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Application of EX-PRESS implants type P-50 in the surgical treatment of open angle glaucoma in pseudophakic eyes

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ABSTRACT

Inroduction: To report the efficacy and safety of the EX-PRESS Glaucoma Filtration Device type P-50 in pseudophakic eyes with primary or secondary open angle glaucoma.

Material and methods: This retrospective analysis included 36 pseudophakic eyes (14 eyes with primary open angle glaucoma and 22 eyes with secondary open angle glaucoma) after glaucoma surgery with the EX-PRESS type P-50 without mitomycin C. The preoperative and postoperative intraocular pressure (IOP), best corrected distance visual acuity (BCDVA) and topical antiglaucoma medications were evaluated. The postoperative complications and surgical failure were analyzed. The effectiveness of treatment was assessed at the follow-up visit (mean 8.63 months). Surgical success was defined as complete (without antiglaucoma medications) with IOP ≤ 18 mmHg in criterion A and IOP ≤ 14 mmHg in criterion B. Qualified success was determined as the same IOP levels, but with one or two topical antiglaucoma medications.

Results: The mean intraocular pressure was 29.98 mmHg (SD = 10.85) before surgery and 13.67 mmHg (SD = 6.19) at the follow-up visit ($p < 0.05$). The complete success rate was 55.56% in criterion A and 44.44% in criterion B. The qualified success rate was 25.00% in criterion A and 16.67% in criterion B. No serious postoperative complications were observed.

Conclusions: This study suggests that the EX-PRESS Glaucoma Filtration Device type P-50 reduces the IOP in most pseudophakic eyes with primary or secondary open angle glaucoma, but the reduction is not always sufficient to reach the target IOP. The use of antiglaucoma medications after EX-PRESS implantation is lowered.

KEY WORDS: intraocular pressure, postoperative complications, EX-PRESS Glaucoma Filtration Device, glaucoma filtration surgery, glaucomatous optic neuropathy.

INTRODUCTION

Target intraocular pressure (IOP) is a range of IOP that prevents further visual field loss and maintains patients' quality of life [1, 2]. Filtration surgery aims to achieve a target IOP in advanced glaucoma, but sometimes topical medications should be added [1]. Before surgery, one should consider a multitude of factors including the patient risk profile, previous history (degree of visual field loss, medications, surgery), complication rates or functional outcomes [1]. Some glaucoma surgeons advocate using the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Fort Worth, TX, USA). To date, there have been some analyses of its safety and efficacy in reducing IOP [3-9], including in combined surgery [10-13]. This non-valved, stainless steel device is also an option for patients after previous glaucoma surgery [14]. The EX-PRESS device is implanted *ab externo* under a scleral flap with an injector [15] (Figure 1), which was found to be safe and effective, in contrast to placing it under the conjunctiva, as it was originally developed [16]. During this procedure, a new shunt between the anterior chamber and the subconjunctival space is created [15] (Figure 2). Several EX-PRESS implant series and models have been designed, but not all are currently available [17]. The two models (P-50 and P-200) of the present P series differ in their internal diameter (50 µm or 200 µm), which affects the flow and the flow resistance [18].

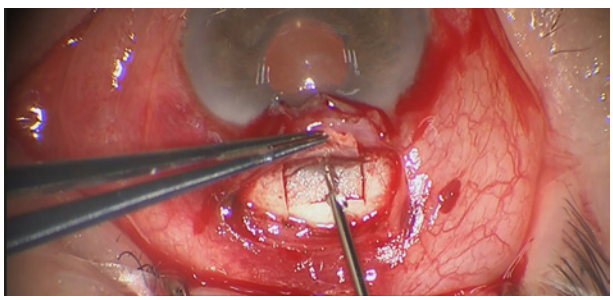

Figure 1. Intraoperative photograph showing implantation of the EX-PRESS device

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AIM OF THE STUDY

To present and analyze the efficacy and safety of the EX-PRESS Glaucoma Filtration Device type P-50 in pseudophakic eyes with primary or secondary open angle glaucoma.

