Special Focus, Glaucoma, Original Article

Long-term outcomes of blebs repaired with scleral patch graft and conjunctival advancement in late-onset leak post-trabeculectomy

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Purpose: To report long-term outcomes in eyes that developed late-onset bleb leak post trabeculectomy, with or without hypotony and/or maculopathy, due to a scleral melt/fistula and who required a scleral patch graft and conjunctival advancement for repair. **Methods:** Retrospective, non-comparative, interventional case series over a decade (2010–2019), presenting with late bleb leak post-filtration-surgery. All cases required a scleral patch graft and conjunctival advancement for management via a standard technique, performed by an experienced glaucoma surgeon. **Results:** A total of 18 eyes were included. Mean age was 51.5 ± 10.2 years (95% CI [46.4–56.7]) and were followed up after repair for 52.4 ± 26.9 months, 95%CI [39.1–65.8]. 66.7% eyes (n = 12) had IOP ≦6 mmHg and also had hypotony maculopathy. None of the eyes presented with blebitis. 44.5% (n = 8) eyes underwent phacoemulsification as significant cataract was present. LogMAR best-corrected visual acuity (BCVA) was 0.8 ± 0.7 (95% CI [0.4–1.1]) prior to intervention and improved to 0.4 ± 0.6 (95% CI[0.1–0.6], P = 0.004). 22.3% (n = 4) eyes had persistent choroidal folds but BCVA was improved. Mean pre-intervention intraocular pressure (IOP) was 6.3 ± 3.8 mmHg (95% CI 4.4–8.2]) which increased to 12.1 ± 2.9 mmHg (95%CI[10.6–13.5], (P < 0.001). 27.8% (n = 5) eyes needed laser suture lysis post repair to control IOP; two needed further surgical intervention. Number of anti-glaucoma medications at last follow-up was 0.4 ± 0.9 (95% CI [−0.1–0.8], P = 0.09). No serious complications were encountered. **Conclusion:** Scleral patch graft and conjunctival advancement is a useful technique for repair of a scleral fistula post-filtering surgery, and this is recommended not only for the restoration of anatomy for prevention of infection and control of IOP, but also for visual rehabilitation.

Key words: Bleb leak, conjunctival advancement, hypotony, mitomycin C, scleral fistula, scleral melt, scleral patch graft, trabeculectomy

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The overall success of trabeculectomy (trab) with regard to intraocular pressure (IOP) control has increased with the use of mitomycin C (MMC), making it possible to achieve a low target IOP.[1] However, the use of MMC has been a burdensome trade-off as there are known associated complications.[2] These include over-filtration, thin-walled cystic blebs, late leakage and associated hypotony with or without maculopathy, blebitis and bleb-associated endophthalmitis (BAE). Late or chronic bleb leak is a risk factor for infection and requires immediate attention.[3] Some of the characteristics of a late leaking bleb are large and overhanging, thin-walled, cystic [Fig.1a, pinpoint breakdown of thinned epithelium, black arrow], Seidel positive [Fig. 1b], localized, avascular and ischemic due to "ring of steel" [Fig. 1c, squiggly white line], and greyish area visible underneath thin conjunctival epithelium, presumptive of a full-thickness scleral melt or fistula [Fig. 1c, white arrow]; these can be reversed with surgical intervention. When leaking, blebs are at risk of hypotony and associated maculopathy, variable choroidal folds in the macular region and/or disc edema. It is a cause of reduced vision which may be permanent if the hypotony is not corrected.

In a study of the efficacy and safety of primary trab + MMC over 5-years, Bindlish *et al*.[2] have reported a rate of 15.6% of late bleb leak after a mean of 27.9 ± 24.6 months post trab + MMC.

There are several reported techniques of bleb leak repair (BLR). Relatively less invasive means of treating hypotony in over-filtering or leaking blebs include autologous blood injection (ABI) with or without compression sutures (CS). On the other hand, needling has also been described in leaking blebs,[4] for aqueous diversion posteriorly away from the site of the leak, may help to seal the leak. Our standard approach in late leaking blebs entails-bleb excision, scleral patch graft (SPG) with conjunctival advancement (CA) and our objective is to report the long-term outcomes of such a management.

