Effectiveness of Needling Revision with Mitomycin-C for Failing Blebs
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Abstract
This surgical technique study was designed to evaluate the efficacy of surgical needling revision using Mitomycin-C to restore filtering function in scarred or encapsulated filtering blebs, and thereby minimize reliance on adjunctive medications. Twenty-eight eyes of 23 consecutive patients were studied, all having undergone operating room based bleb revisions for inadequate IOP-control during 2008-10. The standard needling procedure was performed as described with our previous data set, now using a 1-minute intra-bleb cannulation of 0.6 ml of 0.4 mg/ml MMC rather than multiple postoperative subconjunctival 5-fluorouracil injections. Outcome measures were IOP, number of anti-glaucoma medications, and acuity. Both mean IOP reduction and decrease in anti-glaucoma medications at all four measured time intervals (1 week, 1 month, 2 months, 6 months) post-operatively were highly significant (p<0.0001). IOP was reduced from a mean of 27.2 ± 10.6 mmHg pre-op to 15 ± 7.8 mmHg 6 months post-op (Δ -45%), with 86% of eyes requiring glaucoma medication prior to the procedure and only 16% thereafter. At six months, 60% of eyes had IOP ≤15 mmHg without medications, and 76% ≤18 mmHg. Visual acuity was stable or improved in 69% of cases. Mitomycin-C augmented needling revision appears to be a reasonably safe and reliable option for restoring bleb function in glaucomatous eyes with failed filters.

Introduction
Filtering procedures remain the most popular surgical option for controlling intraocular pressure (IOP) in medically refractory glaucoma. Incorporation of adjunctive anti fibrotic treatment has enhanced IOP control and prolonged filtering efficacy [1-3], but for various reasons some blebs are prone to failure months or years later. Sometimes that failure may take the form of hyperfiltration and hypotony, but more commonly it comes in the form of scarring or encapsulation of the bleb, with or without sclerostomy or scleral flap obstruction. In such cases the surgeon must decide whether to attempt to restore filtration or find other means for lowering IOP. Reversion to medical therapy is typically inadequate in patients who merited filtering surgery in the first instance. Various laser, tube shunt, canalostomy, and trabecular stripping procedures are among the options available today, each with its own merits and drawbacks. However, as long as there is no direct uveal obstruction of the internal sclerostomy or nonpenetrating drainage zone, restoration of the original filter remains a viable option [4-13].

We typically perform such bleb revisions as a major operative procedure under regional anesthetic block, allowing for very thorough elevation of the superior teno-conjunctival complex. Having the patient comfortably supine under the operating microscope facilitates introduction of viscoelastic to maintain ocular integrity and bleb elevation, simplifies re-opening the sclerostomy site, and provides for controlled introduction of antimetabolite treatment and thorough wound closure.

Methods
Twenty-eight eyes from 23 consecutive patients were evaluated. All had undergone needling revision between 2008-2010 using the same technique we described previously [14], with the only modification being the use of a single intraoperative intra-bleb infusion with MMC rather than multiple subconjunctival 5-fluorouracil (5-FU) injections for antimetabolite treatment.

As previously, all procedures were performed in the operating room with a retro bulbar and lid block using a mixture of anesthetic and hyaluronidase. Bleb re-elevation was performed with a pre-bent 25-gauge needle introduced through the conjunctiva 8-10 mm from the filtering site, at least 6mm posterior to the limbus. There was no fluid injected before or during the dissection, and both scarred and encapsulated blebs were dissected in similar fashion. Initially, a small, fan shaped area of teno-conjunctiva was elevated and removed to create the entry site and the old sclerostomy by rotating the tip of the needle through the fulcrum of the conjunctival puncture site. Once the shaft of the needle was fully inserted, the beveled needle-tip edge was used to cut the fibrous tissue beneath the conjunctiva until free movement of the entire needle across the bleb was attained from the superior rectus insertion to the limbal margin, without breaching the conjunctiva.

Once the bleb was completely dissected, a paracentesis was formed using a 25-gauge needle, and Healon viscoelastic (Abbott Medical Optics, Inc.; Abbott Park, IL) was injected intracameral to fill the anterior chamber and to confirm patency of the filtering site. Where necessary, the needle was used to effect an ab externo re-elevation of the old external sclerostomy flap and reopen the internal sclerostomy site. Next, 0.6 ml of 0.4 mg/ml MMC was carefully introduced throughout the bleb via the conjunctival entry site, and allowed to remain for 60 seconds. Care was taken to avoid introducing any antimetabolite into the viscoelastic-filled anterior chamber. This was followed by a thorough intrablble rinse-out through the conjunctival wound with 5 ml of balanced salt solution via a 27-gauge cannula. The needling entry site was then closed with a single 8-0 Vicryl (Ethicon Inc.; Somerville, New Jersey).

