShunt was then inserted into the AC, with the wings of the device securely inserted into the scleral pocket. Flow was confirmed by observing drainage at the posterior tip of the MicroShunt. A 10-0 nylon suture in a crossed mattress configuration was used to secure the distal portion of the MicroShunt to the globe. Watertight conjunctival closure was achieved with 2 wing sutures and mattress sutures at the limbus using 10-0 nylon. Intracameral cefuroxime and dexamethasone were injected. There were no intraoperative complications.

The patient was commenced on topical preservative-free dexamethasone every 2 hours and chloramphenicol 4 times a day. At postoperative day 5, the left eye IOP was 6 mm Hg, and had a well-positioned implant and a diffuse posterior bleb.

At postoperative week 3, the left eye developed early bleb encapsulation and elevated IOP of 45 mmHg. Left eye bleb needling was performed at the slit lamp under local anesthetic. Topical tetracaine 1% followed by povodone iodine 5% was instilled in the left eye. Starting temporal to the MicroShunt, a long subconjunctival track was created using a 29G needle. The needle was used to pierce through the fibrotic capsule, to needle the bleb posterior to the MicroShunt and to clear the area surrounding the tip of the MicroShunt. Topical preservative-free dexamethasone was continued every 2 hours and chloramphenicol was re-started 4 times a day.

IOP reduced to 10 mmHg post-procedure and 0.15 mL/3.75 mg of subconjunctival 5-fluorouracil (5-FU) was injected superotemporally. The 10-0 nylon mattress suture used to secure the distal portion of the MicroShunt was noted to be loose following the needling procedure.

Following the needling procedure, the patient was seen weekly for 2 visits, then every 2 weeks for 2 visits. 5-FU was given on these 4 visits following needling in order to mitigate scarring response. 5-FU 0.15 mL/3.75 mg was administered with a 30G needle, superotemporally, 10–12 mm away from the bleb. The eye was washed with normal saline following 5-FU injection. A Siedels test performed at each visit was negative. IOP remained stable throughout this time.

Throughout this postoperative period the right eye also required bleb needling for encapsulation. The IOP was reduced to 10 mmHg from a pre-procedure IOP of 23 mmHg. There were no complications relating to bleb needling. IOP remained stable in the right eye, on two topical IOP lowering medications, and BCVA stable at 6/7.5.

At postoperative week 11 (8 weeks post needling procedure), a bleb leak was noted on fluorescein examination of the left eye, which originated from an area of conjunctival erosion and MicroShunt exposure (Fig. 1 and 2). The area of exposure was adjacent to the loose nylon suture. The IOP was 15 mmHg, BCVA 6/6 and there was no sign of infection. The patient reported a new onset of gritty sensation in the left eye in the days preceding examination, but was otherwise comfortable. He was commenced on topical moxifloxacin to his left eye four times a day and topical dexamethasone four times a day, and scheduled for revision of the MicroShunt to be performed within two weeks.

Revision of the left eye MicroShunt was performed under peribulbar local anaesthesia, with the aim of re-positioning the shunt temporal to the original location (Fig. 3). The subconjunctival and sub tenon's space was dissected posteriorly, focusing on the area temporal to the superiorly positioned MicroShunt. The existing MicroShunt was kept in situ for the initial stages of the surgery to maintain intraocular pressure and allow for ease of surgery. MMC 0.4 mg/mL soaked sponges were used in the subtenons space for 2 minutes and washed out with BSS. During this time, the distal tip of the MicroShunt was positioned external to the conjunctiva to prevent MMC from entering the AC. The MicroShunt was

