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Original Article

COMPARISON BETWEEN EX-PRESS MINI SHUNT IMPLANTATION AND DEEP SCLEROTOMY IN PATIENTS WITH PRIMARY OPEN-ANGLE GLAUCOMA (POAG)

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Abstract

Purpose: *is to compare the success rate of Ex-PRESS implantation vs deep sclerotomy (DS) in patients with primary open-angle glaucoma (POAG).* ***Patients and methods:*** *This is a randomized prospective interventional comparative study between Ex-PRESS and DS maneuvers in patients with POAG. The study included 47patients (50 eyes) with POAG. The patients were divided into two groups. Group 1 included 25 patients (25 eyes) who underwent Ex-PRESS device implantation. Group 2 included 22 patients (25 eyes) who underwent DS. All included patients underwent a thorough ophthalmic examination. At the end of the 1st year postoperatively, best corrected visual acuity (BCVA) [logMAR], intraocular pressure (IOP), number of anti-glaucoma medications in use were obtained.* ***Results:*** *In group 1, complete success rate was 76%, qualified success rate was 20% and failure rate 4% occurred in 1 eye of patients which needed explantation of the device and another glaucoma filtering surgery due to device-corneal touch. Meanwhile in group 2, complete success rate was36% and qualified success rate was 64% without any recorded failure in this group (Both Ps<0.01) in both groups.* ***Conclusion:*** *favorable effects on IOP and the need for IOP-lowering medications in both Ex-PRESS and DS groups. However, in DS group, higher preoperative IOP is associated with increased failure rate necessitating more postoperative IOP adjustments than Ex-PRESS group.*

Keywords: *POAG, Deep sclerotomy, IOP, Ex-PRESS, Trabeculectomy*

1. Introduction

Since the mid-1960s, trabeculectomy has been the gold standard anti glaucoma operation [1,2]. Although it is successful in controlling intraocular pressure (IOP) it has been associated with a considerable number of complications either early or late and this has given rise to the development of other techniques with some less complications [3-5]. The Ex-PRESS mini shunt (Alcon Laboratories, Fort Worth, TX, USA) is a non-valved, stainless steel device that can be an alternative to trabeculectomy. The advantages of the Ex-PRESS shunt are its ease to be inserted and the absence of peripheral iridectomy [6]. Deep sclerectomy (DS) is a nonpenetrating filtration maneuver, which preserves the trabeculo-descemet membrane. It has been shown to have same

IOP-lowering effect as trabeculectomy with a lower rate of early and late postoperative hypotony [7,8]. The aim of this work is to compare the success rate of Ex-PRESS implantation vs deep sclerotomy in patients with primary open-angle glaucoma (POAG).

2. Patients and Methods

This is a randomized prospective interventional comparative study between Ex-PRESS and DS maneuvers in patients with POAG. The study included 47 patients (50 eyes) with POAG. The patients were divided into two groups. Group 1 included 25 patients (25 eyes) who underwent Ex-PRESS device implantation. Group 2 included 22 patients (25 eyes) who underwent DS. The study was carried out between December 2017 and January 2021 at ophthalmology dept., Al-Azhar univ. hospital, Assiut branch. The research adhered to the tenets of the Declaration of Helsinki. All included patients underwent a thorough ophthalmic examination including clinical history taking, best-corrected visual acuity measurement (BCVA [logMAR]), autorefraction examination, slit lamp examination of the anterior segment, gonioscopic examination to evaluate of the angle of AC, posterior segment evaluation using an indirect ophthalmoscope and slit lamp biomecroscopy with 78 D lens.

Inclusion Criteria; included all patients with the following criteria: **1)** Primary open-angle glaucoma requiring surgical lowering of IOP. **2)** Age older than 35 years.

