• Clinical Research •

Modified deep sclerectomy combined with Ex-PRESS filtration device versus trabeculectomy for primary open angle glaucoma

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Abstract

• AIM: To compare the efficacy of modified deep sclerectomy combined with Ex-PRESS shunt versus trabeculectomy in primary open angle glaucoma.

• METHODS: This is a prospective cohort comparative single-center study. Forty-nine eyes of 49 patients were enrolled in the study. Patients were randomly divided into two groups. Group A (22 patients) underwent classic trabeculectomy and group B (27 patients) underwent modified deep sclerectomy combined with insertion of Ex-PRESS model P50 drainage device.

• RESULTS: Mean age was 69±7y in group A and 64±8y in group B (*P*=0.03). The mean reduction was 11.1±5.7 mm Hg in group A compared to 15.8±5.7 mm Hg in group B at 6mo (*P*=0.006), and 9.8±4.9 mm Hg and 15.4±4.7 mm Hg respectively at 1y (*P*=0.0001). Regarding the postoperative glaucoma medication, significant difference was observed between the two groups (in favour of group B) only at 6mo (*P*=0.017). At the end of the follow-up period complete success rate in group A was 68.2% compared to 92.6% in group B (χ^2 test, *P*=0.07) and qualified success rate was 100% in both groups.

• CONCLUSION: Modified deep sclerectomy combined with Ex-PRESS shunt may provide comparable IOP reduction with fewer complications in management of primary open angle glaucoma.

• **KEYWORDS:** modified deep sclerectomy; Ex-PRESS drainage device; trabeculectomy; glaucoma

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INTRODUCTION

Trabeculectomy is currently considered the standard surgical procedure for treatment of glaucoma since its first description by Cairns[1]. This technique has many advantages regarding the hypotonic effect, however it can cause early postoperative complications, including hyphema, excessive filtration leading to shallow or flat anterior chamber, choroidal detachment, hypotony, maculopathy, and suprachoroidal hemorrhage[2-6].

The Ex-PRESS glaucoma filtration device (Alcon Laboratories, Fort Worth, TX, USA) was developed as an alternative to the classic trabeculectomy with the advantages of inducing minimal inflammation, as no iridectomy is required, decreasing early postoperative complications and a reduced requirement for postoperative hypotonic medications[7].

Deep sclerectomy is a non-penetrating filtering procedure alternative to trabeculectomy, for the surgical treatment of open angle glaucoma, with advantages of decreased postoperative complications[8-11].

In this study we describe the technique of modified deep sclerectomy combined with insertion of Ex-PRESS filtration device (MDS-XPress) and we compare it with the classic trabeculectomy.

SUBJECTS AND METHODS

This is a prospective cohort comparative study, which has been conducted according to the tenets of the Declaration of Helsinki and after local Ethics Committee approval. Informed written consent was obtained from the patients.

Forty-nine eyes of 49 patients were enrolled in the study. Patients were randomly divided into two groups. Patients of group A underwent classic trabeculectomy as described by Cairns[1] and patients of group B underwent modified deep sclerectomy combined with insertion of Ex-PRESS model P50 drainage device as described below.

Description of the Technique

Modified deep sclerectomy combined with Ex-PRESS filtration device The first step of the surgical technique is a fornix based conjunctival and Tenon's dissection with peeling of the Tenon's remnants. A 5×5-mm^2 superficial sclera flap one third of the sclera thickness is dissected into clear cornea at 12 o'clock or slightly nasally. Mitomycin-C (MMC) is used at a concentration 0.2 mg/mL or 0.02% for 2min using soaked weck cell sponges under the conjunctiva/Tenon's space and under the superficial scleral flap at the same time, followed by 20 mL irrigation of balanced salt solution (BSS). Then a 4×4-mm^2 deep sclera flap is fashioned to create a trabeculo-descemet membrane. The extent of the excision is up to the Schlemm's canal. The deep flap is then excised. The inner wall of the Schlemm's canal is left intact. In this way no aqueous percolation occurs.