Methods

This is a retrospective, non-comparative, interventional case series, of consecutive patients, referred between 2010 and 2019 to one of the tertiary center/s. These eyes presented

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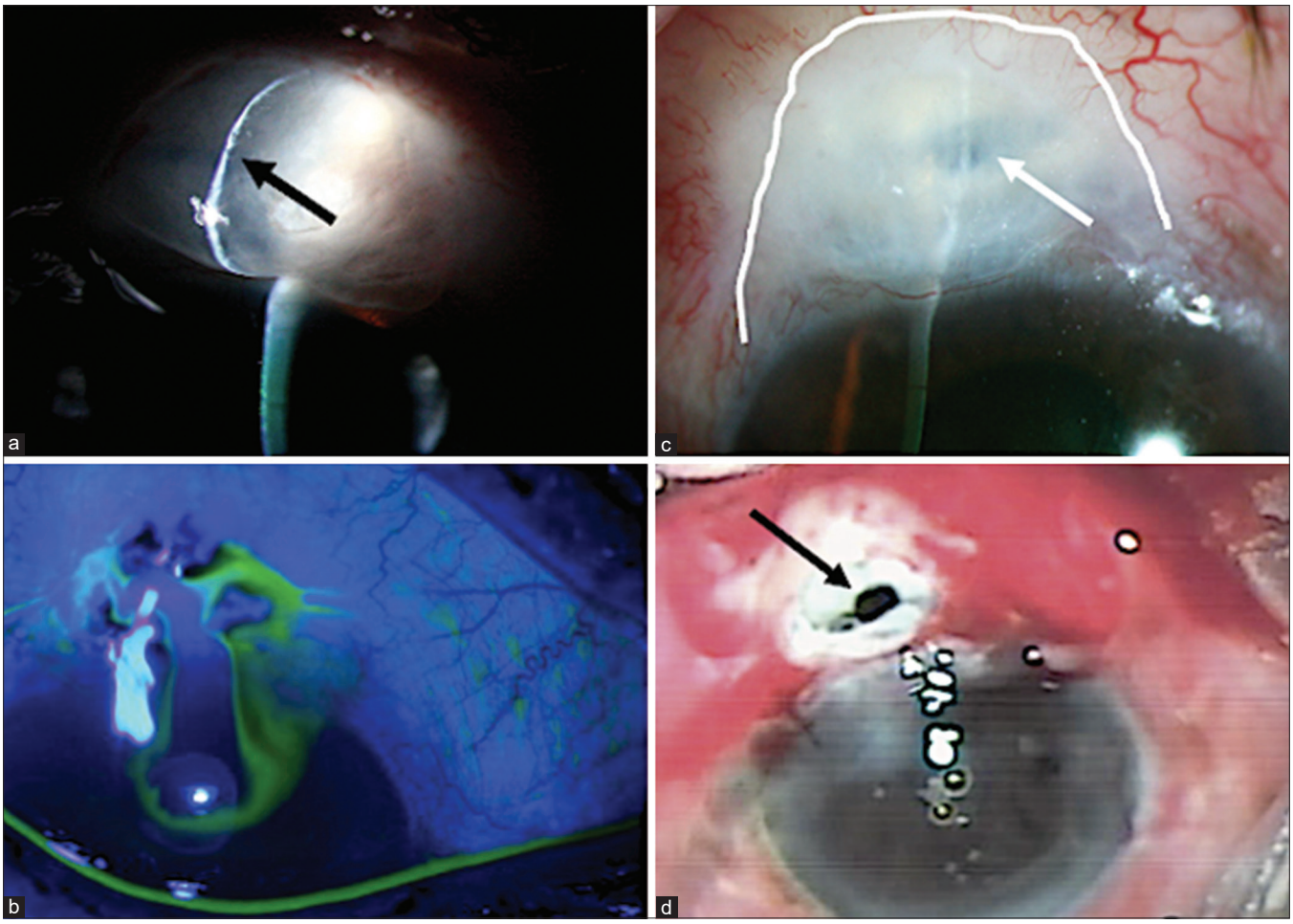

Figure 1: (a) Large and overhanging, thin-walled, cystic bleb with pinpoint breakdown of thinned epithelium (black arrow) (b) Seidel positive (c) Localized, avascular and ischemic bleb due to "ring of steel" (squiggly white line) and greyish localized depressed area visible with optical section on the slit lamp at high magnification, underneath the thinned conjunctival epithelium, suggestive of a scleral fistula (white arrow) (d) Intra-operative photograph showing a large scleral fistula (black arrow)

with a point leak (Seidel positive) post trabeculectomy with mitomycin C (trab + MMC); all the blebs with diffuse transudation of fluid ("sweating blebs") were excluded. All the eyes underwent a standard SPG and CA surgery between 2010 and 2019, performed by an experienced glaucoma surgeon. Ethics Committee Approval for Outcomes of Trabeculectomy surgery and adjuvants (including complications) was obtained, of which this study is a sub-part.

