Evaluation of Ex-PRESS® Mini Glaucoma Shunt (P 200) Implantation Outcomes In Pseudophakic Eyes

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ABSTRACT

Purpose: To evaluate the outcomes of Ex-PRESS (P 200) mini-glaucoma shunt implantation surgery in pseudophakic eyes with medically uncontrollable open-angle glaucoma (OAG) for efficacy and safety.

Materials and Methods: Twenty-one eyes of 21 patients who had primary open-angle or pseudoexfoliation glaucoma were undergone Ex-PRESS shunt implantation surgery. Patients with a minimum of 12 months follow-up were included in the study, and files were reviewed retrospectively. Preoperative (pre-op) demographic characteristics, intraocular pressure (IOP), visual acuity (VA), the number of medications used were assessed. Postoperative (post-op) 1st, 6th, 12th month IOP, VA, medication use, complete success (CS) (5 ≤IOP ≤18 mmHg without medication and no additional surgical intervention), qualified success (QS) (5 ≤IOP ≤18 mmHg with or without medication) and complications were evaluated.

Results: The mean age was 72.3±13.4 (30-86) years; the mean follow-up time was 16.6±3.4 (12-24) months. The mean pre-op IOP was 31.34±8.18 (23-53) mmHg, first month 14.76±5.85, 6th month 14.28±3.62, and 12th month 14.00±4.07 mmHg. Mean IOP reduction was statistically significant in all post-op examinations (P<0.01). Drop in mean IOP was 55% approximately in the 12th month. The mean number of pre-op medications was 3.52±0.51; it decreased significantly to 0.95±1.28 in the 12th month (P<0.01). Pre-op VA was 0.51±0.66, and the 12th month was 0.44±0.72 logMAR. This difference was no statistically significant (P= 0.2). CS rate was 57%, and the QS rate was 90.5% in 12th months. The complication rate was 14% (3/21)

Conclusion: Ex-PRESS shunt surgery in pseudophakic eyes with OAG is effective and safe with low complication rates in reaching target IOP and decreasing antiglaucomatous drug use.

Key Words: Glaucoma drainage implants, Aqueous humor shunts, Open-angle glaucoma, Pseudophakia.

INTRODUCTION

Open-angle glaucoma is chronic, progressive optic neuropathy. In patients with glaucoma, elevated intraocular pressure (IOP) is the only modifiable risk factor, which may lead to injury of the retinal nerve fiber layer (RNFL) and ganglion cells (GCs).[1] Surgical treatment is indicated in cases in which medical treatment was failed or in those with incompliance to medical treatment. Trabeculectomy remains to be the gold standard in the surgical treatment.[2,3,4] The complications such as hypotonia due to excessive filtration at the early period and bleb failure in the late period after trabeculectomy surgery have promoted seeking novel techniques.[5] Ex-PRESS® Mini Glaucoma Shunt (Alcon laboratories, Forth Worth, TX, USA) was introduced into the market in 2002 with a claim of fewer complications compared to trabeculectomy. It is a valve-free implant with fixed lumen width and was designed to mimic the physiological efflux of humor aqueous. In the last two decades, it has become an alternative in glaucoma surgery. The procedure does not require iridectomy or sclerotomy, using a selected, standard lumen diameter. Till now, model R, X, and P have been manufactured with lumen diameters of 50µ and 200µ. Combining the shunt with trabeculectomy has many advantages such as less inflammation at the postoperative period, rapid visual recovery, and decreased rates of complications, including hypotonia and hyphema.[3, 14] In this study it was aimed to evaluate postoperative effectiveness and complication of Ex-PRESS® Mini Glaucoma Shunt P200 in pseudophakic eyes. The model P200 was preferred to enhance filtration

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due to higher IOP levels at the preoperative period and to minimize anti-glaucomatous agent use at postoperative period if possible.[6, 7]

MATERIALS AND METHODS

This retrospective study was approved by the Ethics Committee of İstanbul University, Medicine School. The study was conducted in accordance with the tenets of the Helsinki Declaration. All patients gave written informed consent. We retrospectively reviewed data from 21 pseudophakic eyes of 21 patients (with at least 12 months of follow up) who underwent model P200 implantation among 79 eyes of 66 patients underwent Ex-PRESS® Mini Glaucoma Shunt implantation between January, 2016 and June, 2018. The study included pseudophakic patients aged>18 years. The patients previously underwent ocular surgery other than non-complicated phacoemulsification surgery at the preoperative period, those with angle glaucoma, those with secondary glaucoma other than pseudoexfoliation, those with conjunctival scarring or connective tissue disorder were excluded.

