Predictability and outcome of Ex-PRESS glaucoma miniature filtration device

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Introduction

Glaucoma is a progressive optic neuropathy, resulting in loss of retinal ganglion cells leading to progressive loss of vision. Treatment for glaucoma is directed at lowering the intra ocular pressure either pharmacologically or surgically. Traditional glaucoma surgery, such as trabeculectomy, has been performed for decades and has a proven track record of success. Unfortunately, many complications such as hypotony and slow visual recovery are known to occur and can lead to significant patient morbidity. New devices are being developed to allow surgeons to have increased control with more predictable postoperative results. One such device, the Ex-PRESS mini glaucoma shunt, has undergone changes in design and method of insertion making it more appealing for use in patients requiring IOP-lowering surgery. The purpose of this study was to establish the efficacy and safety of this miniature glaucoma filtration device in open angle glaucoma.

The Ex-PRESS device is a small, flow restricting, non valved device that was designed to lower intraocular pressure in eyes with glaucoma. In the initial clinical trials, the implant was inserted near the limbus, directly under the conjunctiva, thereby draining aqueous humor from the anterior chamber into the sub conjunctival space. However, this was associated with complications, owing to hypotony, erosion of the conjunctiva over the device. To avoid these complications, Dahan and Carmichael implanted the Ex-PRESS device under a partial-thickness scleral flap. The biocompatibility of the Ex-PRESS implant was evaluated in rabbits and in humans, showing little or no inflammatory reaction to the device.

Method

This is a prospective study of 28 patients who underwent Ex-PRESS implantation under the scleral flap. Eligibility criteria included age more than 20 years, who has uncontrolled IOP on maximally tolerated medical therapy. Modified trabeculectomy with Ex-PRESS implant was combined with cataract surgery in patients with visually significant cataract.

A fornix-based conjunctival flap was used. Surgery combined with phacoemulsification was performed at two sites again with a fornix-based conjunctival flap. In all eyes, a partial-thickness (approximately 50% depth) rectangular scleral flap was prepared, measuring approximately 4mm at the limbus. Mitomycin C 0.4 mg/mL was placed under the scleral flap for 2 minutes before irrigation with balanced salt solution in all eyes. Scleral flap dissected up to the clear cornea. Then a pre-incision was made into the anterior chamber using a 26G needle entering parallel to the iris. The device is a preloaded injectable device. The Ex-PRESS implant was inserted through the 26-gauge-needle tract at the limbus. No iridectomy was performed. Only balanced salt solution was used to maintain or restore the anterior chamber, by injection through an additional corneal incision. The scleral flap was then sutured using 10-0 nylon sutures. The number of nylon sutures used to close the scleral flap depended on the judgment of the amount of filtration by the surgeon. The conjunctiva was sutured over the limbus with interrupted, 10 O sutures.

Postoperatively, corticosteroids, and topical antibiotics were used 4 times a day. Antibiotics were used for 12 days. The steroids were tapered over 10 weeks according to the extent of wound healing. If pressures were below 8 mmHg or the anterior chamber flattened, atropine 1% twice daily was added.

Preoperative information included, patient age, sex, glaucoma diagnosis, history of surgical treatment for glaucoma, glaucoma medications, IOP and visual acuity. Postoperative data regarding IOP, medications, visual acuity, and complications were obtained on day 1, day 3, week 1, week 2, and months 1, 2, 3, 6.

Results of the most recent examination were used for the analysis of IOP, visual acuity, and success at the last follow-up examination.

The main outcome measures were mean intraocular pressure, postoperative medication use, visual acuity and incidence of complications. Surgical success was defined as an IOP of > 6 mmHg and <18 mmHg without the use of anti-glaucoma medication. Laser suture lysis and bleb needling to improve bleb function were not considered as failures of the procedure.