Informed written consent for the surgery was obtained from all the patients prior to the procedure and the study adhered to the tenets as laid down by the Declaration of Helsinki.

Baseline parameters including age, gender, glaucoma type, previous glaucoma surgery, best-corrected visual acuity (BCVA), preoperative intraocular pressure (IOP) mmHg obtained by Goldmann applanation tonometry (GAT), gonioscopy with Sussman 4-mirror gonioscope were recorded and where possible dilated stereo fundoscopy with +66D Volk lens (Volk Instruments, OH, USA) was done. BCVA, IOP, complications and need for anti-glaucoma medications (AGM) and any further intervention to control the IOP, were recorded in the post-operative period and time interval for collection of data were—day 1, week 1, week 6, month 3, month 6, year 1, and yearly thereafter and at final-visit postoperatively. Eyes may have had more frequent follow-up as necessary.

Standard surgical technique

Under peribulbar anesthesia and sterile conditions, a paracentesis was made at 9 o'clock (or 3 o'clock) and Trypan blue was injected to delineate the bleb [Fig.2 - dashed arrows]. The avascular bleb was excised with Westcott scissors. Adequate hemostasis was achieved with bipolar cautery. A full-thickness scleral melt/fistula was noted in all cases, with either a necrotic or no scleral flap overlying it. [Fig. 1d, black arrow). The fistula was reduced in size with 10/0 nylon interrupted suture, if required. A full-thickness scleral patch graft was cleaned and trimmed to the requisite size (usually 3 mm × 2.5 mm) and sutured over the fistula with interrupted 10/0 nylon suture. Two interrupted sutures were placed anteriorly, at and parallel to the limbus, as well as a mattress suture between the two. [Fig. 2] Two more interrupted sutures were placed posteriorly, akin to suturing of a rectangular scleral flap in trab. The tension of the anterior sutures was tight, whilst the posterior sutures were titrated for filtration. Standard minimum 5-suture patch graft suturing was followed in all cases [Fig. 2]; additional sutures were placed if required. Blunt-tipped Westcott scissors were used to separate the tenons and conjunctiva posteriorly

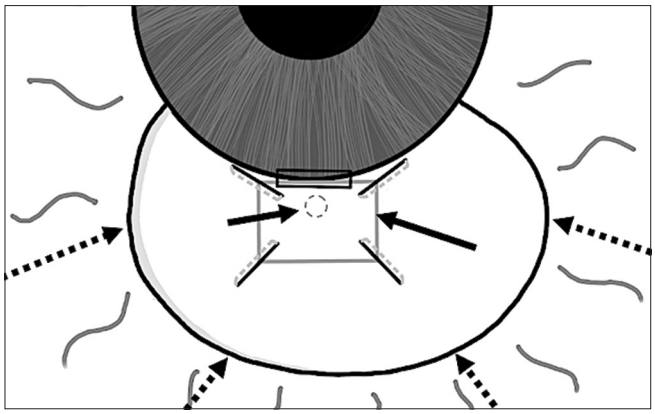

Figure 2: Diagrammatic representation of the surgical steps – conjunctival excision of the previous thinned avascular bleb (extent shown with dashed arrows), scleral melt/fistula (short black arrow) covered with adequately sized scleral patch graft (long black arrow), and standard 5-suture fixation of graft (interrupted X 4 at the corners, mattress X 1 at the limbus)

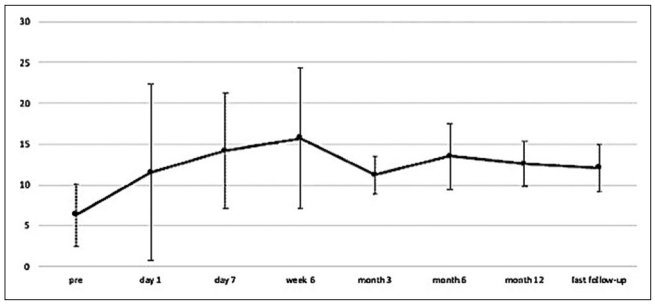

Figure 4: Mean intraocular pressure at various time intervals following bleb leak repair with scleral patch graft