Exclusion Criteria; we excluded all patients with: **1)** Prior history of glaucoma surgery. **2)** Prior history of conjunctival injury or surgery. **3)** Glaucoma other than POAG. **4)** Other causes of diminution of visual acuity (corneal pathology, cataract, retinal pathology)

2.1. *Surgical techniques*

2.1.1. Ex-PRESS device implantation

Under peribulber anesthesia, the scleral flap (diameter of 3×4 mm and thickness of l/2 of scleral flap) was made. The 25 G needle was punctured into anterior chamber from the scleral flap corneal limbus gray line parallel to the iris surface, part of aqueous fluid was replaced with viscoelastic substance, and the Ex-PRESS drainage device was implanted. The scleral flap was sutured using 10-0 nylon suture; the bulbar conjunctiva at the corneal limbus was sutured in water tight fashion. Topical tobramycin and dexamesathone eye drops and ointment were applied locally after operation for two weeks.

2.1.2. Deep sclerotomy

Under peribulber anesthesia, a 5×5 mm partial thickness scleral flap (one third to one half of the scleral thickness) was fashioned The deep flap borders were outlined 1.0 mm within the edge of the superficial flap and up to 90% of the scleral thickness using a super blade number (no.) 15. The deep flap was fashioned and dissected anteriorly over Descemet's membrane. The deep scleral flap was excised using super blade no. 15. Schlemm's canal was de-roofed with blunt microforceps. A synthetic absorbable ologen implant was placed in the center of the DS and sutured with 10-0 nylon. The scleral flap was closed with 10/0 nylon sutures. The conjunctiva was closed in water tight fashion. Topical tobramycin and dexamesathone eye drops and ointment were applied locally after operation for two weeks. A complete ophthalmologic follow-up examination was carried out postoperatively at the 2nd day and the end of 1st week, 1st, 3rd and 6th months and 1st year. At the end of the 1st year postoperatively, best-corrected visual acuity (BCVA [logMAR]), IOP, number of anti-glaucoma medications in use were obtained. The out-

come measure of success was IOP between 6 and 18 mmHg on two consecutive follow-up visits after 1 month postoperatively. Failure was defined as IOP greater than 18 mmHg on two consecutive follow-up visits after 1 month with or without single antiglaucoma medication, IOP ≤5 mmHg on two consecutive visits after 1 months and, or when the patient required another glaucoma procedure to lower the IOP. Surgical success was classified as complete or qualified success. Complete success was defined as eyes that had an IOP of less than 18 mmHg without the use of any antiglaucoma medications. Qualified success was defined as eyes that had an IOP of less than 18 mmHg but with supplemental single antiglaucoma medications for IOP control. Dividing patients to patients with baseline IOP <30 mmHg and ≥30 mmHg in both groups, group 1 included 11 eyes and group 2 included 13 eyes with baseline IOP <30 mmHg, while there was 14 eyes in group 1 and 12 eyes in group 2 with baseline IOP ≥30 mmHg. Rate of success and IOP reduction were compared in theses subgroups.

2.2. *Statistical analysis*

All statistical analyses were calculated using Statistical Package for the Social Sciences (IBM® SPSS® software version 22.0) (SPSS, Inc., Chicago, IL, USA). Eyes were taken as individual units of analysis in our study. Quantitative data was represented as mean (±) standard deviation; and qualitative data was presented as number and frequency percentage.

3. Results

The baseline demographic and clinical characteristics are shown in tab. (1). There was no statistically significant difference between the two groups regarding age, sex, and baseline IOP level. The number of antiglaucoma medications and BCVA were similar in group 1 and 2. The outcome and success rate are shown in tab. (2) & fig. (1). In group 1, complete success rate was 76%, qualified success rate was 20% and failure rate 4% occurred in 1 eye which needed explantation of the device and another glaucoma filtering surgery due to device-corneal touch. Meanwhile in group 2, complete success rate was 36% and qualified success rate was 64% without any recorded failure in this group (P<0.01). Regarding one year follow-up of IOP, the results are shown in tab. (3) & fig. (2). In both groups, the mean IOP was significantly reduced throughout the postoperative follow up period compared to the baseline level (p< 0.001 in both groups). However, when comparing the achieved postoperative IOP level in the two groups there was statistically significant IOP reduction in group 1 (about 12 mmHg) than in group 2 (about 9 mm Hg) (P< 0.001) and this reduction maintained till the end of follow up period (P< 0.001). Tables (4 & 5) & figs. (3 & 4) are showing the rate of success and IOP reduction in patients with baseline IOP< 30 mmHg. In group 1, complete and qualified success rates were 72.7% and 27.3% respectively without any failure. While in group 2, 69.2% and 30.8% were classified as complete and qualified success respectively without any failure (P= 1.00). In group 1 and group 2, the mean IOP was significantly reduced by about 9 mmHg and 7 mmHg respectively from baseline at 3 months after surgery and this reduction was maintained throughout the follow up period which considered statistically significant in both group (P< 0.001). When comparing the two groups postoperatively, both groups achieved comparable IOP reduction and there was no statistically significant difference between the two groups till the end of the follow up period (P= 0.39). Tables (6 & 7) & figs. (5 & 6) are showing