All patient files were screened retrospectively; all patients had at least 2 preoperative IOP measurements between 08:00 and 10:00 AM by Goldmann applanation tonometry (Haag-Streit, Bern Switzerland); a third measurement was performed in case of difference more than 2 mmHg between measurements; and mean IOP value calculated for each patient was used in the analysis. The best-corrected visual acuity (BCVA) was assessed using Snellen charts and converted to logMAR. In all patients, the biomicroscopic examination was performed to evaluate the anterior chamber, and findings specific to optic nerve head were recorded in fundus examination. Visual field testing was performed using automated perimetry (30/2 full threshold Humphrey Field Analyzer; Carl Zeiss Meditec, Dublin, CA, USA); central corneal thickness was measured using ultrasonic pachymetry (Ocuscan® RxP, Alcon, Inc, Irvine, California); angle elements were assessed using gonioscopy (Goldman 3 mirror lens, Shaffer classification) and open-angle was confirmed. As morphological tests, optical coherence tomography, retinal nerve fiber layer (RNFL) and optic head nerve measurements were performed, and results were recorded according to age and ethnicity normograms. The number of preoperative anti-glaucomatous agents was recorded as active substance; thus, combined preparations were counted as two agents. Postoperative examinations were performed on day 1 and 7 and at months 1, 3, 6 and 12. Interim controls were performed if needed. In all visits, a comprehensive examination was performed, including BCVA assessment using Snellen charts (which was converted to logMAR), IOP measurements using Goldmann applanation tonometry (GAT), evaluation of anterior segment, implant, and bleb morphology by biomicroscopy, fundus examination and optic nerve head assessment. The structural tests such as RNFL and visual field testing were repeated at months 6 and 12. All complications and additional procedures were recorded. Preoperative fi ndings and postoperative findings at months 1, 6, and 12 were analyzed.

Shunt material: Currently, there are only two types of Ex-PRESS® Mini Glaucoma Shunt with lumen diameters of 200 µm (P200) and 50 µm (P50). The Ex-PRESS® Mini Glaucoma Shunt P200 used in the study is a blunt-tipped shunt (2.6 mm in length) with an internal diameter of 200 µm and external diameter of 400 µm. It is manufactured from stainless steel. It was intended to achieve an external flow with a resistance similar to physiological efflux resistance.[8]

Surgical technique: Surgical indication was defined as uncontrolled IOP of 21 mmHg or higher despite maximum tolerable medical treatment due to preoperative primary open angle glaucoma or pseudoexfoliation and >2 dB increase in mean deviation in 2 consecutive visual field testing and/or thinning in RNFL in total or in sectors as detected by objective examination. All surgical procedures were performed by two surgeons (MCY and AA) experienced in glaucoma surgery. The surgery was performed under subtenon anesthesia (lidocaine 2% plus bupivacaine 5%) with sedation or general anesthesia. A fornix-based conjunctival incision (3 quadrants in width) was performed at upper quadrant; following mild cauterization, a scleral flap (4x4 in size, partial thickness) was prepared until observing blue line (projection of trabecular meshwork) and then a sponge soaked mitomycin C 0.4% (MMC) was applied to scleral bed and subconjunctival area over 4 minutes. This was followed by irrigation with 50 ml of normal saline. At the blue line, a 25-G needle was inserted to the anterior chamber as being parallel to the iris, and Ex-PRESS® Mini Glaucoma Shunt P200 was implanted into the fistula created; two 10-0 nylon sutures sutured the scleral flap. Suture tension was adjusted by irrigating normal saline from side port and a third suture was applied if needed. Conjunctiva was sutured using 8-0 polyglactin sutures; bleb formation and wound site leakage was controlled by normal saline given from side port. Dispersive viscoelastic material (Viscoat, Alcon) was given to anterior chamber to prevent shallowing; the surgery was completed after subconjunctival gentamicin-dexamethasone injection. At the postoperative period, topical moxifloxacin (eye drop, 4x1 over two weeks) and prednisolone acetate (eye drop, initial dose 6x1, gradually tapered over 4 weeks) were prescribed to the patient.

Complete success (CS) was defined as 5 mmHg ≤ IOP ≤ 18 mmHg, being medication-free, and lack of need for re-operation during the postoperative period. The same conditions with or without drug were defined as the qualified success (QS). Additional filtering surgery in case of failure to achieve target IOP or bleb revision was considered as failure. However, laser suture lysis for improving bleb functions, suture removal, or 5-Fluorouracil (5-FU) needling for cystic bleb was not considered as failure. Hypotonia more than a week or requiring additional intervention was considered as complication.

Statistical analyses were performed using SPPS version 21.0 (IBM Corp., Armonk, NY). In paired samples, two-tailed t-test and one-way ANOVA were used for parametric, repeated measurements while Wilcoxon rank sign test and Mann Whitney U test was used for non-parametric repeated measurements. Levene's variance homogeneity was used for independent samples while t-test was used for average homogeneity. A p value≤ 0.05 was considered as statistically significant.

RESULTS

Table 1 presents demographic characteristics and findings of the patients. Figure 1 and Table 2 shows IOP changes in the patients.

In all postoperative time points, IOP reduction was found to be significant compared to preoperative value (p<0.01). IOP changes after month one were found to be insignifi cant (p=0.6). Table 2 summarizes IOP values.

Table 3 summarizes changes in BCVA. No signifi cant difference was detected in BCVA at any time point. The mean number of anti-glaucomatous agents was 3.52±0.51 at the preoperative period, whereas it was significantly decreased to 0.95±1.25 (p<0.05).