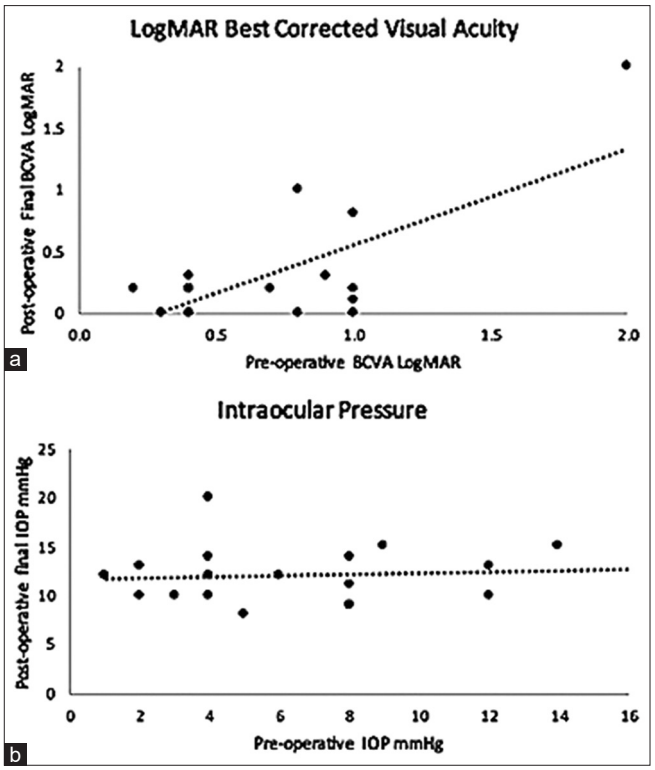

Figure 3: (a) Scatter plot of postoperative best-corrected visual acuity (BCVA) against pre-operative BCVA in LogMAR. The line of equivalence is shown (b) Scatter plot of postoperative intraocular pressure (IOP) against pre-operative IOP in mmHg. The line of equivalence is shown

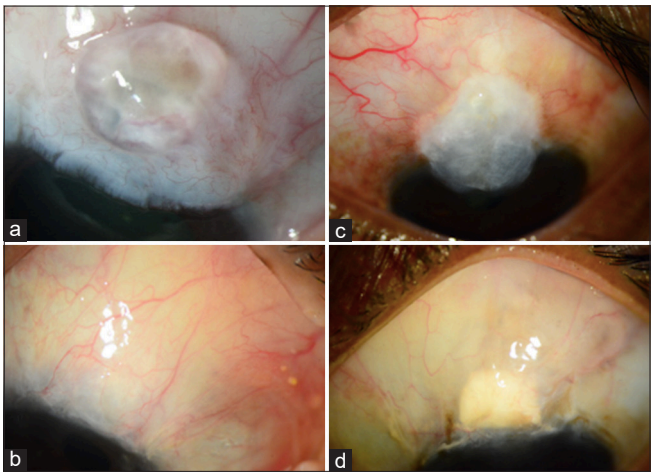

Figure 5: Pre-operative photographs of blebs (a and c) which underwent bleb repair with scleral patch graft and conjunctival advancement, showing favorable bleb morphology (b and d) respectively

until the free margin of the conjunctiva could be easily advanced anteriorly to the limbus. The conjunctival edge was approximated at the limbus with a combination of interrupted and continuous 8/0 polyglactin suture. One mattress suture was also placed at the limbus. To finish off, balanced salt solution was injected into the anterior chamber through the paracentesis to confirm watertight closure and good bleb elevation.

If a cataract was co-existent, then simultaneous phacoemulsification (phaco) surgery was also performed through a clear-corneal 2.2 mm or 2.8 mm incision adjacent to the patch graft; synechiolysis and iris hooks were used for pupillary management in complicated cataracts. An anterior chamber maintainer (ACM) was also used, if required. All the eyes had a foldable IOL placed in the bag. The clear-corneal phaco wound was sutured with an interrupted 10/0 nylon suture.

All the eyes received subconjunctival 2 mg dexamethasone injection.

The eye was patched for 24-hours; thereafter, patients were started on topical moxifloxacin/gatifloxacin for 1 week, prednisolone acetate 1%, generally 6–8 times daily, tapered over 6–12 weeks, and homatropine HCl for 1 week (if required).

