Minimally Invasive External Mini-Glaucoma Shunt Implantation Without Conjunctival Dissection

Richard S. Hoffman, MD,* Alan S. Crandall, MD,† David A. Crandall, MD,‡ I. Howard Fine, MD,* Mark Packer, MD,* and Annette C. Sims, MD*

Abstract: The current method for implantation of the Ex-PRESS Glaucoma Filtration Device requires a conjunctival peritomy and shunt insertion under the guarded protection of a scleral flap. This technique requires suture closure of the flap and conjunctiva. A new minimally invasive technique for Ex-PRESS shunt implantation allows for insertion through a scleral tunnel originating from a grooved clear corneal incision. This new method avoids the need for conjunctival dissection and closure and offers the advantages of eliminating conjunctival wound leaks while maintaining the protection of a partial thickness scleral covering. This new technique may offer a faster safer means for shunt implantation with the potential for less conjunctival scarring.

Key Words: Ex-PRESS shunt, trabeculectomy, glaucoma surgery, glaucoma shunt

(J Glaucoma 2012;00:000-000)

We describe a new approach for implanting the Ex-PRESS mini shunt that utilizes a scleral tunnel starting from a clear corneal incision. The technique allows for shunt implantation without the need for conjunctival incisions and may offer a faster and safer method for glaucoma surgery.

TECHNIQUE

Before beginning the surgical dissection, the location for the shunt placement should be determined. A region with minimal episcleral vascularization with small caliber vessels should be chosen and areas which have undergone previous scleral incisions for cataract surgery should be avoided. The superior bulbar conjunctival vessels can be constricted with a circular Merocel sponge soaked in phenylephrine 2.5% and placed for 10 to 15 minutes. In addition, a superior subconjunctival injection of xylocaine 1% with epinephrine helps constrict the episcleral vessels and reduce the severity of subconjunctival bleeding when the scleral dissection is opened into the subconjunctival space.

The first step of the procedure involves a clear corneal incision placed just anterior to the conjunctival insertion. This incision can be created with a diamond or steel-step

Received for publication January 23, 2012; accepted June 5, 2012. From the *Drs Fine Hoffman & Packer LLC, Eugene, OR; †John A. Moran Eye Center, University of Utah, Salt Lake City, UT; and

[‡]Henry Ford Health System, Detroit, MI. Disclosure: Dr A.S.C. is a consultant for Alcon Laboratories. The

remaining authors declare no conflict of interest.

Reprints: Richard S. Hoffman, MD, 1550 Oak Street, Suite 5, Eugene, OR 97401 (e-mail: rshoffman@finemd.com).

Copyright © 2012 by Lippincott Williams & Wilkins

DOI: 10.1097/IJG.0b013e31826a7edf

knife and should be approximately 350 µm in depth and 4 mm in length (Fig. 1). A scleral pocket is then dissected posteriorly with a beveled crescent blade for approximately 3 mm (Fig. 2). The scleral pocket is opened into the subconjunctival space with either the crescent knife or a sharptipped diamond or metal keratome (Fig. 3). Most recently, a Sharpoint 1.1 mm paracentesis knife (Model 78-2010) has been found to facilitate entry into the subconjunctival space (DAC). A 90-degree bend is made at the tip of the knife and after passing the knife into the sclera pocket with the bent tip parallel to the plane of dissection, the tip is rotated into a vertical orientation to perforate the roof of the pocket (Fig. 4). The tip is then used to slice a complete full-length opening into the subconjunctival space.

After completion of the scleral tunnel, the wound is then opened by placing a small skin hook or Kuglin hook under the roof of the scleral tunnel and a Sinskey hook within the corneal stroma of the anterior aspect of the grooved clear corneal incision. An assistant would hold the Sinskey hook while the surgeon holds the skin hook in their nondominant hand. With gentle opposing traction, the Sinskey hook will pull the external anatomic structures overlying the trabecular meshwork anteriorly as the skin hook retracts the roof of the scleral tunnel, thus exposing



FIGURE 1. A 4-mm long grooved incision is made with a $350 \,\mu m$ step-knife just anterior to the conjunctival insertion.

J Glaucoma • Volume 00, Number 00, ■ ■ 2012

www.glaucomajournal.com | 1



FIGURE 2. A crescent knife is used to dissect a scleral pocket 3 mm posterior to the grooved incision.

the site for the mini-shunt placement (Fig. 5). A 27-G needle with a bent tip is then inserted into the anterior chamber, just anterior to the posterior aspect of the blue zone that overlies the region of the trabecular meshwork (Fig. 6). The needle tip should be bent and inserted so that the resulting microincision is parallel to the plane of the iris. The Ex-PRESS shunt is then inserted into the incision, initially rotated 90 degrees from its ultimate final position (Fig. 7). Once it is seated with the external flange against the sclera, it is rotated 90 degrees into the proper orientation and the injector is squeezed to release the shunt. Although it is not possible to orient the shunt insertion in the iris plane because of the current limitations in the injector design and the limited anatomic exposure; a properly constructed perforating microincision and the overlying scleral tunnel roof apposed against the shunt's external flange will ultimately orient the shunt tip parallel with the iris.



