Efficacy and safety of a steel drainage device implanted under a scleral flap

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ABSTRACT • RÉSUMÉ

Objective: To evaluate the efficacy and safety of a stainless steel miniature glaucoma drainage device (Ex-PRESS X200) implanted under a scleral flap for the surgical treatment of primary open-angle glaucoma (POAG).

Study Design: Clinical, prospective, noncomparative, nonrandomized study. The efficacy and safety were evaluated on the full sample, with a minimum follow-up of 12 months (maximum 24, mean 18).

Participants: Thirty-seven eyes of 35 patients.

Methods: The Ex-PRESS device was implanted under a scleral flap in patients with POAG.

Results: Preoperative intraocular pressure (IOP) was 27.6 (SD 8.7) mm Hg; at last follow-up, IOP was 12.4 (SD 3.4) mm Hg (55.1% reduction). The success rates (IOP < 18 mm Hg and < 15 mm Hg at last visit without medications) were 78.4% (29/37) and 70.3% (26/37), respectively. Kaplan-Meier analyses (probability of IOP < 18 mm Hg and < 15 mm Hg without medications) at last follow-up were 72.6% and 47.9%, respectively. Early postoperative complications were clinically mild and included postoperative IOP < 5 mm Hg; 12 cases at 1 day, 8 cases at 1 week, 3 cases at 1 month, 1 case at 3 months; serous choroidal detachment: 9 cases, of which 3 spontaneously resolved, whereas in 6 cases, hypotony and flat chamber were treated with viscoelastic injection in the anterior chamber. At last follow-up, 6 patients were treated with 2 IOP-lowering medications. No sight-threatening consequences of surgery were observed. There were 8 cases (21.6%, n = 37) of bleb needling.

Conclusions: Our data support the efficacy and safety of the implantation of this device under a scleral flap. The IOP reduction obtained was significant and long standing and complications were mild.

Objet : Évaluation de l’efficacité et de la sécurité des appareils miniatures en acier inoxydable pour le drainage du glaucome (Ex-PRESS X200) insérés sous le volet scléral lors du traitement chirurgical du glaucome primaire à angle ouvert (GPAO).


Participants : Trente-sept yeux de 35 patients.

Méthodes : L’appareil Ex-PRESS X200 a été inséré sous le volet scléral chez les patients atteints de GPAO.

Résultats : La pression intraoculaire (PIO) postopératoire était de 27,6 (ÉT 8,7) mm Hg; au dernier suivi, la PIO était de 12,4 mm Hg (ÉT 3,4); une baisse de 55,1 %. Les taux de réussite (PIO < 18 mm Hg et < 15 mm Hg à la dernière visite sans médicament) étaient de 78,4 % (29/37) et 70,3 % (26/37), respectivement. Les analyses de Kaplan-Meier (proabilité de PIO < 18 mm Hg et < 15 mm Hg sans médicament) du dernier suivi étaient de 72,6 % et 47,9 % respectivement. Les complications postopératoires précoces étaient cliniquement légères et comprenaient une PIO post opératoire < 5 mm Hg; 12 cas au 1er jour, 8 cas à 1 semaine, 3 cas à 1 mois, 1 cas à 3 mois; un décollement choroïdien sereux : 9 cas, parmi lesquels 3 se sont résolus spontanément, alors que dans 6 cas, l’hypotonie et la chambre plate ont été traitées avec des injections viscoélastiques dans la chambre antérieure. Au dernier suivi, 6 patients ont été soignés avec 2 médicaments pour abaisser la PIO. On n’a observé aucune conséquence menaçant la vue. Il y eut 8 cas (21,6 %, n = 37) de révision à l’aiguille de la bulle.

Conclusions : Nos données soutiennent l’efficacité et la sécurité de l’insertion de cet appareil sous le volet scléral. La réduction de la PIO obtenue était significative et durable et les complications étaient légères.

The Ex-PRESS (Optonol Ltd, Neve Ilan, Israel) is a miniature stainless steel drainage device, developed as an alternative to trabeculectomy filtration surgery for patients with primary open-angle glaucoma (POAG).1 The aim was to create a more reproducible and less traumatic procedure.