the rate of success and IOP reduction in patients with baseline IOP ≥ 30 mmHg. In group 1, complete and qualified success rates were 78.6% and 14.3% respectively and 7.1% failed to achieve controlled IOP. While in group 2, 100% were classified as qualified successes without any complete success or failure (*P*< 0.001). In group 1 and 2, the mean IOP was significantly reduced by about 46% and 35% from baseline at 3 months after surgery and this reduction was maintained throughout the follow up period which considered statistically significant in both groups (*P*< 0.001). When comparing the two groups postoperatively, group 1 achieved more IOP reduction and there was statistically significant difference between the two groups till the end of the follow up period (*P*< 0.001). Regarding the whole study group; the operative time, pre- and post-operative no of anti-glaucoma medications in use and BCVA are recorded in fig. 8. Regarding operative time, group 1 had a significantly shorter operative time than group 2 (*P*< 0.05). Regarding BCVA, it showed no statistically significant difference after glaucoma surgery in either group (P= 0.89) and (P= 94) in group 1 & 2 respectively. Moreover, there was statistically insignificant difference in BCVA between both groups one year postoperatively (P= 0.92). One year after surgery, the number of glaucoma medications significantly decreased in both study groups compared with baseline in both groups (both *P*s< 0.001). Group 2 required more medications at 1 year than group 1 (*P*< 0.01). None of the eyes developed intraoperative complications. Table (9) shows the postoperative complications that occurred during follow-up, and the postoperative IOP adjustments and re-operations carried out during that period. In our work, we did not take releasable sutures. In group 1, postoperative IOP adjustments were only carried out in 2 eyes (8%); 1 eye had laser scleral flap suture lysis and 1 eye (4%) showed a device-corneal touch which needed explantation of the device and another glaucoma filtering surgery, fig. (7). In group 2, postoperative adjustments were only carried out in 1 eye (4%) which had conjunctival suture due to bleb leak but no hypotony has developed (*P*= 0.56). Postoperative surgical complications occurred at similar rates in both groups (*P* = 0.78). In group 1, complications were recorded in 10 cases (40%), including 6 cases (24%) of hyphema, 4 cases (16%) of subconjunctival hemorrhage, 4 cases (16%) of shallow anterior chamber. In group 2, complications were recorded in 11 cases (44%), including 5 cases (20%) of hyphema, 5 cases (20%) of subconjunctival hemorrhage, 3 cases (12%) of shallow anterior chamber. All complications spontaneously resolved within 2 weeks. No diffuse corneal epitheliopathy, hypotony with choroidal effusion, collapsed anterior chamber, or other serious complications were encountered with either group. During postoperative follow-up, 3 eyes (12%) in the group 1 underwent phacoemulsification with posterior chamber intraocular lens implantation, vs2 (8%) in the group 2 (*P*= 64).

Table 1: Comparison of baseline demographic and clinical characteristics between the two groups

Variable		Group 1 (mean±SD) n (%)	Group 2 (mean±SD) n (%)	*P* value
Age		56.08±9.84	53.32±14.13	0.73*
Sex	*Male*	13 (52%)	15 (60%)	0.78^
	Female	12 (48%)	10 (40%)	
	Total	25 (100%)	25 (100%)	
IOP (mmHg)		28.40±3.46	28.00±4.30	0.46**
BCVA (LogMAR)		0.5±0.3	0.6±0.2	0.94*
No. of medications		1.88±1.05	1.80±1.12	0.84*

