Ex-PRESS Glaucoma Filtration Device: Theory, Technique and Results

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ABSTRACT: The Ex-PRESS glaucoma filtration device (Alcon Laboratories, Fort Worth, TX, USA) is designed to drain aqueous fluid from the anterior chamber to the subconjunctival space and form a filtration bleb, akin to a trabeculectomy1. The Ex-PRESS glaucoma device is currently available in two models: an R-model and a P-model. The Ex-PRESS R-model has a beveled tip, an external diameter of 400 microns (27-gauge), an internal lumen of 50 microns, a total device length of 2.96 mm and a uniform back plate. The Ex-PRESS P-model has a decreased bevel angle, an external diameter of 400 microns, a total device length of 2.64 mm and a vertical channel back plate. It is available in both a 50-micron and 200-micron internal lumen size (Figure 1).1

The Ex-PRESS glaucoma device is composed of biocompatible stainless steel with a spur to prevent extrusion of the device and a flat external backplate to prevent intrusion2. The backplate and spur are designed to conform to angle anatomy, and the distance between them approximates that of the scleral tract made by the device3.

The P-model features vertical channels in the plate, designed to enhance posterior flow of aqueous and formation of a more diffuse posterior bleb. The devices also contain a relief port designed to provide an alternative pathway for aqueous should the axial lumen become occluded by iris, fibrin or blood1.

Surgical indications

The Ex-PRESS glaucoma device is indicated for use in open angle glaucoma. It is the authors’ experience that the device is effective in both wide open and narrow angles, as long as there is no peripheral anterior synechia in the area of intended implantation. The Ex-PRESS may be considered in patients who are candidates for a traditional trabeculectomy. Implantation of the Ex-PRESS shunt may be combined with lensectomy and intraocular lens (IOL) implantation.

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Figure 1. The Ex-PRESS R-model and P-model, with the dimensions and specifications of each.
Preoperative evaluation

It is important to determine the preoperative status, mobility, and health of the sclera and conjunctiva at the planned surgical site. Gonioscopy should be used to evaluate the anterior chamber angle for peripheral anterior synechiae at the planned insertion site. The crystalline lens should also be evaluated for the possibility of cataract, which can be treated with combined cataract-glaucoma surgery.

Original surgical technique

The original surgical technique involved placement of the device under a conjunctival flap only. Under local or topical anesthesia, a 2-4 mm circumferential conjunctival opening was created 10-15 mm posterior to the limbus. The device was introduced using an injector, and slid under the conjunctiva and Tenon’s capsule. The device was implanted parallel to the iris plane, radial to the limbus. This was routinely combined with phacoemulsification and insertion of an intraocular lens. Particular advantages to this approach included reproducibility and simplicity: the procedure does not require a scleral flap and is easily taught.

This technique is no longer utilized due to high failure rates secondary to postoperative complications with flow control and positioning of the device. Specifically with regards to flow control, there were concerns with persistent hypotony, flat anterior chamber, choroidal detachment, and suprachoroidal hemorrhage. Specific positioning concerns included conjunctival erosion, shunt extrusion, conjunctival scarring and tube exposure.

Current surgical technique

Under sterile field, the eye is first anesthetized with topical lidocaine. In combined surgery, the lensectomy and IOL implantation is performed prior to the Ex-PRESS implantation in order to ensure stability and deepen the anterior chamber, and to prevent excessive irrigation of fluid into the subconjunctival bleb. A temporal clear corneal or limbal incision is suggested for the cataract extraction to minimize manipulation and disturbance to the superior tissues where the bleb will ultimately form. Upon successful lensectomy and IOL insertion, viscoelastic should be left in the anterior chamber to maintain its stability. A suture is placed in the main incision to maintain watertight closure. The combination of viscoelastic and injected balanced saline solution ensures that intraocular pressure (IOP) remains adequately high to maintain globe and scleral rigidity.

