The Ex-Press Implanted Under a Scleral Flap

An overview of the technique, research data, and clinical results.

BY PETER A. NETLAND, MD, PHD

Approved by the FDA, the Ex-Press Mini Glaucoma Shunt (Optonol Ltd., Neve Ilan, Israel) is a small device without a valve that lowers the IOP by shunting aqueous from the anterior chamber into the subconjunctival space. In experimental studies, the device showed good biocompatibility.[1]

During initial clinical trials, the device was placed near the limbus without a scleral flap, which was associated with erosion through the conjunctiva, hypotony, and other adverse effects.[2-6] These problems have been minimized by placing the device under a partial-thickness scleral flap,[7,8] which provides resistance to aqueous outflow and reduces the risk of conjunctival erosion. Unlike during trabeculectomy, the surgeon performs no iridectomy and no sclerectomy when implanting the Ex-Press device under a partial-thickness scleral flap. Despite similarities between the procedures, the implantation of the Ex-Press does not involve the excising of trabecular tissue.

This article focuses on the device's implantation and its results in studies and the clinic.

TECHNIQUES

After preparing a fornix- or limbus-based conjunctival flap, surgeons create a partial-thickness scleral flap, similar to that used for trabeculectomy,[8] and then apply mitomycin C to the area according to their preference. The Ex-Press is placed at the limbus, under the flap, through a 25-gauge needle tract.

Most commonly used is the P model (Figure 1). The R model, which has a longer stem, can be placed through a 27-gauge needle tract (Figure 2). Most surgeons use the device with a 50-µm internal diameter, although a version with a 200-µm internal diameter is available. The Ex-Press now comes preloaded on an inserter, which helps to guide the

Figure 1. Model P of the Ex-Press implant has a shorter stem than model R and is inserted in a 25-gauge needle tract under a partial-thickness scleral flap. The surgeon performed laser suture lysis during the postoperative period, with the subsequent formation of a well-functioning bleb and lowering of the IOP.

Figure 2. The earliest-available Ex-Press implant (model R) has a longer stem than model P of the device and can be inserted in a 27-gauge needle tract. Placed under a scleral flap during surgery, the device can be visualized with the slit lamp during the postoperative period.

DISCUSSION

BY ADAM C. REYNOLDS, MD

Using the Ex-Press Mini Glaucoma Shunt (Optonol Ltd., Neve Ilan, Israel) under a scleral flap as an adjunct to trabeculectomy appears to have numerous advantages over standard trabeculectomy. In several retrospective comparative and case-controlled series, including those cited in his article by Peter Netland, MD, PhD, the device's use appears to decrease the chances of early postoperative complications (including choroidal effusions, hypotony maculopathy, and shallowing of the anterior chamber) when compared with standard trabeculectomy.[1] Because an iridectomy is unnecessary when the Ex-Press is used in this fashion, the incidence of postoperative hyphema and inflammation may be lower as well. Standardization of the trabeculectomy's opening into the anterior chamber and decreased variation in aqueous egress are possible mechanisms to explain these results.

Nevertheless, few peer-reviewed prospective comparisons of trabeculectomy with or without the Ex-Press have been published to eliminate confounding variables and other biases that may influence these conclusions. One can expect that the ongoing Ex-Press Versus Trabeculectomy Study will satisfy this requirement to confirm these findings. This author is also curious whether the increased IOP lowering with the Ex-Press shunt seen in some early retrospective and prospective comparative studies[2,3] will be observed in a large, multicenter, randomized, prospective trial as well, especially after the first year. If the risk of early hypotony-related complications is indeed decreased by placing the Ex-Press under the trabeculectomy flap, surgeons may feel more comfortable about aggressively lowering the IOP during the early postoperative period, thus leading to lower long-term IOPs. Although subconjuctival fibrosis is thought to be the major cause of bleb failure over time in trabeculectomy, differences in aqueous dynamics and tissue healing at the trabeculectomy's ostia or scleral flap with the use of the Ex-Press may be important in determining long-term IOP.

As Dr. Netland points out, the long-term bleb-related complications of trabeculectomy are probably not affected by the use the Ex-Press. This acknowledgment highlights the major issue in the debate over whether to use the device in this way. As Dr. Netland states, the conjunctiva eroded over the Ex-Press in many cases in which the device was implanted subconjunctivally, as it was used originally. Additional case reports have described the device's erosion through the scleral flap and displacement into the anterior chamber when it was implanted under a scleral flap in trabeculectomy. Because the Ex-Press is fabricated from inflexible stainless steel, many surgeons are concerned that, over time, these adverse events will become much more common. The question that needs to be addressed is whether the apparent short-term decrease in early complications will be worth the added risk of as yet unknown rates of long-term complications. Only long-term study over the next 5 to 10 years can provide the answer. As Dr. Netland also acknowledges, the added cost of the device is another important consideration, although it needs to be balanced with the cost of complications, especially in the short term if they are indeed fewer.