FIGURE 3. The scleral pocket is opened into the subconjunctival space with a sharp-tipped keratome creating a scleral tunnel.



FIGURE 4. A 1.1-mm paracentesis knife with the tip bent 90 degrees is used to open the sclera pocket into the subconjunctival space.

Once the shunt is in position, the hooks are removed and a single tangential 10-0 nylon suture is placed at the limbus to close the anterior aspect of the scleral tunnel. Beginning the suture placement in the floor of the tunnel will bury the knot in the grooved incision without the need for suture rotation (Fig. 8). No sutures are needed in the posterior aspect of the scleral tunnel and as no incisions are made in the conjunctiva, conjunctival closure is unnecessary (Fig. 9).

DISCUSSION

The idea of a minimally invasive glaucoma filtering procedure is not a new concept. Van Buskirk described a corneal trabeculectomy without conjunctival incisions that



FIGURE 5. A skin hook retracts the roof of the scleral tunnel while a Sinskey hook pulls the external anatomic structures overlying the trabecular meshwork anteriorly, exposing the site for minishunt placement.

2 | www.glaucomajournal.com

© 2012 Lippincott Williams & Wilkins



FIGURE 6. A 27-G needle with a bent tip is inserted into the anterior chamber parallel to the iris and anterior to the posterior aspect of the blue zone.

was started in clear cornea with a trapezoidal flap. The flap was dissected posteriorly into sclera to create a limbal pocket followed by entry into the subconjunctival space with a bent irrigating cystotome.¹ This technique required stromal tissue removal to create a fistula in addition to an iridectomy and sutured corneal flap closure. One year follow-up in 20 eyes undergoing this procedure demonstrated a 50% reduction in mean intraocular pressure (IOP) with 88% of patients having postoperative IOP <18 mm Hg without medications. In addition, rabbits undergoing this technique were found to have less subconjunctival inflammation and fibrosis compared with matched eyes that underwent traditional trabeculectomy utilizing conjunctival dissection.²

Lerner described a similar technique but differed in that a small limbal conjunctival peritomy was performed followed by dissection of the limbal pocket beginning anterior to the insertion of Tenon's capsule. It was expected that by avoiding dissection of Tenon's capsule and cauterization of episcleral vessels, less stimulus of the wound healing process would transpire. This technique also required creation of a fistula, an iridectomy, and closure of the conjunctival peritomy.³



FIGURE 8. A 10-0 nylon suture initiated in the base of the incision is utilized to close the wound.

The use of the Ex-PRESS shunt under a guarded scleral flap offers several advantages over traditional trabeculectomy. The restricted outflow from the 50 µm lumen limits the incidence of hypotony and flat anterior chambers. Thus, iridectomies are not required and this should result in a lower incidence of iridectomy related hyphemas. Eyes undergoing mini-shunt placement have been found to have higher IOPs in the immediate postoperative period compared with traditional trabeculectomy which has been demonstrated to result in fewer hypotony related complications such as choroidal effusions.⁴ Despite the higher IOP in the immediate postoperative period, shunt placement under a scleral flap was found to have similar or better results and success as trabeculectomy.^{4,5} Although the use of a guarded scleral flap has basically eliminated the



FIGURE 7. The Ex-PRESS shunt is inserted into the incision, initially rotated 90 degrees from its ultimate final position.



FIGURE 9. Bleb formation after closure of the tunnel opening with single horizontal 10-0 nylon suture.

© 2012 Lippincott Williams & Wilkins

www.glaucomajournal.com | 3

| Patient Number | | | | Postoperative Data | | | | | |
|-------------------|--------------------------|-----|--------------------------|--------------------|-----------------|------|-----------------|------|----------------|
| | Preoperative Data | | | Day 1 | | 1 Mo | | 3 Mo | |
| | Dx | IOP | No. Glaucoma Medications | IOP | No. Medications | IOP | No. Medications | IOP | No. Medictions |
| 1 | PXF | 13 | 4 | 16 | 0 | 17 | 0 | 14 | 0 |
| 2 | OAG | 19 | 2 | 16 | 0 | 14 | 0 | 18 | 0 |
| 3 | OAG | 13 | 3 | 4 | 0 | 9 | 0 | 10 | 0 |
| 4 | OAG | 13 | 4 | 9 | 0 | 13 | 0 | 11 | 0 |
| 5 | PXF | 18 | 1 | 12 | 0 | 13 | 0 | 13 | 0 |

TABLE 1. Minimally Invasive ExPRESS Shunt Implantation

occurrence of implant extrusion,^{6,7} complications can still develop including conjunctival wound leaks and procedure failure due to conjunctival scarring.