A conjunctival peritomy is performed as the surgeon would normally do for a trabeculectomy, which is followed by light cautery to prepare the scleral surface. The surgeon should plan for an adequately sized scleral flap that is positioned according to where the Ex-PRESS device will be implanted, in an approach similar to a trabeculectomy scleral flap. The flap may need to be slightly larger in order to provide full scleral coverage over the footplate of the implant. A partial thickness scleral flap of one-half to two-thirds scleral thickness is created using a crescent blade just as the surgeon would normally do for a trabeculectomy. The shape of the flap is up to the surgeon’s discretion. The scleral dissection should be carried forward to the clear cornea to gain adequate exposure of the scleral spur, where the shunt will be implanted into the anterior chamber. Once the flap is prepared, an
Figure 4. (all measurements in millimeters): It is important to position and size the scleral flap in accordance with the anticipated site of implantation for the ExPRESS device. The surgical flap should be planned to provide adequate coverage lateral and posterior to the device in order to control aqueous flow.

Figure 5. Creation of a partial thickness scleral flap (about one-half to two-thirds scleral thickness). It is important to identify the scleral fibers and the scleral spur (the anticipated site of implantation), and continue the scleral dissection forward to the blue zone and clear cornea in order to ensure adequate exposure.

antimetabolite such as mitomycin-C (MMC) may be applied subconjunctivally and under the scleral flap, again in an approach similar to trabeculectomy.

After appropriate irrigation of the antimetabolite from the surgical field, a pilot hole is then fashioned using a sapphire blade (Alcon Laboratories, Fort Worth, TX, USA), a 26-gauge needle (if using a hypodermic needle) or a 25-gauge EdgePlus Trocar Blade (Alcon Laboratories, Fort Worth, TX, USA). The pilot hole is an opening into the anterior chamber and important for successful placement of the implant. The eye should be positioned pointing down, and the needle should enter at the anterior spur at the level of the iris plane (Figure 6). Angling the needle appropriately is of the utmost importance: a posteriorly directed shunt may result in iris touch and subsequent occlusion of the shunt’s ostia, while an excessively anterior shunt may result in corneal touch and consequent endothelial trauma.

After creation of the pilot hole, the implant is ready for insertion (Figure 7). The Ex-PRESS implant comes preloaded on an injector system. The injector device is rotated 90 degrees prior to insertion, and is rotated to its final position once inside the eye. It is important to ensure that the back plate is flush with the scleral bed (Figure 8). The device is released at the tip of the injector system when the surgeon’s index finger depresses a portion of the injector’s shaft. An adequately planned scleral flap should now provide good lateral and posterior coverage of the Ex-PRESS device.

Good closure of the scleral flap is achieved using 10-0 nylon sutures. Two sutures are placed in each corner, with a slipknot that can be locked. Additional sutures can provide more flow control, if required (Figure 9). Similarly, the slipknots can be tightened or loosened to adjust the tension on the flap. The rate of flow can be assessed by continuously injecting balanced salt solution into either the anterior chamber or through a side port.

Firm conjunctival closure is achieved using 10-0 Vicryl sutures in a running horizontal mattress
technique. This technique allows a good conjunctival closure which prevents early leakage, while reducing the amount of tension on the bleb, which may help with bleb morphology.

Postoperative considerations

Despite the resistance provided by the fixed lumen size, the use of sutures to control flow, and intraoperative evaluation of aqueous egress, postoperative hypotony remains a potential complication of the Ex-PRESS implant. This may be caused by flow around the shunt through the pilot hole incision in which it is placed. Early postoperative hypotony warrants careful assessment for conjunctival leak at the site of wound closure as it may be due to a conjunctival leak. Early or late hypotony may necessitate pressurization or reformation of the anterior chamber using ophthalmic viscosurgical devices (OVDs). The smaller lumen of the Ex-PRESS device calls for a stepwise approach in

Figure 7. The ExPRESS glaucoma filtration device comes preloaded on an injector device (7A). The injector is rotated 90 degrees prior to insertion (7B). The device enters the anterior chamber parallel to the iris (7C).

Figure 8. Final placement of the ExPRESS in the anterior chamber is slightly above and parallel to the iris (8A). The backplate of the device should be flush with the scleral bed (8B).