***** *Mann-Whitney U-test was used,* ****** *Kruskal Wallis one way ANNOVA test was used,* ^ *Fisher exact test was used*

Table 2: Success rates in the two groups

Type of success	Group 1: n (%)	Group 2: n (%)	*P* value*
Complete success	19 (76)	9 (36)	<0.01
Qualified success	5 (20)	16 (64)	
Total success	24 (96)	25 (100)	1.00
Failure	1 (4)	0 (0)	

*****Chi-square test or fisher's exact test*

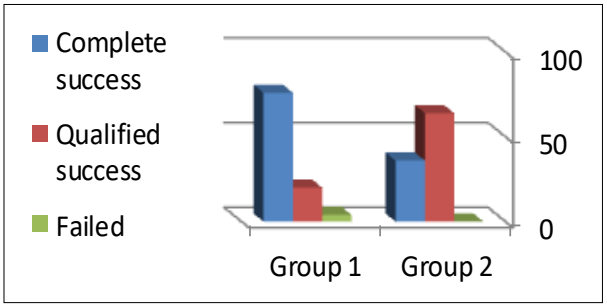

Figure 1: Success rates in the two groups

Table 3: Evolution of IOP over time in both groups

IOP		Group 1 (mean±SD)	Group 2 (mean±SD)	*P* value*
Pre-operative		28.40±3.46	28.00±4.30	0.46
Post-operative	*3 ms*	16.28±2.51	19.16±2.56	<0.001
	6 ms	16.52±2.50	19.16±2.85	
	1 yr	16.92±2.25	19.16±2.67	
P* value*		<0.001	<0.001	

***** Kruskal Wallis one way ANNOVA test was used, ****** Friedman two way ANNOVA test was used*

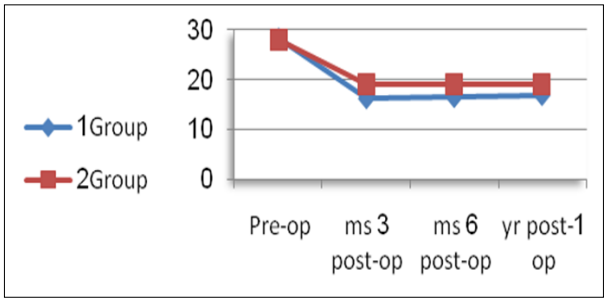

Figure 2: Evolution of IOP over time in both groups

Table 4: Success rates in eyes with baseline IOP < 30 mmHg in both groups

Type of success	Group 1: n (%)	Group 2: n (%)	*P* value*
Complete success	8 (72.7)	9 (69.2)	1.00
Qualified success	3 (27.3)	4(30.8)	
Total success	11 (100)	13 (100)	
Failure	0 (0)	0 (0)	

*****Chi-square test or fisher's exact test*

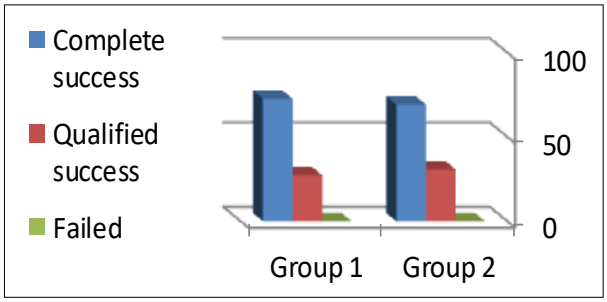

Figure 3: Success rates in eyes with baseline IOP < 30 mmHg in both groups

Table 5: Evolution of IOP over time in eyes with baseline IOP < 30 mmHg in both groups

IOP		Group 1 (mean±SD)	Group 2 (mean±SD)	*P* value*
Pre-operative		25.18±2.36	24.77±2.59	0.515
Post-operative	*3 ms*	16.09±2.43	17.69±2.75	0.07
	6 ms	16.36±2.58	17.31±2.87	0.34
	1 yr	16.64±2.46	17.62±2.87	0.39
P* value*		<0.001	<0.001	