MATERIAL AND METHODS

This retrospective analysis included 36 pseudophakic eyes of 35 patients who underwent glaucoma surgery with the EX-PRESS Glaucoma Filtration Device type P-50 without mitomycin C in the Department of Ophthalmology, Medical University of Lodz. The EX-PRESS implant was applied in 14 eyes with primary open angle glaucoma (POAG) and in 22 eyes with secondary open angle glaucoma (SOAG). There were several types of secondary glaucoma, i.e. 8 eyes with pseudoexfoliation glaucoma, 2 eyes with traumatic glaucoma, 2 eye with uveitic glaucoma, 3 eyes with neovascular glaucoma, 5 eyes after *pars plana* vitrectomy with silicone oil tamponade for retinal detachment and 2 eyes after *pars plana* vitrectomy with silicone oil tamponade in severe diabetic retinopathy. Patients were characterized by progressive, glaucomatous optic neuropathy in moderate or severe stages despite used antiglaucoma medications, laser or surgical procedures. There were 13 eyes after previous trabeculectomy in the group. This study included 18 females (19 eyes, 52.78%) and 17 males (17 eyes, 47.22%) aged from 35 to 89 (mean = 69.58 years; SD = 12.64). The preoperative and postoperative intraocular pressure (IOP), best corrected distance visual acuity (BCDVA) and topical antiglaucoma medications were evaluated. IOP was measured using applanation tonometer, while BCDVA was evaluated using Snellen charts. The topical antiglaucoma medications were documented according to the number of active ingredients. The effectiveness of treatment was assessed on postoperative day 1 (POD1) and at the follow-up visit (mean 8.63 months, SD = 3.28). The EX-PRESS implant location and the bleb morphology were checked. Postoperative complications were analyzed. Surgical IOP-lowering effect was assessed in two ranges termed as criterion A and B. Criterion A was IOP ≤ 18 mmHg. Criterion B was IOP ≤ 14 mmHg. The following categories of surgical success were adopted: complete, qualified and cumulative success. Complete success was defined as IOP lowering without antiglaucoma medications. Qualified success was defined as the same IOP reduction with one or two topical antiglaucoma medications. Cumulative success was defined as the sum of complete and qualified success. The complete, qualified and cumulative success rates were assessed in criteria A and B. Surgical failure was determined

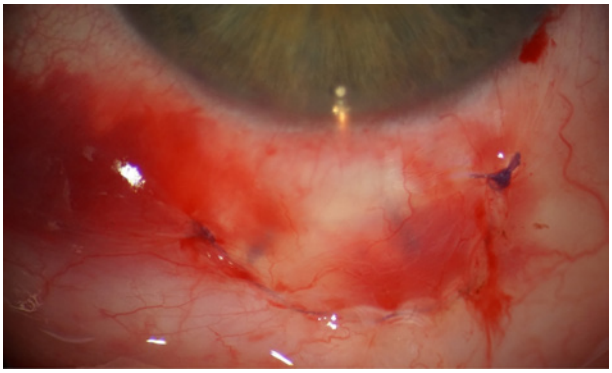

Figure 2. Intraoperative photograph demonstrating the final position of the EX-PRESS device

Table I. Number (*n*) and percentage (%) of eyes according to the number of antiglaucoma topical drugs used at the follow-up visit in relation to the IOP

IOP [mmHg]	*n* (%)			
	Total	No drugs	1-2 drugs	≥ 3 drugs
≤ 4.0	4 (11.11)	4 (11.11)	0 (0.00)	0 (0.00)
4.1-10.0	2 (5.56)	2 (5.56)	0 (0.00)	0 (0.00)
10.1-12.0	5 (13.89)	4 (11.11)	1 (2.78)	0 (0.00)
12.1-14.0	12 (33.33)	6 (16.67)	5 (13.89)	1 (2.78)
14.1-16.0	3 (8.33)	0 (0.00)	2 (5.56)	1 (2.78)
16.1-18.0	5 (13.89)	4 (11.11)	1 (2.78)	0 (0.00)
18.1-21.0	3 (8.33)	0 (0.00)	0 (0.00)	3 (8.33)
> 21.0	2 (5.56)	0 (0.00)	0 (0.00)	2 (5.56)