Figure 9. The scleral flap is closed with two sutures (10-0 nylon) in each corner, with a slipknot that can be locked (9A). Additional sutures can be used as required to control flow (9B).
Similarly, a study of 93 eyes found no difference in mean IOP lowering from 27.6 ± 8.7 mmHg to 12.4 ± 3.4 mmHg (significance not reported). Another report of 37 eyes demonstrated mean IOP lowering from 27.2 ± 7.1 mmHg to 14.5 ± 5.0 mmHg (p < 0.01). A report of 15 eyes with post-penetrating keratoplasty demonstrated mean IOP lowering from 41.5 ± 14.3 mmHg to 12.1 ± 5.2 mmHg (p < 0.001). Another report of 37 eyes demonstrated mean IOP lowering from 27.6 ± 8.7 mmHg to 12.4 ± 3.4 mmHg (significance not reported).

Several retrospective non-randomized case-control studies have compared the IOP lowering effects of the Ex-PRESS glaucoma device under a scleral flap with conventional trabeculectomy. A study of 100 eyes found no difference in mean IOP or success rates between groups, but the Ex-PRESS group demonstrated statistically significant lower rates of early postoperative hypotony and choroidal effusion. Similarly, a study of 93 eyes found no difference in mean IOP lowering or success rates, but the Ex-PRESS group had less early postoperative hypotony and choroidal effusion (although not statistically significant). A study of 70 eyes also reported no difference in success rates or mean IOP reductions, but higher IOP in the Ex-PRESS group at last follow-up (p = 0.008). The study also reported reduced rates of postoperative hypotony and hyphema in the Ex-PRESS group (although not statistically significant), faster visual recovery (p = 0.028), and less postoperative visits (p < 0.001). A study of 21 eyes found no difference in mean IOP but lower rates of shallow anterior chamber, hypotony, choroidal detachment (although not statistically significant), and hyphema in the Ex-PRESS group as well as improved visual recovery (p < 0.05).

A large retrospective non-randomized case-control study of 345 eyes found no difference in success rates when comparing Ex-PRESS alone with Ex-PRESS combined with phacoemulsification, both under scleral flaps. It is not possible to compare the postoperative IOPs directly between the groups because baseline IOPs were significantly different.

A prospective randomized control trial of 80 eyes comparing the Ex-PRESS device under scleral flap with conventional trabeculectomy demonstrated higher rates of success (p = 0.023) and lower mean IOP (12.0 ± 2.7 mmHg vs. 13.9 ± 4.3; p = 0.02) in the Ex-PRESS group at 1-year follow-up with similar complication rates. The same group reported 5-year follow-up data and found no difference in mean IOP or success rates between the two groups. 59% of Ex-PRESS patients and 46% of trabeculectomy patients demonstrated complete success (IOP < 18 mmHg without medications) (p = 0.25). 97% of Ex-PRESS patients and 100% of trabeculectomy patients demonstrated total success (IOP < 18 mmHg with or without medications).

From the data currently available on the Ex-PRESS glaucoma device implanted under a scleral flap (Table 1), the implant appears to provide an improved early postoperative safety profile without compromising IOP lowering efficacy when compared to trabeculectomy. Implantation of the Ex-PRESS device is a more predictable and reproducible technique, and less subject to the variability seen with trabeculectomy. In particular, there appears to be early postoperative advantages such as reduced rates of hypotony and choroidal effusion, faster visual recovery, and less postoperative visits.

Many of the studies are limited by their retrospective, non-randomized design.
Table 1. Data currently available on the Ex-PRESS glaucoma device implanted under a scleral flap