** Kruskal Wallis one way ANNOVA test was used, ** Friedman two way ANNOVA test was used*

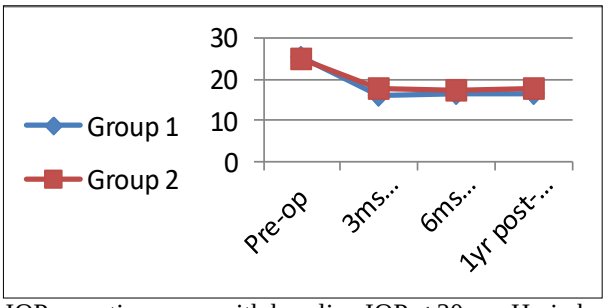

Figure 4: Evolution of IOP over time eyes with baseline IOP < 30 mmHg in both groups

Table 6: Success rates in eyes with baseline IOP > 30 mmHg in both groups

Type of success	Group 1: n (%)	Group 2: n (%)	*P* value*
Complete success	11 (78.6)	0 (0)	<0.001
Qualified success	2 (14.3)	12 (100)	
Total success	13 (92.9)	12 (100)	<0.001
Failure	1 (7.1)	0 (0)	

**Chi-square test or fisher's exact test*

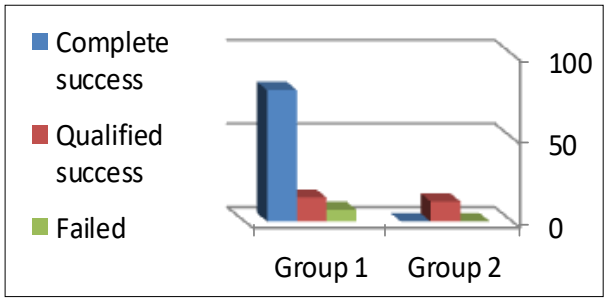

Figure 5: Success rates in eyes with baseline IOP > 30 mmHg in both groups

Table 7: Evolution of IOP over time in eyes with baseline IOP >30 mmHg in both groups

IOP		Group 1 (mean±SD)	Group 2 (mean±SD)	*P* value*
Pre-operative		30.93±1.49	31.5±2.71	0.504
Post-operative	*3 ms*	16.43±2.65	20.75±0.87	<0.001
	6 ms	16.64±2.53	21.17±0.58	<0.001
	1 yr	17.14±2.14	20.83±0.84	<0.001
P* value*		<0.001	<0.001	

** Kruskal Wallis one way ANNOVA test was used, ** Friedman two way ANNOVA test was used*

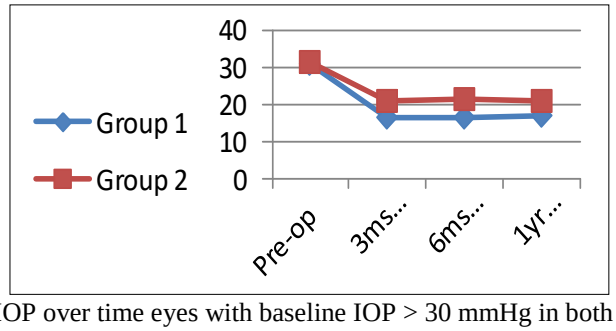

Figure 6: Evolution of IOP over time eyes with baseline IOP > 30 mmHg in both groups

Table 8: Operative time, No of glaucoma medications and BCVA

Variable		Group 1 (mean±SD)	Group 2 (mean±SD)	*P* value*
Operative time (min)		34.26±2.31	42.51±5.36	<0.05
No. of medications	*Pre-operative*	1.88±1.05	1.80±1.12	0.84
	Post-operative	0.28±0.54	0.72±0.61	<0.01
	*P value***	<0.001		
BCVA (LogMAR)	*Pre-operative*	0.5±0.3	0.6±0.2	0.94
	Post-operative	0.6±0.2	0.6±0.3	0.92
	*P value***	0.89	0.94	

***Mann-Whitney U-test was used, ** Wilcoxon Signed-Rank test was used*

Table 9: Post-operative complications and IOP adjustments

Variable		Group 1 n (%)	Group 2: n (%)	*P* value*
IOP adjustments		2 (8)	1(4)	0.56
Complications	Hyphema	6 (24)	5 (20)	0.76
	Subconjunctival hemorrhage	4 (16)	5 (20)	0.72
	Shallow AC	4 (16)	3 (12)	0.69
	Total	10 (40)	11 (44)	0.78
Cataract progression and/or development		3 (12)	2 (8)	0.64