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NJ) purse-string suture and the corneal paracentesis were recannulated, injecting intracameral viscoelastic until a large, firm bleb was formed.

Patients’ progress was monitored for 6 months, at 4 time intervals (1 wk, 1 mo, 2 mo, 6 mo) post-op. Outcomes monitored were change in IOP, the number of anti-glaucoma medications required, and the visual acuity achieved. To eliminate non-independent variable bias, the data for IOP and medication use was averaged for the 5 patients that had both eyes included, providing a single data point for each of these variables for each subject.

**Results**

The patient population was 57% Hispanic, 30% Caucasian and 13% African American. Mean patient age was 72.3 ± 11 years. Two-thirds of eyes requiring the procedure had some form of chronic angle closure glaucoma, and the remainder had primary open angle glaucoma (POAG). The mean IOP pre-op was 27.2 ± 10.6 mmHg. Both the mean IOP decrease and the decrease in anti-glaucoma medications at all 4 measured time intervals (1 wk, 1 mo, 2 mo, 6 mo) post-op were highly significant (p<0.0001), with no evident divergence of the predominating Hispanic subpopulation’s IOP responses from those of the remainder.

The mean (±SD) IOP at 2 months was 10.6 ± 5.5 mmHg, which was a 61% decrease. By 6 months the IOP was 15 ± 7.8 mmHg, a 45% decrease from baseline (Figure 1). There were a mean of 2.5 ± 1.5 medications required preoperatively with a mean of 0.33 ± 0.73 needed six months post-operatively, an 88% reduction (Figure 2). All these results were highly significant (p<0.001). At six months, 60% of eyes had IOP levels ≤15 mmHg without meds, and 76% had pressures ≤18 mmHg overall.

Visual acuity was stable or improved in 69% of cases. An improvement of ≥2 lines, measured using standardized lane-length computer-generated semi-scotopic LogMar testing (Acuity System 3.8; Canela Software, Temecula, CA), was observed in 23% of cases, with a decline of ≥2 lines observed in 12% of cases. The remaining 50% of patients demonstrated no significant change in visual acuity (Figure 3).

**Discussion**

When a previously effective bleb fails, it is gratifying to be able to restore its function, and, in the process, restore the patient’s confidence in their original filtering surgeon’s work. The approach described above reutilizes fibrosed tissue rather than sacrificing adjacent virgin conjunctiva and sclera. The results of this study affirm that needling revision with Mitomycin-C can be very effective [15-20]. The mean IOP reduction from baseline and mean post-treatment IOP value attained at each time interval were all the same or better than those reported earlier among a similar patient population receiving multiple injections of 5-FU [14]. Conservation of visual function and reduction in medications and complication rates were also comparable. In this data set there were 8 patients that experienced one or more periods of hypotony, 3 patients generated hyphema, and 2 developed a bleb leak that required resuturing. Four patients required re-operation, highlighting the fact that although needling revision can significantly reduce IOP in many patients, it must always be undertaken with alternative options and risks in mind.

Latinos constitute the largest ethnic group in the Western Hemisphere. It has been anecdotally inferred that there could be a greater tendency for post-operative vascularization and scarring among the Mexican-American Latino population who made up a sizable proportion of this study group. If so, this might be expected to translate to a greater tendency for failure of bleb needling revision procedures. This study demonstrated no such difference between these two broad ethnic groups. Our earlier study using 5-Fluorouracil [14] also
demonstrated no greater tendency for postoperative scarring among the local South Texas Latino majority. One important shortcoming of the present Mitomycin-C needling study was that there were only 3 African American patients in the surgical study group. Since individuals of African heritage worldwide have a high prevalence of glaucoma, it is especially important to note here that 2 of the 4 eyes requiring re-operation in the total study group arose from among those 3 African American patients. A similar disproportionately high association for surgical failure with needling was found among the African American subgroup in our earlier published study with 5-Fluorouracil [14]. It would thus seem prudent to consider clinical or surgical approaches other than needling revision for patients of African heritage with failed glaucoma filters.

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References

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