<table>
<thead>
<tr>
<th>AUTHOR, YEAR</th>
<th>Lankaranian 2011*</th>
<th>Dahian 2005*</th>
<th>Badhet 2009*</th>
<th>De Feo 2009*</th>
<th>Seider 2011*</th>
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<tbody>
<tr>
<td>STUDY TYPE</td>
<td>Retrospective non-control case series</td>
<td>Retrospective non-control case series</td>
<td>Retrospective non-control case series</td>
<td>Prospective non-control case series</td>
<td>Retrospective non-randomized case-control study</td>
</tr>
<tr>
<td>PATIENTS</td>
<td>100 eyes of 100 patients, mean age 77.4y, mean F/U 27.0m ± 13.2</td>
<td>15 eyes of 15 patients, mean age 60.7y, mean F/U 71.0m (26-104)</td>
<td>37 eyes of 35 patients, mean age 69y, mean F/U 18m (12-24)</td>
<td>93 eyes of 93 patients, mean age 71.0y, minimum F/U 6m</td>
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<tr>
<td>INTERVENTION</td>
<td>Ex-PRESS under scleral flap</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Resident-performed Ex-PRESS under scleral flap (n=36) + MMC</td>
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<tr>
<td>CONTROL</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Resident-performed trabeculectomy (n=57)</td>
</tr>
<tr>
<td>OUTCOME MEASURES</td>
<td>IOP success range: 5-21mmHg</td>
<td>IOP, number of glaucoma meds</td>
<td>IOP, number of glaucoma meds</td>
<td>IOP, number of glaucoma meds</td>
<td>IOP success range: 6-21mmHg, medications</td>
</tr>
<tr>
<td>RESULTS</td>
<td>Complete success in 60% at last F/U, mean IOP 27.2±7.1 decreased to 13.3±3.7 at 6m*, 14.5±5.0 at 12m*</td>
<td>Mean IOP 41.5±14.3 decreased to 12.1±5.2*. Complete success: 86.6% at last F/U. Total success: 93.3% at last F/U. Glaucoma medications: 3.2(2-4) decreased to 0.3(0-3)*</td>
<td>IOP: 27.6±8.7 decreased to 12.4±3.4 at last FU (significance not reported). Complete success &lt;18: 78.4%, qualified 5.4% Stringent IOP success range &lt;15: 70.3%, qualified 10.8%</td>
<td>No difference in IOP or proportional IOP decrease between groups at all FU points. Complete success higher in EX group at 3m (81% vs 61%, p=0.057), 6m (69% vs 47%, p=0.076) No difference at 12m (48% vs 45%, p=1.0) Total success similar at all time points. EX group used less medications at 3m, no difference at 6m or 12m</td>
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* statistical significance (p < 0.05); IOP: Intraocular pressure, measured in mmHg; F/U: Follow up; VA: visual acuity; AC, anterior chamber; w, weeks; m, months; y, years; EX, Ex-PRESS; Trab, trabeculectomy