Trabeculectomy2 represents the most widely used filtering surgical procedure for uncontrolled POAG when medical and laser treatments are not sufficient.3 However, success rates are still not ideal and complications exist.4–7 Postoperative hypotony and bleb infections are of concern, especially when antifibrosis agents are required.8–13
The Ex-PRESS device bypasses the aqueous from the anterior chamber to the retroequatorial area, where a plate determines the minimum area of episcleral filtration. Tube shunts are employed when the conjunctiva cannot be mobilized to allow the dissection of a flap or when filtration surgery is deemed unsuccessful. Tube shunts are employed when the conjunctiva cannot be mobilized to allow the dissection of a flap or when filtration surgery is deemed unsuccessful.

The original technique of implanting this device directly under a conjunctival flap may cause conjunctival erosion, especially when mitomycin C has been used and if positioning is suboptimal. Because the conjunctiva alone is insufficient to control the initial aqueous flow during the early postoperative period, implantation under a scleral flap is currently recommended to prevent conjunctival erosion and to increase resistance to aqueous outflow in the immediate postoperative period.

Despite a number of studies that support the safety and efficacy of the subscleral technique, complications include hyphema, transient hypotony and associated hypotony maculopathy, bleb leak, transient choroidal effusion, device iris touch or dislocation into the anterior chamber, shallow anterior chamber requiring reformation, and endophthalmitis.

The implant is inserted at the limbus under a scleral flap, without excision of the corneoscleral tissue block and iridectomy, and diverts the aqueous humor from the anterior chamber to the episcleral space, forming a conjunctival filtration bleb, similar to trabeculectomy. The implantation can be performed on its own or in combination with phacoemulsification cataract extraction.

We report the long-term efficacy and safety of the X200 device implanted under a scleral flap (Flap-Ex-PRESS) for the surgical treatment of POAG.

**Methods**

This clinical, prospective, noncomparative, nonrandomized, unmasked study was conducted at Clinica Oculistica, DiN OG, Azienda Ospedaliera Universitaria San Martino, University of Genoa, Italy.

Patients were recruited consecutively. Eligibility criteria included an indication for glaucoma filtering surgery based on uncontrolled intraocular pressure (IOP) despite medications. Patients who required combined cataract surgery were excluded from this study. Eyes with angle-closure glaucoma, neovascular glaucoma, congenital or juvenile glaucoma, secondary glaucomas, or previous filtration surgery, and monocular patients were also excluded. All patients had had visual field examinations within 6 months prior to recruitment and had a confirmed diagnosis of POAG.

Upon enrolment, each patient had a complete ophthalmic examination; postoperative evaluations for the study were performed on days 1 and 7, and at months 1, 2, 3, 6, 12, 18, and 24 postoperatively. Measurements were made of best-corrected visual acuity (BCVA), slit-lamp biomicroscopy of the anterior and posterior segments, and IOP by applanation tonometry and gonioscopy. History and all medication details were recorded.

The drainage device is manufactured from medical-grade stainless steel. It has an external plate and an inner penetrating tip with 3 holes: 1 distal and 2 on its side. The lumen diameter is 200 μm and plate-to-spur distance is 1.2 mm. These devices (X200 series) were specifically designed for implantation under a scleral flap.

*Surgical technique: implantation under a scleral flap (Flap-Ex-PRESS)*

After dissecting a fornix-based conjunctival flap, a limbus-based scleral flap was fashioned as in trabeculectomy, but without the excision of a corneoscleral block and without iridectomy. Mitomycin C, 0.2 mg/mL, was applied for 3 minutes using filter paper cut to cover an area of at least 10 mm × 12 mm. The implant was then positioned directly under the scleral flap through a preparatory incision performed with a 25-gauge needle at the junction of the sclera and cornea, aiming the needle parallel to the iris plane. The scleral flap and the conjunctiva were closed with sutures (10-0 Nylon), as in trabeculectomy (Fig. 1).