A paracentesis is performed temporally followed by injection of viscoelastic material 1%. After that, the paracentesis is sealed by using BSS injection. The anterior chamber is then entered at the trabeculodescemetic membrane level with a 25 G needle and the Ex-PRESS mini shunt is inserted. The superficial flap is sutured with at least two 10/0 Nylon (the number of the sutures is left at the surgeon's discretion). The viscoelastic material is removed by the temporal paracentes is and sealed again with BSS. A meticulous observation of the filtration site and the anterior chamber depth is performed (this parameter determines the final number of sutures) and finally, the conjunctiva/Tenon's layers are sutured with 10/0 Nylon sutures. No space maintainer was used, other than viscoelastic.

Trabeculectomy Trabeculectomy was performed with the use of Luntz-Dodick punch 0.5 mm, creating a flap of 5×5-mm^2 size and thickness equal to half of the sclera. MMC 0.2 mg/mL was injected under the flap and under the conjunctiva in all cases for 2min.

All patients were operated by the same experienced surgeon (Kozobolis V).

Postoperative management in both groups included frequent application of topical steroids tapered down over several weeks.

Inclusion criteria Patients with uncontrolled [intraocular pressure (IOP) >21 mm Hg] primary open angle glaucoma (POAG), despite maximally tolerated drop therapy, were included.

Exclusion criteria Patients with any previous glaucoma surgical procedure, co-existing retinal diseases or history of eye injury and/or trauma were excluded from the study.

Postoperative follow-up Postoperative data were collected at 1wk, 1, 3, 6 and 12mo. Complete success was defined as a final IOP ≤21 mm Hg without antiglaucoma drops, qualified success was defined as IOP ≤21 mm Hg with or without drops, and failure was considered when IOP was >21 mm Hg despite medications, when an eye required further glaucoma surgery or when hypotony with IOP <4 mm Hg was present.

Table 1 Intraocular pressures over time

Time point	Group A	Group B	*P*
Preoperative	27.3±3.5	32.1±5.6	0.002 (Mann-Whitney *U* test)
1wk	8.8±4.6	7.7±2.9	0.372 (Mann-Whitney *U* test)
1mo	12.5±4.8	12.4±2.2	0.875 (unpaired *t*-test)
3mo	15.5±4.8	14.3±3.1	0.349 (unpaired *t*-test)
6mo	16.2±4.4	16.3±3.3	0.808 (Mann-Whitney *U* test)
12mo	17.5±3.4	16.7±2.8	0.227 (Mann-Whitney *U* test)

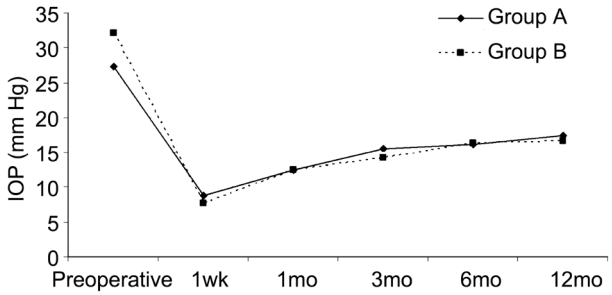

Figure 1 Mean IOP overtime in eyes undergoing MDS-Xpress or trabeculectomy.

Statistical Analysis All parameters used in the study were expressed as the mean±standard deviation (SD). Normality of the data was tested with the Kolmogorov-Smirnov test and parametric and non-parametric tests have been applied accordingly. Furthermore, Chi-square (χ^2) test was used to compare success rate between the two groups. A P<0.05 was used to mark statistical significance. All statistics were performed using MedCalc ver.15.2 (MedCalc Software bvba, Ostend, Belgium). Power of all tests was greater than 0.9.

RESULTS

Group A (classic trabeculectomy) consisted of 22 patients (12 males and 10 females), whereas group B consisted of 27 patients (14 males and 13 females). Mean age was 69±7y in group A and 64±8y in group B (unpaired *t*-test, P=0.03).