Complete success: IOP within the predefined IOP range, without any glaucoma medications; Qualified success: IOP within the predefined IOP range, with the use of glaucoma medications; Total success: IOP within the predefined IOP range, with or without the use of glaucoma medications.
<table>
<thead>
<tr>
<th>Maris 2007\textsuperscript{1,2}</th>
<th>Good 2011\textsuperscript{3}</th>
<th>Sugiyama 2011\textsuperscript{4}</th>
<th>Kanner 2009\textsuperscript{5,5}</th>
<th>De Jong 2009\textsuperscript{6,6}</th>
<th>De Jong 2011\textsuperscript{7,7}</th>
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<tbody>
<tr>
<td>Retrospective non-randomized case-control study</td>
<td>Retrospective, non-randomized, case-control series</td>
<td>Retrospective, non-randomized, case-control series</td>
<td>Retrospective non-randomized, case control series</td>
<td>Prospective randomized control trial</td>
<td>Prospective 5 year follow-up (extension of previous trial listed)</td>
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<tr>
<td>100 eyes of 97 patients, mean age 66y, mean F/U 10.8m (3.5-18)</td>
<td>70 eyes of 70 patients, mean age 69y, mean F/U 28m ± 3.2</td>
<td>21 eyes of 21 patients, mean age (EX: 64.2y, trab 71.3y), F/U 12m</td>
<td>345 eyes of 300 patients, mean age 72.4y(combined) and 63.9y (EX\textsuperscript{*}, mean F/U 21.9m ±12.5 (combined) 25.7m ± 11.1(EX)</td>
<td>80 eyes of 78 patients, mean age 62.3y (EX), 68.9y (trab\textsuperscript{*}), mean F/U 49.9w (EX), 51.0w (trab)</td>
<td>78 eyes of 78 patients, mean age 62.4y(EX), 68.6y (trab), mean F/U 262.4w(EX), 265.6(trab)</td>
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<tr>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
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<tr>
<td>Trabeculectomy or phaco-trabeculectomy</td>
<td>Trabeculectomy</td>
<td>Trabeculectomy + MMC</td>
<td>Ex-PRESS under scleral flap + MMC</td>
<td>Trabeculectomy + MMC</td>
<td>Trabeculectomy + MMC</td>
</tr>
<tr>
<td>IOP success range: 5-21mmHg</td>
<td>IOP, bleb morphological features (Moorfields Bleb Grading System), medications, visual recovery, number of postoperative visits, IOP success range: 5-18mmHg</td>
<td>IOP success range: 5-21mmHg</td>
<td>IOP success range: 5-21mmHg</td>
<td>IOP success range: 4-18mmHg</td>
<td>IOP success range: &lt; 18mmHg</td>
</tr>
<tr>
<td>EX: IOP 26.2±10.5 decreased to 11.5±11.1</td>
<td>IOP: higher in EX group at 1y\textsuperscript{<em>} and last F/U\textsuperscript{</em>} (exact IOPs not reported). No difference in complete success: EX 77.1% vs trab 74.3% (p=1.00) or qualified success: EX 5.7% vs trab 8.6% (p=0.99) Bleb: no difference in bleb vascularity, height, diffuseness at last F/U. EX group returned to baseline visual acuity earlier\textsuperscript{<em>}. EX group required fewer visits in first 3 postoperative months (6.05 v 8.23)\textsuperscript{</em>}. No difference in medications at last F/U.</td>
<td>No difference in mean IOP or number of glaucoma medications at 1y. Improved visual recovery in Ex-PRESS group compared to trab\textsuperscript{*}. Higher rate of qualified success (EX 100% vs trab 81.8%) (p=0.167)</td>
<td>Both groups demonstrated statistically significant decrease in IOP at last FU No difference in success at 1y: Ex-PRESS alone (96.9%), combined (95.6%) (p=0.948)</td>
<td>EX had higher rate of complete success at 1y (84.6% vs 60%)\textsuperscript{<em>}, stringent complete success at 1y (76.9% vs 50.0%)\textsuperscript{</em>}. EX had lower IOP at 1y (12.0±2.7 vs 13.9±4.3)\textsuperscript{*}. No difference in glaucoma medications.</td>
<td>No difference in mean IOP at 5y: EX 11.5±2.9 vs. trab 11.3±1.9(p=0.73) or in complete success at 5y: EX 59.0% vs. trab 46.2% (p=0.25) or in total success at 5y: EX 97.4% vs trab 100% (p=0.49) EX group used less glaucoma medications at 5y (significance not reported)</td>
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Table 1. Data currently available on the Ex-PRESS glaucoma device implanted under a scleral flap (cont.)

<table>
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<tr>
<th>AUTHOR, YEAR</th>
<th>Lankaranian 2011</th>
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<th>Ates 2010</th>
<th>De Feo 2009</th>
<th>Seider 2011</th>
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<tbody>
<tr>
<td>ADVERSE EFFECTS</td>
<td>Conjunctival leakage (6%), hyphema (2%), choroidal detachment (2%), wound gap (1%)</td>
<td>Transient hypotony spontaneously resolved (20.8%), device iris touch (12.5%), transient choroidal effusion spontaneously resolved (8.3%), hyphema (8.3%), shallow AC requiring reformation (4.1%)</td>
<td>After Ex-PRESS, all clear grafts remained clear; edematous grafts became clearer; opaque grafts showed no change. No change in central corneal graft thickness. Bleb needling to lower IOP (20%)</td>
<td>Serous choroidal detachment (24.3%, with 2.7% necessitating intervention), hypotony (21.6%, with 16.2% necessitating AC fill)</td>
<td>EX group had lower rates of early postoperative hypotony, choroidal effusion, self-limited bleb leaks, but not statistically significant. Similar rates of prolonged postoperative hypotony, reoperation for glaucoma. EX group had higher rates of multiple laser suture lysis (LSL) procedures, and more LSL were done per patient*. Ex-PRESS group had higher rates of bleb leak requiring additional sutures, patients requiring AC reformation (not statistically significant)</td>
</tr>
</tbody>
</table>