Suture lysis/releasable sutures can be considered; however, they are not made specifically for the use of this device under a scleral flap.

**Follow-up**

At each follow-up, a complete ophthalmic examination was carried out, and the position of the device and the bleb conformation were recorded. Primary outcome measures were the IOP and the use of antiglaucoma medications or further glaucoma surgery procedures during the follow-up period. Secondary outcome measures included visual acuity and postoperative complications.

We certify that all applicable institutional and governmental regulations concerning the ethical use of human...
volunteers were followed during this research. Approval from the institutional review board was obtained. After receiving a comprehensive explanation of the nature of this procedure, each patient gave informed consent.

**RESULTS**

The device was implanted under a scleral flap in 37 eyes of 35 Caucasian patients with uncontrolled POAG. The mean age of the patients was 69 (SD 11.6) years. (Table 1 provides details of other demographic data). The mean follow-up period was 18 months (Table 1), ranging from 12 months \( (n = 9 \text{ eyes}) \) to 24 months \( (n = 14 \text{ eyes}) \). Median follow-up was 18 months.

**Efficacy**

Efficacy was evaluated with a minimum follow-up of 12 months; Kaplan-Meier analysis of survival was performed on the entire sample. Postoperative bleb manipulation and scarring modulation with needling or 5-fluorouracil (5 FU) injections are part of routine management\(^1,2\) and were not considered a criterion for failure.

The following criteria were used to define success:

- IOP < 18 mm Hg without antiglaucoma medications
- IOP < 15 mm Hg without antiglaucoma medications

Mean preoperative (baseline) IOP was 27.6 (SD 8.7) mm Hg, whereas at the final follow-up it was 12.4 (SD 3.4) mm Hg, a mean reduction of 55.1\% (Figs. 2 and 3). The success rate (without medications) was 78.4\% (29/37 eyes) with an IOP <18 mm Hg and 70.3\% (26/37 eyes) with an IOP <15 mm Hg (Table 2).

The success rates as determined by Kaplan-Meier analysis (IOP < 18 mm Hg and < 15 mm Hg without medications) at 12 months \( (n = 37) \), at 18 months \( (n = 28) \), and at 24 months \( (n = 14) \) were 72.6\% and 47.9\%, respectively (Fig. 4).

Before surgery, all patients were treated with IOP-lowering medications (number of active molecules ± SD: 2.9 ± 1.2).

Six patients (16.2\%, \( n = 37 \)) were treated pharmacologically at the final visit with 2 IOP-lowering medications. In 1 case, the postoperative IOP at last follow-up was higher than at baseline (a needling was needed at his last visit).

**Complications**

Short-term complications were clinically mild. There were 12 cases of IOP < 5 mm Hg (32.4\%, \( n = 37 \)) at 1 day, 8 cases (21.6\%) at 1 week, 3 cases (8.1\%) at 1 month, and

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**Table 1—Patient population and follow-up**

<table>
<thead>
<tr>
<th>Number of eyes (POAG)</th>
<th>37</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>35</td>
</tr>
<tr>
<td>Female</td>
<td>21 (60%)</td>
</tr>
<tr>
<td>Male</td>
<td>14 (40%)</td>
</tr>
<tr>
<td>Age ( y \pm SD )</td>
<td>69 ± 11.6</td>
</tr>
<tr>
<td>Range, ( y )</td>
<td>87–47</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>12 mo</td>
<td>37 eyes (100%)</td>
</tr>
<tr>
<td>18 mo</td>
<td>28 eyes (75.7%)</td>
</tr>
<tr>
<td>24 mo</td>
<td>14 eyes (37.8%)</td>
</tr>
</tbody>
</table>

Note: POAG, primary open-angle glaucoma; \( y \), years; mo, months.