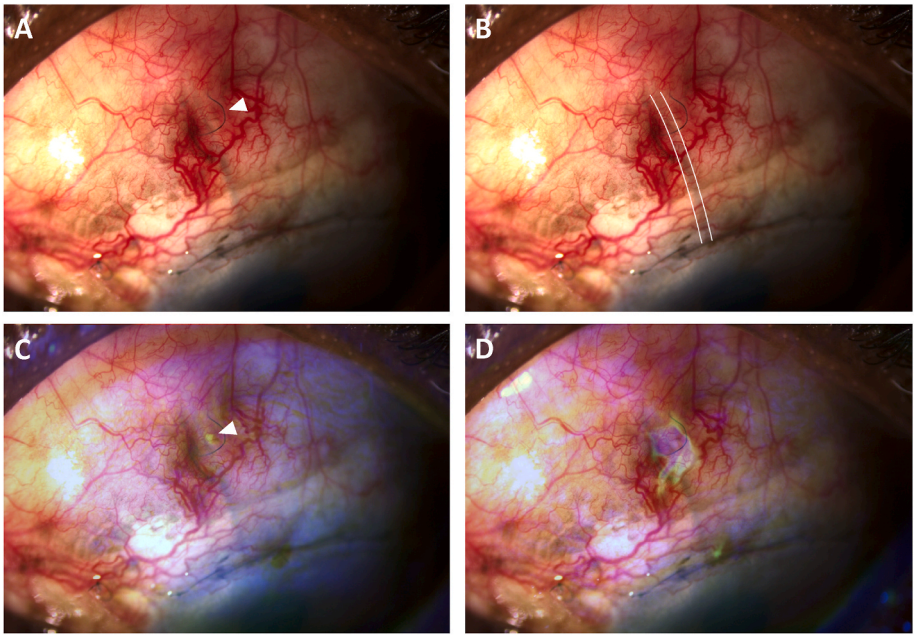

Fig. 1. Photographs of left eye PRESERFLO® MicroShunt and area of conjunctival erosion.
A. Loose suture adjacent to MicroShunt (arrowhead). B. Path of MicroShunt highlighted with white lines. C. Fluorescein uptake noted over area of erosion and exposure (arrowhead). D. Aqueous leak from area of erosion.

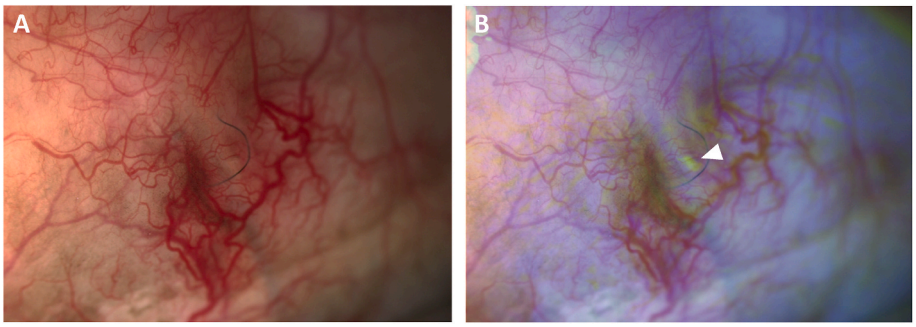

Fig. 2. Close up images of the area of conjunctival erosion over the PRESERFLO® MicroShunt in left eye. A. Path of MicroShunt and adjacent loose suture. B. Fluorescein uptake over conjunctival erosion (arrowhead).