No changes were observed in best corrected visual acuity in either group.

Preoperative and postoperative IOPs are shown in Table 1 and Figures 1, 2. Significant IOP reduction was observed in both groups throughout the follow-up period (Friedman test, P<0.00001). The mean reduction was 11.1±5.7 mm Hg (39.8%) in group A compared to 15.8±5.7 mm Hg (48.4%) in group B at 6mo (IOP reduction, unpaired *t*-test, P=0.006; %IOP reduction, unpaired *t*-test, P=0.04), and 9.8±4.9 mm Hg (35%) and 15.4±4.7 mm Hg (47.3%) respectively at 1y (IOP reduction, Mann-Whitney *U* test, P=0.0001; %IOP reduction, unpaired *t*-test, P=0.001).

Regarding the postoperative glaucoma medication, significant difference was observed between the two groups only at 6mo (P=0.017). Mean medicine free survival time in group A was

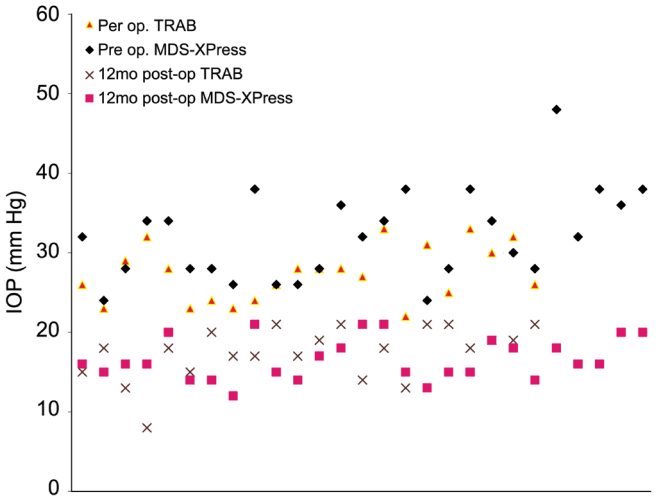

Figure 2 Preoperative and 12mo postoperative IOP in both groups.

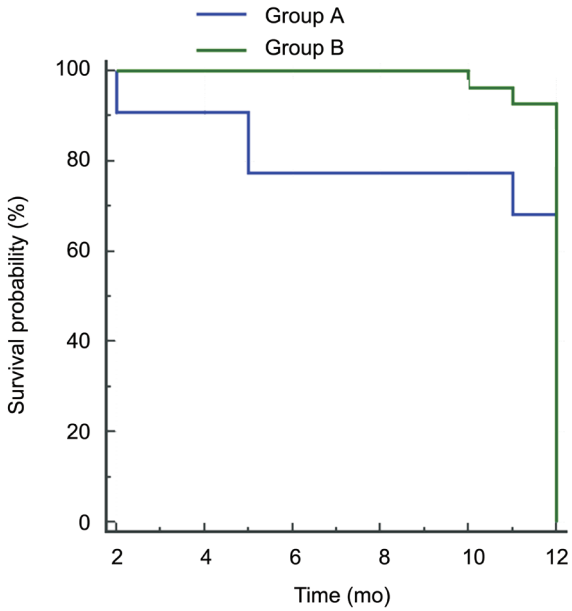

Figure 3 Kaplan-Meier medicine free survival curves in both groups.

10.05±3.55mo, whereas in Group B it was 11.89±0.42mo (log-rank test, P=0.025) (Figure 3). Detailed status of postoperative glaucoma medications is depicted in Table 2.

At the end of the follow-up period (12mo) complete success rate in group A was 68.2% (15 patients) compared to 92.6% (25 patients) in group B (χ^2 test, P=0.07) and qualified success rate was 100% in both groups. In group A 50% of patients (11 patients) and 74.1% (20 patients) in group B had an IOP ≤18 mm Hg without any medication at 12mo (χ^2 test, P=0.15) (Table 3).