The primary outcome measures were BCVA and IOP and secondary outcome measures were the number of AGM and complications. Success was defined as a BCVA which was maintained or improved at an IOP of >6 and ≦ 18 mmHg, with or without medication. Failure was defined as loss of light perception, repeat operating room (OR) intervention to control IOP or recurrence of leak.

Statistics: Descriptive statistics is presented as mean ± standard deviation along with 95% confidence intervals; median and interquartile range is also provided in parenthesis. Univariate comparisons of continuous and quantitative variables were performed using the Paired t-test analysis or

the Wilcoxon Signed-Rank test. Snellen visual acuity was converted to LogMAR acuity for statistical analysis. A *P* value of <0.05 was considered statistically significant and all tests were two-tailed. All statistical analyses were performed using IBM® SPSS® Statistics software (Chicago, IL, USA).

Results

A total of 18 eyes of 15 patients who underwent SPG and CA for chronic bleb leakage were included. The mean age was 51.5 ± 10.2 years (95% CI [46.4–56.7], median 54, IQR 15) and patients were followed up for 52.4 ± 26.9 months, 95% CI [39.1–65.8], median 49 IQR 30.7 range 23–108 months). One eye had fragile conjunctiva and received an amniotic membrane graft (AMG) also, intraoperatively. 83.4% (*n* = 15) eyes had initial filtration surgery augmented with mitomycin C (MMC), but adjuvant remained unknown in 3 eyes. The average time between the index trab and leakage was 96 ± 64.4 months (95% CI [64.2–74.8], median 85 months, IQR 51.5, range19–228 months). All the eyes presented with thin-walled cystic, avascular bleb, and all were Seidel positive with a greyish appearance underneath, suggestive of a scleral melt and each one demonstrated a scleral fistula intra-operatively. [Fig. 1d] None of the eyes presented with blebitis or choroidal effusions. 66.7% eyes (*n* = 12) had IOP ≦ 6 mmHg and also had hypotony maculopathy (HM) demonstrable either clinically or with macular Optical Coherence Tomography or both. Overall, 44.5% (*n* = 8) eyes underwent phacoemulsification as significant cataract (NS grade 2 or more) was present; 33.3% (*n* = 6) had co-existing significant cataract and HM.

The LogMAR BCVA of the cohort overall was 0.8 ± 0.7 (95% CI [0.4–1.1], median 0.7, IQR 0.6) prior to intervention and the range was 20/632–20/30 Snellen acuity; this improved to 0.4 ± 0.6 (95% CI [0.1–0.6], median 0.2, IQR 0.3, range 20/400–20/420 Snellen acuity, *P* = 0.006). The eyes that had HM presented with a mean BCVA of 0.9 ± 0.7 (95% CI [0.4–1.3] median 0.8, IQR 0.6) which improved to 0.4 ± 0.5 (95% CI [0.1–0.7], median 0.2, IQR 0.1, *P* = 0.002). On the other hand, the eyes with co-existing HM and cataract (33.3%, *n* = 6) presented with a mean BCVA of 0.8 ± 0.2 (95% CI[0.6,1], median 0.9, IQR0.3) which improved to 0.2 ± 0.3 (95% CI[−0.1–0.5], median 0.2, IQR 0.2, *P* = 0.012). Overall, 88.8% (*n* = 16) of eyes demonstrated improvement in BCVA or it remained unchanged. [Fig. 3a] 77.7% eyes (*n* = 14) had improved vision, of which 12 eyes (66.6%) had BCVA better than 20/40. 22.3% (*n* = 4) eyes had persistent choroidal folds but BCVA was improved in each of these eyes at final follow-up. None of the eyes lost light perception.