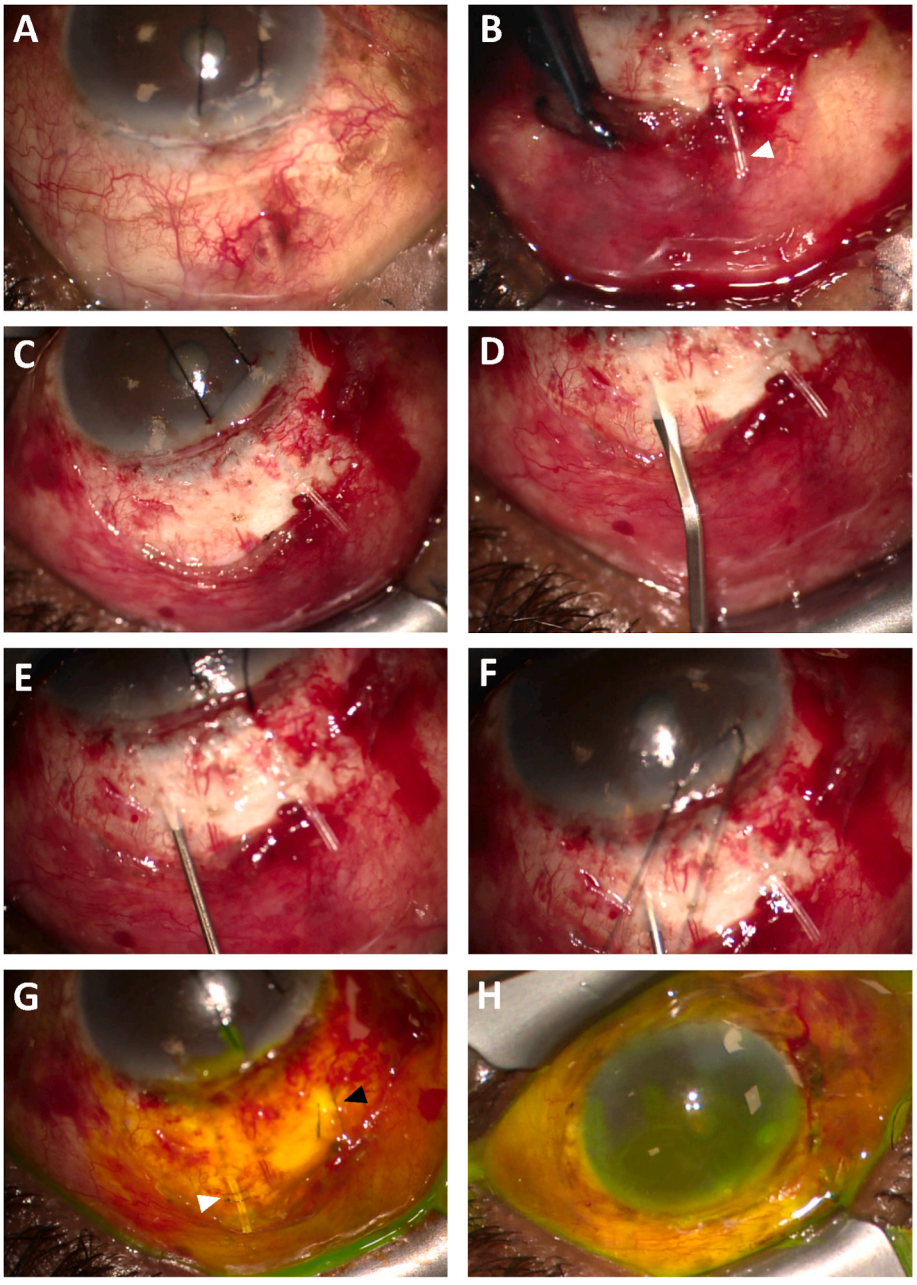

Fig. 3. Revision surgery intraoperative photos. A. At the outset of surgery. B. Distal tip of MicroShunt (arrowhead) external to conjunctiva during MMC application. C. Sclera cleared to site revision MicroShunt. D. Mani angled blade used to create scleral pocket. E. 25G needle inserted into scleral pocket. F. Eye rotated towards primary position as needle inserted into AC. G. Newly sited revision MicroShunt, with 10-0 nylon mattress suture to secure posterior tip (white arrowhead). Old MicroShunt site with two 10-0 nylon sutures and tenons plug (black arrowhead). H. End of case with conjunctival closure and repaired radial conjunctival tear.

removed from its original site and inserted into the AC through a newly fashioned scleral tunnel. The scleral defect of the original MicroShunt site was closed with two interrupted 10-0 nylon sutures and a plug of tenons tissue to create a watertight seal. During conjunctival closure, care was taken with the friable tissue. Despite this, a radial conjunctival tear occurred adjacent to the point of erosion. 10-0 vicryl sutures were used to repair the tear. The conjunctival pocket was closed using 10-0 nylon sutures and intracameral cefuroxime and dexamethasone were administered at the end of surgery.