***Mann-Whitney U-test was used*

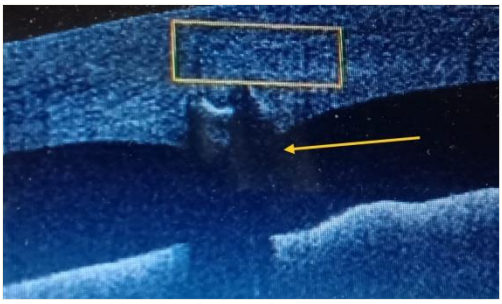

Figure 7: Device-corneal touch in Ex-PRESS (Yellow arrow)

4. Discussion

In agreement with previous studies [9]; regarding long term IOP control, our results showed that postoperative IOP was significantly reduced in the two groups at each follow up session. Moreover, the number of antiglaucoma eye drops decreased significantly one year after the surgery in the two groups. However, the drop in IOP was more in Ex-PRESS group (about 43%) than DS group (about 32%) during the follow up sessions which explains why patients with DS have used more antiglaucoma medications than the Ex-PRESS patients. Previous reports on EX-PRESS maneuver alone showed a complete success rate about 69% to 84.6%, and a qualified success rate ranging between 84% and 97.4% one year after surgery [10]. However earlier studies on the DS surgery alone have revealed a complete success rate about 40% to 79%, and a qualified success rate of 84% and 100% at one year postoperative [11-13]. While in this study, the rate of complete success was 76% for Ex-PRESS group and 36% for DS group. The inconsistent success rate in different studies can be attributed to the different definition of success in each study, surgical technique, and the follow up period (the longer the follow-up period the lower the success rate) [14]. Watson and Grierson found that the mean reduction of IOP after trabeculectomy increased with increasing preoperative IOP [15]. In our study, this was the case in Ex-PRESS group but not in DS group leading to more cases in Ex-PRESS group achieving complete success and more cases in DS group achieving qualified success ($P < 0.01$). Meanwhile, total success rate (complete+qualified) in

this study did not differ between the two groups (P= 1.00) because eyes with elevated IOP in the DS group were treated with antiglaucoma medication. Regarding DS, other studies showed that higher preoperative IOP is associated with increased risk of failure [16] Moreover, a study by Dupas et al. [17] showed that similar control of IOP was achieved by either trabeculectomy or DS, with similar success rates at 12 months. However, to lower IOP to below 21 mmHg, DS required more postoperative control than trabeculectomy. In this study, patients with preoperative IOP≤ 30 mmHg, neither IOP reduction over follow-up period nor success rates differ significantly between the two groups. In agreement with previous studies [18], our study found no statistically significant difference in BCVA after glaucoma surgery in either group or between both groups. Moreover, previous studies [19] revealed that experienced surgeons spent less time in the operating room with the EX-PRESS procedure than with NPDS (p= 0.01), despite their greater experience with the latter. These latter results are in agreement with ours. In this study, the high success rate of DS eyes could be attributable to the close postoperative follow-up, which ensured that interventions to lower IOP were carried out without delay. Trabeculectomy has been shown to significantly increase the incidence of cataract progression [20]. However; in this study postoperative cataract progression requiring phacoemulsification were similar in both groups. Only 3 eyes (12%) in Ex-PRESS group and 2 eyes (8%) in DS group underwent phacoemulsification with posterior chamber intraocular lens implantation. This can be explained by the fact that trabeculectomy is invasive while Ex-PRESS is microinvasive and DS is non-invasive techniques.

5. Conclusion

The intention of this study was to investigate the natural history of IOP outcomes and surgical results with the two different approaches studied and this was accomplished. The results in our study are encouraging, showing favorable effects on IOP and the need for IOP-lowering medications in both Ex-PRESS and DS groups. However, in DS group, higher preoperative IOP is associated with higher IOP necessitating more postoperative IOP adjustments than Ex-PRESS group. This study have highlighted the greater efficacy of the Ex-PRESS compared to the DS.

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