* statistical significance (p < 0.05); IOP, Intraocular pressure, measured in mmHg; F/U, Follow up; VA, visual acuity; AC, anterior chamber; w, weeks; m, months; y, years; EX, Ex-PRESS; Trab, trabeculectomy

Complete success: IOP within the predefined IOP range, without any glaucoma medications; Qualified success: IOP within the predefined IOP range, with the use of glaucoma medications; Total success: IOP within the predefined IOP range, with or without the use of glaucoma medications.

With regards to adverse effects, many of the studies demonstrate an improved early postoperative safety profile with the Ex-PRESS device, particularly in regards to hypotony and choroidal effusion. However, given the relative rarity of the adverse outcomes and the limited sample sizes, many studies do not report statistical significance. Further trials, including prospective randomized control trials with sufficient numbers of patients and follow-up are warranted to strengthen the body of evidence.

**Diagnostic Imaging**

The American Society for Testing and Materials guidelines require magnetic resonance imaging (MRI) safety testing to evaluate materials for torque, displacement force, and radiofrequency heating under magnetic field. The Ex-PRESS glaucoma drainage device is composed of 316L stainless steel and was evaluated for movement with MRI using 1.5-Tesla (T), 3.0-T, and 4.7-T MRI scanning protocols. The process was performed with the Ex-PRESS device with both the P-50 and R-50 models.

The devices showed minimal temperature changes (< 0.3 °C) under all protocols. The devices showed no induced torque, displacement, or rotation under the 1.5-T and 3.0-T MRI protocols. Under the 4.7-T MRI protocol, the device was displaced to the limit of the testing field, and rotational force could not be calculated. Although the 316L stainless steel material is often described as non-magnetic, the Ex-PRESS glaucoma device does have ferromagnetic properties, as demonstrated under the 4.7-T MRI protocol. However, most MRI machines used in clinical settings worldwide use a magnetic field up to 3.0-T, and the device is safe under these conditions.

Seven eyes of five patients with the Ex-PRESS device previously implanted who underwent axial T1-weighted, axial and coronal T2-weighted with fat saturation, and whole brain proton density (PD)/T2-weighted images using a 1.5-T MRI were reviewed. Two (2) of the implants were under the conjunctiva, and 5 were implanted under a scleral flap, and mean time elapsed since surgery was 13 months (1-24 m). Interpretation of MRI scans of the orbit and brain are minimally affected by artifacts from the Ex-PRESS implant. Interpretation of optic nerve...
Biocompatibility

Postoperative inflammation and scarring after implantation of an implant stems from both the trauma of surgery and the biocompatibility of the implant. The biocompatibility of the Ex-PRESS device was established in a rabbit model. The device was implanted in the anterior chamber at the corneoscleral junction in the eyes of 8 white New Zealand rabbits while the other eye served as a control in each of the animals. Histopathological evaluation was carried out at 3 and 6 months postimplantation and found no evidence of active inflammation, and the lumen was patent in all samples at both timepoints. A thin, mature, fibrotic capsule of less than 0.04 mm thickness of fibroblastic nuclei without any inflammatory cells was noted in most cases; it covered up to 25% of the implant’s outer surface area with the lumen remaining devoid of any obstruction in all cases. There was no evidence of pathological reaction at 3 or 6 months in any ocular tissue within the proximity of the device (cornea, limbus, sclera, iris, lens, vitreous body) nor in any ocular tissues distant from the device (choroid, retina). All testing was undertaken in rabbit models, which is suitable due to the greater fibrin formation and cellular proliferation in the rabbit eye compared to the human eye. As such, the low-grade reaction in this rabbit model bodes favourably for application to human eyes.

Conclusion

The Ex-PRESS glaucoma device provides an alternative to conventional trabeculectomy and appears to have similar IOP lowering effects with a possible improved safety profile and improved intraoperative control and predictability. In patients who are being considered for trabeculectomy with or without phacoemulsification, consideration should be made for the Ex-PRESS shunt.
REFERENCES


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