Table II. Descriptive statistics for IOP preoperatively, on postoperative day 1 (POD1) and at the follow-up visit. Statistically significant differences were observed in all three groups between: mean IOP before surgery and on POD1, mean IOP on POD1 and at the follow-up visit, mean IOP before surgery and at the follow-up visit

	IOP [mmHg]								
	Preoperatively			POD1			Follow-up visit		
	Total	POAG	SOAG	Total	POAG	SOAG	Total	POAG	SOAG
Min	12.00	12.00	12.20	4.00	4.00	4.00	4.00	10.20	4.00
Max	54.00	43.80	54.00	17.60	14.40	17.60	34.40	20.00	34.40
Mean	29.98	25.17	33.03	6.47	6.73	6.30	13.67	13.74	13.62
SD	10.85	9.51	10.78	4.08	4.10	4.16	6.19	3.42	7.52
Median	29.60	22.50	31.50	4.00	4.00	4.00	12.20	12.20	12.20

POAG – primary open angle glaucoma; SOAG – secondary open angle glaucoma

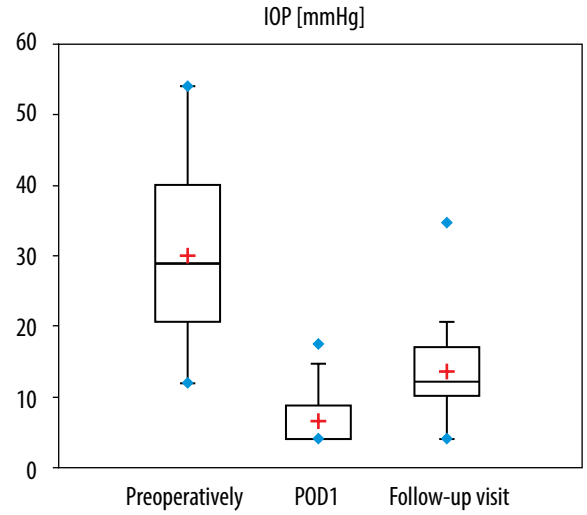

Figure 3. Box plot of intraocular pressure (IOP) of all eyes before surgery, on postoperative day 1 (POD1) and at the follow-up visit

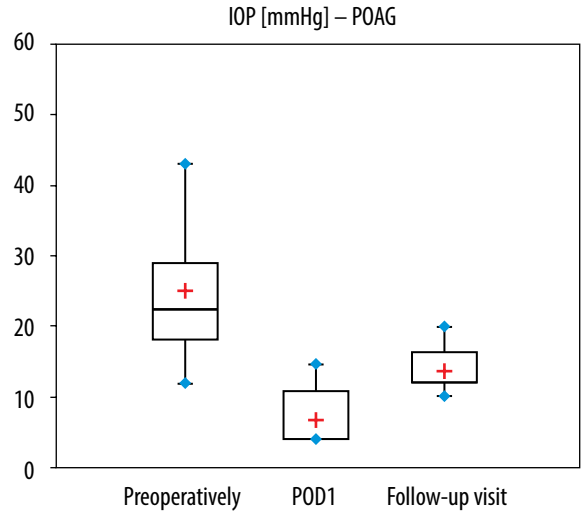

Figure 4. Box plot of intraocular pressure (IOP) of eyes with primary open angle glaucoma (POAG) before surgery, on postoperative day 1 (POD1) and at the follow-up visit

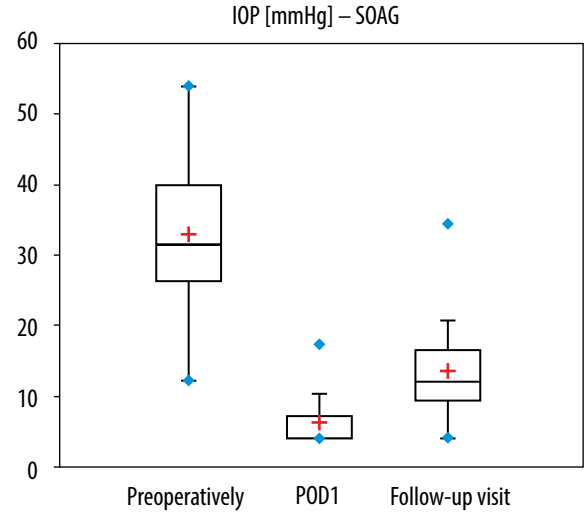

Figure 5. Box plot of intraocular pressure (IOP) of eyes with secondary open angle glaucoma (SOAG) before surgery, on postoperative day 1 (POD1) and at the follow-up visit