The mean pre-intervention IOP was 6.3 ± 3.8 mmHg (95%CI [4.4–8.2], median 5.5, IQR4, range1–14 mmHg) which increased to 12.1 ± 2.9 mmHg (95%CI [10.6–13.5], median 12, IQR 3.75, range 8–20 mmHg, *P* < 0.001) at the final visit. [Figs. 3b and 4] The IOP was highest with great variability at the 6-week point, [Fig. 4]; bleb manipulation was maximum at this time interval. 27.8% eyes (*n* = 5) needed laser suture lysis to control IOP; one eye needed further surgical intervention in the early postoperative period. This eye with ICE syndrome had a rebound rise in IOP, uncontrolled by conservative means. Laser suture lysis was attempted but failed and underwent transscleral diode cyclophotocoagulation (TSCPC) within a month of the procedure. This is the only eye that had a BCVA worse than pre-intervention, by 1 line. Another eye underwent Glaucoma Drainage Device surgery 5 years after BLR and maintained BCVA with controlled IOP. The number of anti-glaucoma medications being used at last follow-up was 0.4 ± 0.9 (95% CI [−0.1–0.8], median 0, range 0–3, *P* = 0.09).

No major complications were seen even when the procedure was combined with phaco. Transient subconjunctival hemorrhage, of variable extent, was seen in all eyes. One eye also had hyphema. Ptosis was also seen in all eyes in the first few weeks post-operatively; none was present at the final visit. None of the eyes had recurrent leaks.

Outcomes: As per our pre-defined criteria, 83.3% (*n* = 15) eyes were successful (complete success = 72.2% and qualified = 11.1%). A total of 16.7% eyes (*n* = 3) failed; 2 eyes (11.1%) were failures due to repeat intervention and one eye failed on IOP criterion. None of the eyes lost light perception, nor BCVA worse than 2 lines. At the final visit, 17 of 18 eyes had controlled IOP, with or without medication.

Discussion

The majority of the eyes in this cohort responded to an SPG and CA procedure for chronic leakage of bleb, with or without hypotony and macular changes, presenting after a mean of 96 months post-trabeculectomy. Each eye presented intra-operatively with full-thickness scleral melting or fistula. BCVA was maintained or improved in all but one of the eyes. Hypotony maculopathy that was present in over half the eyes, resolved post BLR. The eyes with residual choroidal folds at the final visit (*n* = 4, 22.2%) also showed improvement in vision.

To prolong the life of a functioning bleb and to improve long-term success in filtration surgery,[1] MMC is used extensively worldwide, in varying concentrations and also for a variable duration. The concentration of MMC used by the first author, for all index trab + MMC, was 0.4 mg/mL and the exposure time was 2 min; however, this remained unknown for all the other eyes referred for BLR. When MMC is used in a diffuse manner, it has the capability of producing a favorable bleb morphology—low, diffuse, and posteriorly directed; in contrast focal application of MMC makes blebs cystic and thin-walled with eventual breakdown of the thinned conjunctival epithelium predisposing it to infection. Therefore, it is the incorrect usage of anti-fibrotic adjuvants, that is also adversely implicated in bleb leak, blebitis and bleb-associated endophthalmitis (BAE).[2]

All the eyes in this series had virtually similar presentation of thin-walled, cystic, Seidel positive, avascular bleb pre-operatively, and a scleral fistula intra-operatively. All the BLR surgeries were performed by the first author, but only five of these eyes underwent index trab + MMC by this same surgeon over the same decade of performing filtration surgery as well, with or without phaco. This low rate (1 in approximately every 300 cases of filtration surgery) is mostly attributable to the safe application of MMC, as described by Khaw and associates.[5] in the Moorfields Safer Surgical System (MSSS). We adopted a few features of this system—a fornix-based conjunctival incision, diffuse application of MMC with multiple sponges and creation of a rectangular scleral flap. This was performed in a repetitive fashion, with a slight modification of the length and anatomical position of the conjunctival incision. These modifications aided in minimal manipulation of the conjunctiva and imparted a "keyhole"

nature to the technique. This approach, along with separate site phaco, has been described in detail before.[6]

None of the eyes in this series presented with blebitis or BAE which can be devastating and despite successful resolution of the infection, visual outcomes may be poor.[3] Therefore, preventive measures are appropriate, and usage of the MSSS is advocated to minimize the occurrence of such a bleb morphology which is predisposed to these adverse events.[5]

Most eyes presented with an IOP ranging between 1 and 8 mmHg and received conservative management first, without much success. However, there were three eyes where IOP improved (one following needling) to 12–14 mmHg but continued to be Seidel positive. In these three eyes, bleb leakage was not apparent on initial cursory examination, as they tended to be slower, as opposed to the moderately brisk leak in the other eyes and the very brisk leak that is usually the norm in the early postoperative period. Thus, persistence is the key, and such a bleb should be observed for at least 15 s after application of a wetted fluorescein strip.