The need for postoperative needling with the injection of MMC 0.02 mg/mL or 0.002% under the conjunctiva was as follows; group A: 6 patients (27.3%) and group B: 5 patients (18.5%) (χ^2 test, P=0.7). Following this postoperative approach no failure was observed in either group over the 12-month follow-up period.

Table 2 No. of glaucoma medications postoperatively

Time point	Group A	Group B	P (Mann-Whitney U test)
1wk	0	0	-
1mo	0	0	-
3mo	0.09±0.29	0	0.19
6mo	0.23±0.43	0	0.017
12mo	0.36±0.58	0.07±0.27	0.08

Table 3 Success rate in both groups

Parameters	Group A	Group B	P (χ^2 test)
IOP≤18 mm Hg	50%	74.1%	0.15
Complete success	68.2%	92.6%	0.07
Qualified success	100%	100%	-
Failure	0	0	-

DISCUSSION

Trabeculectomy after the initial description became the gold standard surgical treatment for glaucoma[1]. Despite its success in lowering the IOP it has numerous early and late complications[12]. Trabeculectomy also has a low quality of life (especially in early glaucomatous damage) and an increased risk of serious complications such as vision loss compared to medical treatment[13-14].

In order to overcome these issues the notion of non-penetrating glaucoma surgery (NPGS) has been introduced with deep sclerectomy and canaloplasty being the most common procedures of this kind. Indeed these procedures, although less effective than trabeculectomy in lowering the IOP, have a safer profile[15-16].

A recent breakthrough in glaucoma surgery has been the marketing of the Ex-PRESS mini shunt, initially inserted under the conjunctiva[17], but later positioned under a scleral flap[18]. The Ex-PRESS shunt has similar hypotensive effects as does the trabeculectomy but with a similar if not safer profile[19-20].

MDS-Xpress technique aims to combine the safety offered by the NPGS with the high hypotensive effect of the mini shunt. The advantage of the Ex-PRESS is the formation of an episcleral lake as seen with the aid of the optical coherence tomography[21], in which the aqueous can accumulate and then instead of forming a drainage bleb under the conjunctiva, it can be drained away by other routes (suprachoroidal, intrascleral vessels and Schlemm's canal). These routes are opened with the deep sclerectomy technique but not with the standard trabeculectomy. The formation of a smaller bleb obviates the risks associated with the bleb (infection, encapsulation, aqueous leakage).

The combination of deep sclerectomy with the insertion of an Ex-PRESS shunt has been described by other authors. In a similar technique Gindroz *et al*[22] reported in a prospective study on modified deep sclerectomy using the Ex-PRESS LR-50 in combined cataract and glaucoma surgery and showed that this technique efficiently lowers IOP in combined surgery,

preventing conjunctival erosion, a significant complication when using this device without scleral flap coverage. The complete and qualified success rates were 45.6% and 85.2% respectively with target IOP at 18 mm Hg.

Bissig *et al*[23] described the use of the Ex-PRESS X-200 model in conjunction with deep sclerectomy. After a mean follow up period of 18.6mo they report an 85% qualified and a 69% complete success rate with a target IOP of ≤18 mm Hg. The most common complications were hyphaema, encysted bleb, fibrosis and aqueous leakage. In both of the above techniques the deep flap is excised posterior to the Schlemm's canal and the mini shunt is inserted at the level of the canal.

The idea of using an intrascleral lake as a reservoir of aqueous has been advocated by other authors as well. Cabarga-Nozal *et al*[24] reported that phaco-deep sclerectomy and phaco-deep sclerectomy converted to trabeculectomy intraoperatively had the same visual and IOP control outcome although the latter group needed more drops to successfully control the pressure. Rebolleda *et al*[25] also report that phaco-deep sclerectomy converted to phaco-trabeculectomy due to rupture of the trabeculo-descemet's membrane provides better IOP control but has worse visual acuity and more complications in the early postoperative period than the uneventful phaco-deep sclerectomy group. Trabeculotomy can also be combined with deep sclerectomy in order to increase the hypotonic effect of the NPG procedure with few complications[26-27].