This new minimally invasive approach to Ex-PRESS shunt implantation offers several advantages over the current traditional method for shunt implantation. The lack of conjunctival dissection and scleral cauterization should result in less subconjunctival scarring² and perhaps a higher incidence of procedure success. As no conjunctival peritomy is performed, conjunctival wound leaks have been eliminated. There is still the potential for wound leaks from the corneal opening of the scleral tunnel; however, because of the nature of the wound being composed of corneal stroma, this opening can be easily managed with a single 10-0 nylon suture.

Currently, a traditional trabeculectomy is usually performed under a triangular or rectangular scleral flap to create a guarded procedure and gain access to the peripheral iris to perform an iridectomy. However, trabeculectomies have been successfully performed through a posterior scleral incision without the creation of a flap.^{8,9} The effective use of a scleral tunnel that does not require suturing in trabeculectomies¹⁰ validates its use in a minimally invasive shunt procedure. The ability to implant the shunt from an anterior approach and the absence of a required iridectomy obviate the need for a traditional scleral flap with radial incisions. In addition, the limited outflow of the Ex-PRESS shunt lessens the need to use a sutured flap as a means of titrating outflow.

The limitations of this new technique arise from the limited access to the subconjunctival space. Although elimination of scleral cauterization may lessen the degree of wound healing, it also allows for the possibility of significant subconjunctival hemorrhages when the subconjunctival space is entered with a keratome. The severity of hemorrhaging can be lessened with vasoconstriction from topically applied and subconjunctivally injected medications in addition to selecting minimally vascularized regions for shunt placement. What is not known with certainty is the effect subconjunctival hemorrhages would have on fibrosis and shunt failure in the absence of conjunctival dissection. Another drawback of this technique is a limited ability to apply antimetabolites to the subconjunctival space. One surgeon (D.A.C.) has been injecting 20 µg of mitomycin C (0.1 mL of 0.2 mg/mL) into the subconjunctival space through the sclera tunnel at the end of the procedure. In addition, 5-FU injections can also be given postoperatively if desired.

To date, a small number of glaucoma patients have undergone this technique. David Crandall has collected 3-month data on 5 of his patients who underwent combined temporal clear corneal phacoemulsification and superior Ex-PRESS shunt implantation (utilizing subconjunctival mitomycin) with impressive postoperative results (Table 1). All patients had adequate postoperative IOPs and there was an average reduction of 2.8 glaucoma medications. There were no complications other than 1 patient who developed a wound leak resulting from a broken 10-0 nylon limbal suture. The leak was successfully treated with a bandage contact lens. Although 3-month postoperative data are too preliminary to adequately assess the ultimate viability of this technique, it does highlight the possible feasibility and proof of concept.

We believe this technique offers a faster and safer approach to glaucoma filtering procedures and perhaps offers the option of multiple shunt placement sites that would be unaffected by previous surgical scarring. Clinical studies with a larger cohort of patients with longer followup will ultimately be required to assess the long-term viability of this minimally invasive technique.

REFERENCES

- Van Buskirk EM. Trabeculectomy without conjunctival incision. Am J Ophthalmol. 1992;113:145–153.
- Cioffi GA, Van Buskirk EM. Corneal trabeculectomy without conjunctival incision: extended follow-up and histologic findings. *Ophthalmology*. 1993;100:1077–1082.
- Lerner SF. Small incision trabeculectomy avoiding Tenon's capsule: a new procedure for glaucoma surgery. *Ophthalmology*. 1997;104:1237–1241.
- Maris PJ, Ishida K, Netland PA. Comparison of trabeculectomy with Ex-PRESS miniature glaucoma device implanted under a scleral flap. *J Glaucoma*. 2007;16:14–19.
- 5. De Jong LA. The Ex-PRESS glaucoma shunt versus trabeculectomy in open-angle glaucoma: a prospective randomized study. *Adv Ther.* 2009;26:336–345.
- Coupin A, Li Q, Riss I. Ex-PRESS miniature glaucoma implant inserted under a scleral flap in open-angle glaucoma surgery: a retrospective study. J Fr Ophtalmol. 2007;30:18–23.
- Kanner EM, Netland PA, Sarkisian SR, et al. Ex-PRESS miniature glaucoma device implanted under a scleral flap alone or combined with phacoemulsification cataract surgery. *J Glaucoma*. 2009;18:488–491.
- Ophir A. Mini-trabeculectomy as initial surgery for medically uncontrolled glaucoma. *Am J Ophthalmol.* 2001;132:229–234.
- Ophir A, Pikkel J. Mini-trabeculectomy in eyes with high risk of scarring: midterm follow-up. *Am J Ophthalmol.* 2001;131: 13–18.
- Lai JSM, Lam DSC. Trabeculectomy using a sutureless scleral tunnel technique: a preliminary study. J Glaucoma. 1999;8: 188–192.

4 | www.glaucomajournal.com

© 2012 Lippincott Williams & Wilkins