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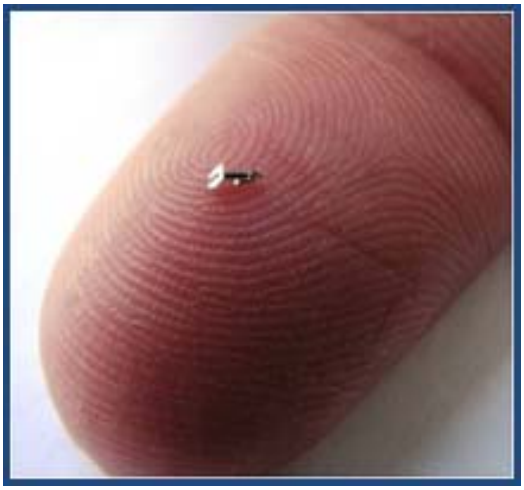
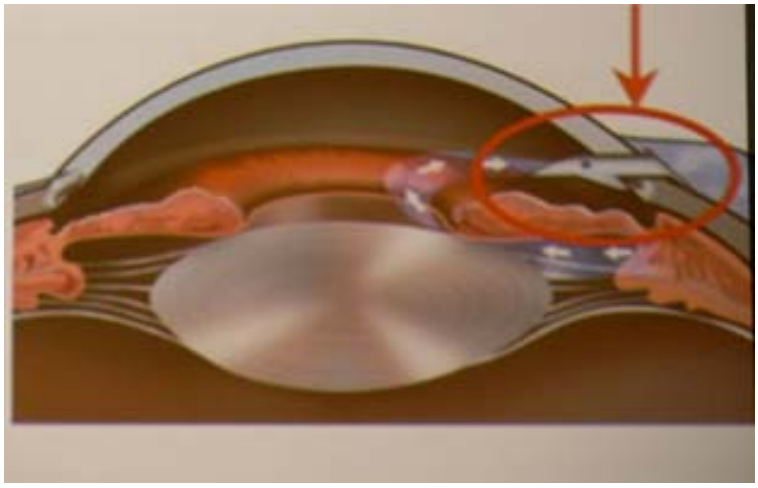
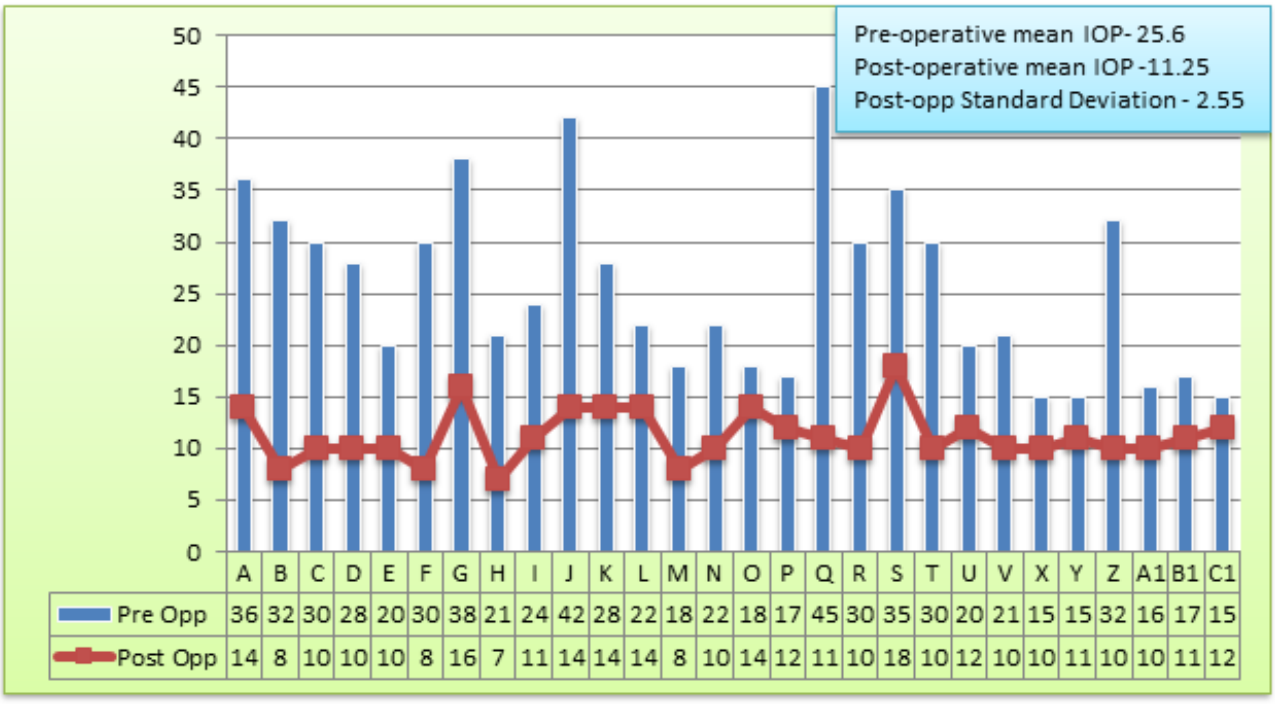