On the other hand, some blebs tend to have diffuse transudation of fluid with a corresponding diffuse appearance of Seidel, without overt leak at any one point; these were excluded.

Repair of blebs with varied techniques has been reported with a variable success rate. Other than needling, ABI into the bleb and CS have been described as relatively less invasive techniques.[7-9] Morgan and colleagues[7] have used the technique to modify bleb morphology in large, dysmorphic over-filtering blebs without leaks whilst Biswas *et al*.[8] have reported a 57% success rate with this management option in bleb leaks. However, the latter study reported early leaks as well, as early as 1-week post-trabeculectomy. ABI and CS may be better options in hypotony due to over-filtering blebs, rather than chronic leak due to a scleral fistula. We believe that when a full-thickness scleral melt/fistula is present, only a patch graft can help with the build-up of resistance to attain a favorable bleb morphology [Fig. 5] not only to overcome the hypotony but also for restoration of the bleb function. Under these circumstances, usage of techniques that only involve the conjunctiva may have an increased likelihood of an eventual repeat break-down of overlying epithelium. Therefore, our standard technique was to patch the sclera overlying the fistula, after excising the bleb and then advancing the undermined conjunctiva for complete restoration of ocular integrity. Generally, there was no requirement of conjunctival autograft (CLAG) as there was no appreciable conjunctival shortening, but one eye had very friable conjunctiva, so it received an AMG as well.

Several patching methodologies have been reported in the literature—including full-thickness sclera, either donor[10,11] or autologous,[12] partial thickness sclera,[13] or even cornea,[14] dural patch graft,[15]and pericardium.[16]

A bleb repaired with SPG is usually thicker than the original, and this can affect its functioning. Therefore, a rise in the IOP post-BLR should be anticipated in the early postoperative period. In our series too, the IOP was highest, at the 6-week point [Fig. 4]; bleb manipulation and commencement of AGM (in some cases) helped to minimize this variability. Five eyes with rising IOP underwent laser suture lysis; four of these responded well.

O'Rourke and colleagues[10] as well as Au and colleagues[11] have described bleb repair techniques similar to ours—but unlike our study, neither cohort consisted exclusively of bleb leaks. They utilized the technique with good effect (overall success 94%) in their cohort of 18 eyes, of which only 11 constituted of leakage. They, however, reported multiple post-operative interventions for re-establishing a good bleb function. Au and colleagues[11] on the other hand, reported a success rate of 79% in eyes that presented with bleb leak ($n = 14$) but also described the usage of multiple manipulations.

Several authors have also reported bleb excision and CA alone for bleb leaks.[15,17] Tannenbaum[17] and associates have a large series of 49 eyes; however, only 13 of these were repaired for leak and no separate analysis is presented. Al-Shahwan *et al*.[15] presented their series of bleb leaks in a Saudi Arabian population and noted a sharp drop-off in success rates after two years, even though the leak was sealed in all.

In our cohort, whenever nuclear sclerosis cataract of ≧ grade 2 was present, we preferred to combine BLR with phaco; this was performed in 8 eyes and has not been described before. All such eyes had controlled IOP at the final visit; vision improved in 6 eyes and was unchanged in 2. O'Rourke *et al*.[10] reported phaco surgery but only in the post-operative period; it is unclear whether the cataract was pre-existing or not.

We encountered failure in three eyes; one ICE syndrome eye underwent conservative TSCPC in the early postoperative period and another failed after 5 years and underwent Glaucoma Drainage Device Surgery. A third eye failed on our pre-defined criteria of success. Complications that were seen were mostly transient and self-limiting.

Even though our study may be limited by the relatively small number of cases and by its retrospective nature, there are several strengths that can be attributed to it. These are—the uniform presentation of late bleb leaks (due to a scleral melt/fistula) and the fact that each one was repaired by a standard technique by a single experienced surgeon and the long duration of follow-up. Our study also demonstrates that phaco can be safely combined with BLR; this is hitherto unreported.

Conclusion

We conclude that a scleral patch graft along with bleb excision and conjunctival advancement is the definitive management of bleb leak due to a scleral fistula, averting potentially catastrophic consequences. It not only restores the ocular integrity but also visually rehabilitates the majority of the eyes, with preservation of bleb function in the long term.

Disclosures:

Vanita Pathak-Ray—Santen, Novartis/Alcon, Allergan (Nil relevant).

Swathi V Badakere—nil.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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