as IOP > 18 mmHg (with or without antiglaucoma medications), loss of light perception and in situations when the eye required further glaucoma surgery. The calculations comprised arithmetic mean, standard deviation (SD), median, minimum (Min) and maximum (Max) value. T-test for two paired samples was used to test the significance of differences in the mean values in the group of all eyes. Due to the small sample size of the subgroups (POAG and SOAG), the Wilcoxon signed-rank test was used to test the significance of differences in the mean values in two dependent samples. The significance level of 0.05 was accepted for all tests. The study fulfilled all the tenets of the Declaration of Helsinki. The clinical study was conducted with the consent of the Bioethics Committee of the Medical University of Lodz (Nr RNN/354/15/KE).

RESULTS

IOP ≤ 18.0 mmHg was obtained in 31 eyes (86.11%), without antiglaucoma medications in 20 eyes (complete success rate in criterion A – 55.56%) and with a maximum of 2 antiglaucoma medications in 9 eyes (qualified success rate in criterion A – 25.00%) (Table I). The cumulative success rate was 80.56% in criterion A. IOP ≤ 14.0 mmHg was obtained in 23 eyes (63.89%), without antiglaucoma medications in 16 eyes (complete success rate in criterion B – 44.44%) and with a maximum of 2 antiglaucoma medications in 6 eyes (qualified success rate in criterion B – 16.67%) (Table I). The cumulative success rate was 61.11% in criterion B. Surgical failure was found in 5 eyes (13.89%) due to higher IOP than 18 mmHg (2 eyes with POAG and 3 eyes with SOAG).

The mean IOP of all eyes was 29.98 mmHg (SD = 10.85) before the surgery and 13.67 mmHg (SD = 6.19) at the follow-up visit (Table II and Figure 3). The difference was statistically significant ($p < 0.05$). The mean IOP of eyes with POAG decreased from 25.17 mmHg (SD = 9.51) to 13.74 mmHg (SD = 3.42) (Table II and Figure 4). The mean IOP of eyes with SOAG was 33.03 mmHg (SD = 10.78) before the procedure and 13.62 mmHg (SD = 7.52) at the follow-up visit (Table II and Figure 5). The differences were also statistically significant ($p < 0.05$).

Before the surgery, topical antiglaucoma medications were used in all 36 eyes (100%), including 3 drugs in 11 eyes and 4 drugs in 21 eyes (Table III). After the EX-PRESS implantation, topical antiglaucoma treatment was administered in 16 eyes (44.44%), but with 3 or 4 medications in 7 eyes (4 and 3, respectively; Table III). There was no need for topical antiglaucoma medications in 20 eyes (55.56%). The most commonly used medications of topical antiglaucoma drugs were β-blockers, both preoperatively (97.22%) and at the follow-up visit (38.89%) (Table IV).

All EX-PRESS implants were still sustained with good positioning at the follow-up visit. The filtration bleb in all eyes was properly formed.

The mean BCDVA of eyes before the surgery was 0.31 (SD = 0.30). There was a temporary deterioration of mean BCDVA (0.17, SD = 0.19) on POD1. However, the mean BCDVA was 0.33 (SD = 0.31) at the follow-up visit. This difference was not statistically significant ($p > 0.05$).

Only mild postoperative complications were observed on POD1, i.e. early hypotony in 27 eyes (75.00%), choroidal detachment in 3 eyes (8.33%), reduction of anterior chamber depth in 2 eyes (5.56%), bleeding into the anterior chamber in 1 eye (2.78%), uveitis in 1 eye (2.78%) and postoperative leakage in 1 eye (2.78%). There was a need for postoperative revision of a filtration bleb in 1 eye (2.78%). The postoperative hypotony was transient in most cases. However, hypotony of 4 mmHg or less was still observed in 2 eyes (5.56%) at the follow-up visit. Additionally, hypotony was also detected in 2 eyes without postoperative hypotony history.