**Table 2—Rate of success of surgery**

<table>
<thead>
<tr>
<th>Final IOP</th>
<th>Rate of success</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18 mm Hg</td>
<td>29/37 (78.4%)</td>
<td>Without medications</td>
</tr>
<tr>
<td>&lt;15 mm Hg</td>
<td>26/37 (70.3%)</td>
<td>Without medications</td>
</tr>
<tr>
<td>&lt;18 mm Hg</td>
<td>2/37 (5.4%)</td>
<td>Requiring 2 adjunctive medications for target IOP</td>
</tr>
<tr>
<td>&lt;15 mm Hg</td>
<td>4/37 (10.8%)</td>
<td>Requiring 2 adjunctive medications for target IOP</td>
</tr>
</tbody>
</table>

Note: IOP, intraocular pressure.
1 case (2.7%) at 3 months. There were 9 cases of serous choroidal detachment (24.3%); in 6 cases (16.2%) a viscoelastic injection in the anterior chamber at the slit-lamp was successfully used at 1 day and 1 week, whereas 3 cases resolved spontaneously (Table 3). In 1 case (2.7%), it was necessary to position 2 transconjunctival sutures to tighten the scleral flap at 3 months because of persistent hypotony (IOP = 4 mm Hg) and chronic choroidal detachment. No sight-threatening consequences of surgery were observed.

No cases of hyphema, shunt rotation, or iris incarceration by the device occurred after surgery.

In the postoperative period, bleb needling was performed in 8 eyes (21.6%, n = 37); these cases also received 5 FU injection, at the same time or on different days.

There were no significant variations in BCVA between preoperative and last follow-up visit, except for 2 patients who lost more than 2 lines of BCVA because of the development of cataract, which had not been operated on yet at the end of follow-up.

There were no other complications observed during the follow-up period.

Conclusions

In our study, the implantation under a scleral flap of the Ex-PRESS stainless steel glaucoma drainage device produced success rates of 78.4% and 70.3%, respectively, for the end points of IOP < 18 mm Hg and < 15 mm Hg, without adjunctive antiglaucoma therapy. Kaplan-Meier calculations of the cumulative proportion of cases that maintained an IOP < 18 mm Hg and < 15 mm Hg without medications at 1 year were 72.6% and 47.9%, respectively. This success rate compares favourably with data reported in the literature for other filtering procedures: 50%–100% for trabeculectomy, up to 87.5% for nonpenetrating surgery, and 25%–90% for other glaucoma drainage devices.

The efficacy and safety of the Ex-PRESS device in combined surgery with phacoemulsification was reported recently. In a sample of 25 patients with a mean follow-up of 23.9 months, the overall success rate (IOP ≤ 21 mm Hg with or without medications) determined via Kaplan-Meier was 76.9%. Preoperative IOP was 21 (SD 4) mm Hg; at 1, 2, and 3 years, IOP was 15.3 (SD 3.1) mm Hg (35% reduction), 16.6 (SD 2.7) mm Hg (29% reduction), and 16 (SD 2.6) mm Hg (22% reduction), respectively. Early postoperative complications were clinically mild and included 6 cases of hypotony (IOP < 5 mm Hg) and 3 cases of hyphema (< 2 mm). Two cases (7.7%) of device rotation and 3 cases (11.5%) of conjunctival erosion at 2 and 3 years were reported.

To prevent complications due to suboptimal positioning, implantation under a scleral flap is now used. This technique was introduced by Dahan and Carmichael for patients with refractory glaucomas. They evaluated 24 eyes of 23 patients: 16 eyes (66%) had had previous failed filtering surgery, whereas the remaining 8 eyes (33%) were at high risk for failure. The IOP was significantly reduced, from 27.2 (SD 7.1) mm Hg preoperatively to 14.5 (SD 5.0) mm Hg at 12 months (n = 21) and 14.2 (SD 4.2) mm Hg at 24 months (n = 8). They reported a success rate (IOP ≤ 21 mm Hg) of 83.3% (20/24 eyes) and few complications.

A recent study rated the difference between Ex-PRESS implant and trabeculectomy in 100 eyes: 50 eyes in 49 patients treated with the Ex-PRESS miniature glaucoma implant under a scleral flap and 50 matched control eyes in 47 patients treated with trabeculectomy. The results showed that early postoperative hypotony and choroidal effusion were significantly more frequent after trabeculectomy compared with Ex-PRESS implant under scleral flap (p < 0.001) and that Ex-PRESS implanted under a scleral flap had a similar capacity to lower IOP as trabeculectomy but with a lower rate of early hypotony. In this study, a device with a lumen equivalent to 50 μm was used. We implanted devices with a 200 μm lumen and this might explain the difference in early hypotony rates between our data.