In the postoperative period, a small leak was noted in the area of the conjunctival tear, but well away from the location of the newly positioned MicroShunt. This leak resolved by postoperative week 4, and at the most recent visit, the IOP in the left eye was 15 on two topical IOP lowering medications and BCVA was 6/6. The patient has been seen a total of 14 times following revision of the left eye MicroShunt, most recently at 6 months post revision surgery. No leak has been detected on Siedels at any subsequent visits.

3. Discussion

We present a case of conjunctival erosion and exposure of a MicroShunt at postoperative week 11, 8 weeks following a bleb needling procedure. We propose that several factors may have contributed to the conjunctival erosion: 1) needling may have damaged conjunctiva overlying the MicroShunt; 2) the loose nylon suture may have caused or perpetuated conjunctival erosion; 3) the MicroShunt itself may have caused erosion of the overlying conjunctiva; 4) a combination of these factors.

The conjunctival entry site during needling was superotemporal and well away from the area of the MicroShunt. However, conjunctival injury may have occurred when needling the area adjacent to the MicroShunt tip. MicroShunt blebs tend to be more posterior (compared to trabeculectomy). Part of our needling was directed towards this posteriorly located bleb. However, we also attempted to clear space surrounding the distal tip of the MicroShunt. During this process the overlying conjunctiva may have been damaged. This experience has informed our current approach to MicroShunt bleb encapsulation. If a bleb is present, we recommend performing needling, directed posteriorly, to avoid the area surrounding the MicroShunt tip. However, if no bleb is present, our preferred approach is a return to the operating theatre, to revise the MicroShunt bleb and clear the obstruction in a more controlled fashion.

The ongoing presence of a loose nylon suture following needling may have caused or perpetuated conjunctival erosion. Use of a 10-0 nylon suture to secure the distal aspect of the MicroShunt is our local practice, but is not a manufacturer-recommended technique. The suture is placed under low tension, and is designed to prevent movement or elevation of the MicroShunt over time (Fig. 3G). The approach has been recommended by another group in the context of deficient tenon's capsule (discussed in more detail below).[7] It is not clear at this point whether the inclusion of a nylon suture provides additional benefit. However, we have not had other similar suture related issues and we continue to incorporate its use with MicroShunt procedures.

There was no obvious movement of the MicroShunt despite a loose nylon suture. However, the presence of the MicroShunt alone, through micro-movements, could have theoretically exacerbated damage to the conjunctiva following needling. MicroShunt exposure in the context of healthy conjunctiva appears to be relatively rare. The two studies with the largest cohorts did not report any cases of conjunctival erosion, albeit with a short follow up period of 1 year.[2,8] The study with the longest follow up of 5 years also reported no cases of erosion, but had a smaller cohort (23 patients), which may be underpowered to detect this complication.[9] Four cases of MicroShunt exposure are present in the literature and may be related to risk factors which are summarised in Table 1 and described below.

In a retrospective study of 85 eyes in 79 patients, MicroShunt exposure was reported at postoperative month 6 in one eye that had prior cataract surgery, trabeculectomy and tube shunt surgery, where the MicroShunt was positioned inferiorly.[3] Another case report described erosion over a MicroShunt implant following revision surgery with intraoperative MMC for bleb failure. A second MicroShunt was placed adjacent to the original MicroShunt, and erosion occurred over the original implant.[4] The authors recommended removal of a non-functioning MicroShunt during revision surgery due to the risk of exposure, and advised caution in the secondary application of MMC in these cases. Finally, a recent series of 2 cases of MicroShunt exposure cited severe blepharitis associated with ocular surface inflammation and deficiency in tenons capsule as common features between them.[7] One of the patients had undergone a non-penetrating deep sclerectomy in both eyes 5 years prior. In situations where there is a deficiency of tenon's capsule, the authors recommend use of a 10-0 nylon suture to fix the distal part of the MicroShunt to the sclera, in a similar manner to which we have described.