Preoperative data

Age (y), 51.38	Preoperative medications,
Right 17	Mean±SD 3.66±0.92
Left 11	Preoperative IOP
Previous glaucoma surgery	(mm Hg), mean±25.6
Yes 6	Type of glaucoma
No 22	Primary open-angle 22
	Combined mechanism 4
	Pigmentary 1
	Pseudoexfoliation 1



Results

out of the 28 patients 6 were repeat glaucoma surgeries. A total of 88% achieved complete success at 6 months follow up with no postoperative ocular hypotony and choroidal effusions.

Discussion

In this prospective study which analyzed the intraocular pressures following the Ex-PRESS implant with modified trabeculectomy, we found a mean IOP, of 11.25 mmHg with a standard deviation of 2.55. The success rate was 88% and this is similar to the success rates published for standard trabeculectomy. In this study non had ocular hypotony or choroidal effusions.

The advantages of this device include, its implantation does not require a sclerectomy or peripheral iridectomy. This may reduce the intraoperative time and minimize the postoperative inflammation. As this device has a controlled predictable flow, it minimizes the postoperative ocular hypotony and variability of results in different patients which occur in standard trabeculectomy.

This device is indicated in patients with open angle glaucoma inadequately controlled by medical treatment, aphakic/pseudophakic candidates for filtration surgery, in combined cataract and glaucoma, in failed previous glaucoma surgery, in uveitic glaucoma and traumatic glaucoma once the inflammation resolved and in neovascular glaucoma in conjunction with anti VEGF treatment. This procedure is contraindicated in patients with congenital glaucoma, chronic or acute angle closure glaucoma, in microphthalmic eyes and in the presence of AC IOL.

Histological biocompatibility of Ex-PRESS device in humans has been tested. A case report had been published in 2009 in Toxicologic pathology by Nyska et al. In that study, corneal endothelium showed normal endothelium with equivalent cell counts in the implanted eye compared to the fellow eye. Ex-PRESS shunt is made out of medical grade stainless steel and the presence of this material has a inhibitory effect on the inflammatory process (Shannon, Thull and Von Recum 1997).

Currently available magnetic resonance (MR) systems operate between 0.2 - 0.3 Tesla A magnetic resonance of up to 3 Tesla is safe for the Ex-PRESS device Interpretation of MRI scans of the orbit and brain were minimally affected but lower imaging quality of the optic nerve was noted in the presence of the Ex-PRESS device.

Bleb related complications still exist with the implantation of Ex-PRESS device and device related complications like erosion through conjunctiva or dislocation to the anterior chamber are also possible. But unlike previous studies of Ex-PRESS implantation without a scleral flap, no eyes in our study developed erosion through the conjunctiva and exposure of the device.

Conclusion

However, this study has potential sources of bias, and the length of the follow-up was relatively short. But certainly implantation of the Ex-PRESS device gives lower rates of complications and faster visual recovery compared to standard trabeculectomy.

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