These issues and others have contributed to many glaucoma surgeons' conservative approach to the Ex-Press such that they limit its use to cases in which the risks of a failed standard trabeculectomy or of short-term complications are higher. Such cases could include patients who have eyes with longer axial lengths or very low target IOPs, those who are of black race or whose skin color is dark, and those whose first eye experienced complications with a standard trabeculectomy. Because of the unknown long-term risks, the Ex-Press' limited use in younger patients requiring a trabeculectomy is likely prudent.

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device into the needle tract and releases the device when it is in the proper position.

After the Ex-Press' insertion, the surgeon should confirm that the tube's tip is properly positioned in the anterior chamber. If the tip is in the corneal stroma, the device must be removed and repositioned. The surgeon closes the flap with interrupted 10–0 nylon sutures (if laser suture lysis is planned) or with releasable sutures. The conjunctival flap is closed in the same manner as for trabeculectomy. In most instances, a viscoelastic is not needed during the procedure.

RESEARCH RESULTS

Maris et al compared the results of trabeculectomy in 50 eyes with the results of the Ex-Press' implantation under a partial-thickness scleral flap in 50 eyes.[8] In this study, the mean IOP in the immediate postoperative period was lower after trabeculectomy than after the device's implantation, although the long-term IOP control and surgical success rates were similar. Early postoperative hypotony and its sequelae were less common in the eyes that received the Ex-Press than in those that underwent a trabeculectomy.

In a series of 345 eyes, investigators compared the results obtained with the Ex-Press under a scleral flap (241 eyes) versus its implantation in combination with cataract surgery (114 eyes).[9] IOP control was similar in both groups, although a few individual time points had a significantly lower mean IOP after the Ex-Press' implantation alone versus in combination with cataract surgery. In this study, the device was effective alone or as a combined procedure with cataract surgery. The most common device-related complication in this series was a blocked tube, which occurred in six eyes (1.7%). Treatment with an Nd:YAG laser effectively removed the obstructing material in all cases. The obstruction was not visible in most of these eyes, although Nd:YAG laser treatment (1 to 2 mJ) of the tube's tip resulted in a dispersion of whitish particles near the tube's tip, an elevation of the bleb, and a reduction in the IOP.

REIMBURSEMENT

A new Ambulatory Procedure Classification group designation (APC 673) for the Ex-Press Mini Glaucoma Shunt (Optonol Ltd., Neve Ilan, Israel) became effective starting January 1, 2009. This designation increased the average reimbursement by more than $1,000 in hospital outpatient settings and $700 in ambulatory surgery centers. The higher payment should allow surgeons in an ambulatory surgery center to utilize the device in appropriate cases. The CPT code when submitting claims is 0192T.

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LONG-TERM COMPLICATIONS

Placing the Ex-Press under the conjunctiva can be associated with conjunctival erosion over the implant such that exposure and even extrusion of the device occurs.[10,11] Placing the device under a partial-thickness scleral flap minimizes but does not completely eliminate the possibility of its exposure.[12] Conjunctival erosion and the implant's exposure are treated with the removal of the device. The Ex-Press can also dislocate into the anterior chamber,[9,13,14] usually necessitating the device's removal. Long-term corneal problems are possible but have not been common in the studies reported to date. Long-term bleb-related problems are probably similar to those observed after trabeculectomy.

The Ex-Press is not ferromagnetic. In vitro testing has shown no movement of the device in an MRI field. Thus, patients with the device may have an MRI scan.

CLINICAL EXPERIENCE

When implanted under a scleral flap, the Ex-Press has certain advantages compared with trabeculectomy. The former causes less trauma to ocular tissue and less inflammation, because its implantation involves no sclerectomy or peripheral iridectomy. Because the internal diameter of the device is the same from procedure to procedure (unlike the preparation of a sclerostomy in trabeculectomy), the Ex-Press' placement has predictable results. Perhaps due to the device's resistance to aqueous flow, there are fewer complications, especially hypotony in the early postoperative period and its sequelae. Because the procedure is simpler and has fewer steps compared with trabeculectomy, the device's implantation requires less intraoperative time.

The disadvantages of the Ex-Press include its cost and the potential for device-related complications. The results obtained by the author and his colleagues suggest

that device-related complications are uncommon when the Ex-Press is implanted under a partial-thickness scleral flap.

The Ex-Press may be used for primary glaucoma surgery and, less commonly, for secondary surgery. Relative contraindications include young age (because of the lack of long-term biocompatibility studies) and chronic inflammation (because of the potential for the tube's/device's blockage).

CONCLUSION

When implanted under a scleral flap, the Ex-Press is effective by itself or in combination with cataract surgery. The device is as effective for long-term IOP control as trabeculectomy, and it minimizes early postoperative hypotony and its sequelae. Device-related complications are uncommon when the device is implanted under a partial-thickness scleral flap. ❑

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