Table 1
Possible risk factors for conjunctival erosion following PRESERFLO® MicroShunt.

Case of MicroShunt erosion	Possible risk factors identified
Durr et al. 2020[3]	Prior glaucoma surgery Inferior MicroShunt placement
Michaels et al. 2021[4]	Revision surgery with MMC for bleb failure
Bunod et al. 2021[7]	Severe blepharitis Deficiency of tenon's capsule
Current case report	Bleb needling Loose nylon suture Higher MMC concentration/duration

It is also relevant to consider the prevalence and risk factors for conjunctival erosion in the setting of the XEN microstent (Allergan, Dublin, Ireland)[10] and conventional drainage tube shunts. The XEN microstent has low rates of exposure reported in the literature, ranging from 0.9 to 1.8%.[11–14] Erosion rates after conventional tube surgery range from 5% in the Tube Versus Trabeculectomy (TVT) Study,[15] 1–3% in the Ahmed Baerveldt Comparison Study,[16] and 2–4% in the Ahmed versus Baerveldt Study.[17] Erosion rates are higher in inferiorly placed tubes, which may be related to increased exposure of the anterior portion of the patch graft and mechanical disruption from the lower lid,[18,19] as well as in eyes with previous surgery, suggesting that prior surgery may impact conjunctival health and potential risk of erosion.[15,20]

Finally, concentration and duration of MMC use in MicroShunt procedures varies throughout the literature.[2,3,8,9,21–23] In our MicroShunt procedures, we use MMC 0.4 mg/mL for 5 minutes. It is possible that this concentration and duration of MMC may contribute to conjunctival thinning and erosion.[24] However, use of higher MMC concentrations (0.4 mg/mL) with the MicroShunt may be associated with lower failure rates,[3,8] reduced need for postoperative glaucoma medication,[21] lower mean IOP at 12 months[22] and lower rates of needling.[3,8] Prior research into MMC use and trabeculectomy has suggested a dose-response relationship between MMC concentration, exposure time and surgical success, in which duration of exposure may be more important than concentration.[25] Our use of MMC 0.4 mg/mL for 5 minutes takes into account the reduced risk of hypotony with the MicroShunt,[2] the potential for increased scarring associated with a drainage device, as well as our high proportion of Afro-Caribbean patients. Key studies investigating MicroShunt surgery have highlighted the need for further research into MMC dose and exposure time.[2,8,9,21,23] Evidence will be imperative to guide our optimal approach to issues such as MMC and aspects of postoperative management including bleb needling. We hope that this report provides insight into technical aspects of MicroShunt bleb needling and possible risk factors for conjunctival erosion in this setting.

4. Conclusion

Conjunctival erosion following MicroShunt implantation appears to be relatively rare, based on existing studies with up to 5 years of follow up. However, erosion can occur and may be associated with specific risk factors mentioned above. We present a case of conjunctival erosion following a bleb needling procedure in which we speculate that several factors may have played a role. We recommend that bleb needling is directed posterior to the distal MicroShunt tip to ameliorate the potential risk. We also recommend that sutures, if used to secure the MicroShunt, are tied securely to prevent any potential complications relating to their use.

Patient consent

Informed consent was obtained from the patient to publish this report, but does not contain any personal information which could identify the patient.

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Intellectual property

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

Research ethics

We further confirm that any aspect of the work covered in this manuscript that has involved human patients has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

Written consent to publish potentially identifying information, such as details or the case and photographs, was obtained from the patient.

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