Similarly, Chihara *et al*[28] in a retrospective study evaluated the outcome of modified deep sclerectomy (D-lectomy MMC) for medically refractory glaucoma patients and concluded that the addition of a slit incision to the trabecular meshwork and peripheral iridectomy (D-lectomy MMC) improved postoperative IOP of the deep sclerectomy to the level comparable with trabeculectomy MMC, with a less frequency of the bleb formation. In a prospective series of 14 patients Yuen[29] reported that modified non-penetrating deep sclerectomy combined with early Nd:YAG laser goniopuncture and phacoemulsification without scleral implant is a safe and effective procedure with complete success at 6mo for patients with POAG and cataract.

In the present study, we described the modified deep sclerectomy combined with insertion of EX-PRESS model P50 filtration device and compared it with the classic trabeculectomy in terms of efficiency.

MDS-Xpress showed a more potent hypotensive effect than the classic trabeculectomy. Mean IOP reduction in group B was significantly greater at 6 and 12mo (P=0.006 and P=0.0001 respectively). Moreover, the postoperative IOP was comparable in both groups throughout the follow-up period (all P>0.05), but the baseline IOP was significantly higher in group B (P=0.002), suggesting that the efficiency of the MDS-Xpress was significantly greater, despite the fact that the mean age of patients in group B was significantly lower (P=0.03) and a possible healing reaction could reduce the efficacy of the surgical procedure.

The success rate at the end of the follow-up period (12mo), qualified success was 100% in both groups, on the other hand complete success with target pressure at 21 mm Hg and 18 mm Hg was greater in group B, but the difference between the two groups was not significant (all P>0.05).

Regarding the number of anti-glaucoma medications needed, in group B the mean number of drops was lower at all follow-up visits, however the difference between the two groups was significant only at 6mo (P=0.017).

The advantage of the MDS-Xpess, described in the present study, is the existence of the intrascleral space and therefore the possibility of the aqueous humor outflow from different routes (suprachoroidal, intrascleral vessels and Schlemm's canal) other than that of the subconjunctival space as it happens in the classic trabeculectomy, consequently even in case of partial or total bleb encapsulation the hypotonic effect can be satisfactory. Additionally, both surgical techniques (deep sclerectomy and Ex-PRESS) cause less inflammation compared to trabeculectomy decreasing consequently the possibilities of failure.

There is substantive evidence in the international literature that adding a penetrating element in the NPGS (trabeculectomy trabeculotomy, Ex-PRESS mini shunt) increases the hypotensive action of the NPGS while maintaining its increased safety profile.

With our technique the dissection of the deep flap is performed up to Schlemm's canal without peeling the inner wall. Two similar previous publications described a technique in which the excision of the deep flap did not reach the Schlemm's canal[22-23]. It seems that the Ex-PRESS shunt can be placed in the anterior chamber through the trabeculo-descemet's membrane at the level of the canal. In this way the volume of the episcleral lake created is even larger.

Our study carries some limitations. The 2 groups of patients in this study were not matched in terms of age, and preoperative IOP and follow-up (12mo) is limited. Although the difference in preoperative IOP could be considered a weakness, we believe that, in fact, it supports the main conclusion that both techniques are comparable in terms of IOP reduction. The small difference in the preoperative IOP is due to the fact that this is not a randomized study, but an observational, cohort study. A randomized prospective study with longer follow-up is required to further evaluate the safety and long-term efficacy of the MDS-Xpress procedure and to compare the outcomes to standard non-penetrating deep sclerectomy.

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Conflicts of Interest: Kozobolis V, None; **Panos GD**, None; **Konstantinidis A**, None; **Teus M**, None; **Labiris G**, None.

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