Table III. Number (*n*) and percentage (%) of eyes on topical antiglaucoma treatment according to the number of administered drugs (active ingredients) preoperatively and at the follow-up visit

Active ingredients	*n* (%)	
	Preoperatively	Follow-up visit
0	0	20 (55.56)
1	1 (2.78)	2 (5.56)
2	3 (8.33)	7 (19.44)
3	11 (30.56)	4 (11.11)
4	21 (58.33)	3 (8.33)

Table IV. Number (*n*) and percentage (%) of eyes according to the type of topical antiglaucoma medications preoperatively and at the follow-up visit

Type of drugs	*n* (%)	
	Preoperatively	Follow-up visit
Prostaglandin analogues	30 (83.33)	11 (30.56)
β-blockers	35 (97.22)	14 (38.89)
Carbonic anhydrase inhibitors	29 (80.56)	9 (25.00)
Adrenergic agonists	27 (75.00)	6 (16.67)

DISCUSSION

The EX-PRESS device was designed to improve the safety of filtration surgery [17], patient outcomes and visual recovery [19]. The surgical procedure of EX-PRESS implantation is more predictable, standardized and technically easier than trabeculectomy [8]. It does not require peripheral iridectomy, which may shorten the duration of the procedure and potentially reduce postoperative inflammation [8, 20]. An additional benefit seems to be the decreased risk of severe postoperative complications [7], which is consistent with this study. Furthermore, a faster return of postoperative visual acuity to preoperative values was observed in the eyes after EX-PRESS implantation than after trabeculectomy [3], which may increase patient satisfaction with the procedure. Similarly, satisfactory reduction of IOP was confirmed by other surgeons using EX-PRESS type P-50 [21-24] or P-200 [5, 25-27], but in some studies the EX-PRESS implant was less effective than trabeculectomy [28] or its implantation had higher reoperation rates [29]. The main risk factors for failure found in the literature are diabetes, non-Caucasian race, and previous glaucoma surgery [30]. A significant reduction of IOP was also noted in this study. In addition, most patients could opt out of topical antiglaucoma therapy or reduce the number and the frequency of drug applications per day. This paper presents the results of the application of the EX-PRESS implant type P-50, as it was the first model used in our department. Currently, the EX-PRESS implant P-200 is also used.

A review of the literature also suggests the efficacy of the EX-PRESS implant in refractory glaucoma [31, 32], greater safety in neovascular glaucoma surgery [28, 33] and the possibility of use in secondary glaucoma after other ophthalmic procedures, i.e. keratoplasty [34], *pars plana* vitrectomy with silicone oil or SF6 tamponade [35]. There was also observed a reduction of IOP in vitrectomized eyes with secondary glaucoma after silicone oil tamponade for retinal detachment and in severe diabetic retinopathy in this study. However, this paper also shows mild postoperative complications after EX-PRESS implantation, especially early hypotony (75%). Some researchers have used other glaucoma drainage devices, e.g. the Ahmed glaucoma valve (AGV). The analyses of long-term outcomes of AGV implantation showed its effectiveness with the rate of early-postoperative hypotony of 16.3% in refractory glaucoma [36] and 17.5% in neovascular glaucoma [37]. The surgical method should be selected according to the specific situation of the patient [38].

Limitations of this study include its retrospective nature with the potential for investigator bias in selection of cases, small sample size and short follow-up.

In conclusion, this study suggests that the EX-PRESS Glaucoma Filtration Device type P-50 reduces the IOP in most pseudophakic eyes with primary or secondary open angle glaucoma, but the reduction is not always sufficient to reach the target IOP. The use of antiglaucoma medications after EX-PRESS implantation is lowered. Only mild postoperative complications were observed, which did not significantly affect the final result of the procedure.

DISCLOSURE

The authors declare no conflict of interest.

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