Coupin et al. studied a series of 82 Caucasian patients (99 eyes) with open-angle glaucoma. The Ex-PRESS devices were inserted under the scleral flap in the anterior chamber; where indicated, a combined surgery was performed (28 eyes). The IOP decreased from 22.9 (SD 5.3) mm Hg preoperatively to 14 (SD 2) mm Hg at 6 months and

Table 3—Rate of surgical complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>n (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serous choroidal detachment</td>
<td>9 (24.3%)</td>
<td>8 spontaneously resolved, 1 required transconjunctival suturing of the scleral flap</td>
</tr>
<tr>
<td>Hypotony (&lt;5 mm Hg)</td>
<td>8/37 (21.6%)</td>
<td>6 (16.2%) treated with injection of viscoelastic in the anterior chamber at the slit-lamp</td>
</tr>
<tr>
<td>Hyphema</td>
<td>None</td>
<td>—</td>
</tr>
<tr>
<td>Shunt rotation</td>
<td>None</td>
<td>—</td>
</tr>
<tr>
<td>Iris touch</td>
<td>None</td>
<td>—</td>
</tr>
</tbody>
</table>

Note: wk, week.
14.3 (SD 2.3) mm Hg at 1 year. The success rate was 86.9% (IOP < 21 mm Hg with or without drugs). Success, defined as IOP < 21 mm Hg without medications, was achieved in 62.6%. In 13 eyes, IOP was not controlled with eye drops, and 9 eyes underwent further glaucoma surgery.

In our study, a relatively small number of short-term complications were observed. The rate and type of complications, such as shallow or flat chamber, were similar to other filtering surgery techniques and without long-term complications. At the last visit, only 6 patients in our sample required antiglaucoma medications, a better rate than commonly reported for trabeculectomy.\(^5,6,7,28,35\) This finding is relevant because hypotensive topical medications can induce subclinical inflammation of the conjunctival and subconjunctival tissues, further compromising the success of filtering surgery by stimulating fibroblast activation.\(^27\) Avoiding topical medications obviously also improves the patient’s quality of life.

Bleb subconjunctival scarring leading to bleb encapsulation or failure is the main cause of insufficient IOP control in conventional filtering surgery; fibroblast proliferation is triggered by the surgical trauma. To minimize the risk of scarring, intraoperative antimetabolites and postoperative bleb manipulation with or without injection of antimetabolites are commonly used.\(^3,4,24,27,29,36\) We used intraoperative mitomycin C in all cases and in 8/37 eyes (21.6%) 5 mg 5 FU injections in the postoperative follow-up. Modulation of wound healing and bleb management are standard of care and should not be considered as an indication of failure.\(^1,24\)

Recent data\(^37,38\) report percentages of needling after standard trabeculectomy of 42.1% and 25.2%, respectively. Our data seem to support the hypothesis that a lower intraoperative traumatism with this technique (e.g., no need for iridectomy) could have a positive effect in reducing any fibrotic tissue reaction.

In summary, our results demonstrate that the Ex-PRESS device positioned under a scleral flap is effective in lowering the IOP in POAG and is not associated with significant complications, either in the short or long term.

Our data indicate that this procedure can be considered as an alternative to conventional filtering surgery for the control of IOP in patients with open-angle glaucoma. Randomized prospective studies are needed to confirm these and other results\(^33\) suggesting better surgical success than conventional trabeculectomy, and to assess whether the additional expense due to the cost of the implant will be justified.

Further studies comparing this technique prospectively with trabeculectomy and other procedures are warranted to assess precisely the role and relative advantages and disadvantages of each filtration surgery technique.

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References

Steel glaucoma drainage device—De Feo et al.


**Keywords:** filtration surgery, glaucoma drainage devices, Ex-PRESS device.