On postoperative month 12, QS was achieved in 19 cases (90.5%) and CS in 12 cases (57%). Two cases with failure underwent bleb revision surgery and achieved target IOP value (9.5%).

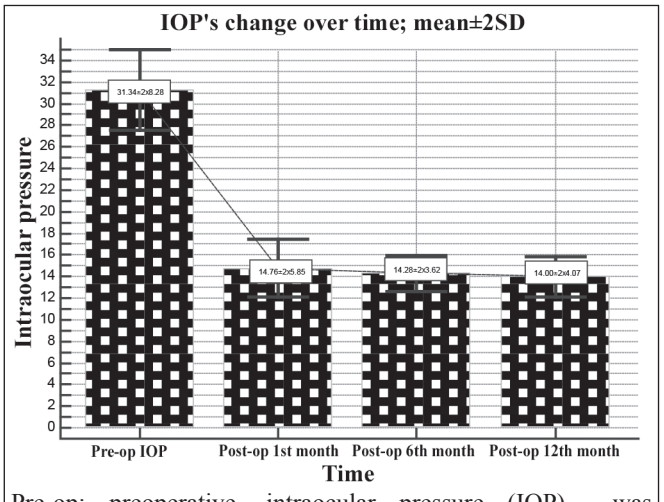
In two cases, bleb revision surgery was performed due to persistent cystic bleb despite needling, and these cases were considered as surgical failure.

Laser suture lysis was performed in 3 cases (14%) while

Table 1. *Demographic characteristics and preoperative data of patients.*

Number of patients	21
Gender: Female/Male	11/10
Age (years)	72.3±13.44 (30-86)
Follow-up time (month)	16.6±3.4 (12-24)
Glaucoma type: POAG/PEXG	POAG 16 / PEXG 5
Pre-op IOP (mmHg)	31.34±8.18 (23-53)
Pre-op number of medication	3.52±0.51
Pre-op BCVA (logMAR)	0.51±0.66

Pre-op: preoperative, POAG: Primary open angle glaucoma PEXG: Pseudo-exfoliative glaucoma, IOP: Intraocular pressure, BCVA: Best-corrected visual acuity



Pre-op: preoperative, intraocular pressure (IOP) was significantly decreased on postoperative month 1 while changes after month 1 were insignificant.

Figure 1. *Changes in mean intraocular pressure over time.*

Table 2. *IOP changes over time.*

Time	**IOP** (mmHg)	**IOP reduction and percent reduction**	**P value: ***
Pre-op (mean±SD)	31.34±8.18		
Post-op month 1 (mean±SD)	14.76±5.85	16.48±11.29 (%53)	0.000
Post-op month 6 (mean±SD)	14.28±3.62	16.95±9.24 (%54)	0.000
Post-op month 12 (mean±SD)	14.00±4.07	17.24±8.70 (%55)	0.000

Pre-op: Preoperative Post-op: postoperative, IOP: Intraocular pressure, SD: Standard deviation, ¥: (mmHg and %) Compared to pre-op period, *:T-Test and ANOVA , between IOP change at pre-op and post-op control visits

Table 3. *BCVA changes over time.*

Time	BCVA (logMAR)	P value:*
Pre-op (mean±SD)	0.51±0.66	
Post-op month 1 (mean±SD)	0.50±0.84	0.888
Post-op month 6 (mean±SD)	0.50±0.84	0.925
Post-op month 12 (mean±SD)	0.44±0.72	0.225

BCVA: Best-corrected visualacuity, SD: Standard deviation *: T-Test and ANOVA (between BCVA changes at pre-op and post-op control visits)

5-FU needling in 3 cases (14%) for cystic bleb. The target IOP value was achieved in 4 of 6 patients.

Hypotonia was developed at the immediate postoperative period in 4 cases (19%), which recovered by medical treatment within the first week. These cases were not considered as complications. Anterior chamber shallowing was observed at early postoperative period in 2 eyes (9.5%). These patients were treated by giving viscoelastic material into the anterior chamber. It was seen that these patients were recovered in the control visit on month 1. Delayed onset, prolonged choroidal detachment followed by central retinal vein occlusion (CRVO) was detected in one patient (4.7%); the patient was treated with intravitreal triamcinolone injection. Overall, the severe complication rate was found at 14% (3/21). No apparent hyphema, blebitis, endophthalmitis, or corneal decompensation, as well as tube occlusion, implant dislocation, or scleral or conjunctival dehiscence over the tube, was detected.

DISCUSSION

At the first time of Ex-PRESS® Mini Glaucoma Shunt production, it was originally recommended to implant directly anterior chamber through subconjunctival area; however, excessive filtration and conjunctival dehiscence over implant appeared as frequent complications.[9] Dahan and Carmicheal reported that such complications were prevented by implantation beneath partial-thickness scleral flap allowing adjustment of filtration via sutures and scleral barrier over implant.[10] We used same technique in our study. It is an important advantage that no sclerotomy or iridectomy is required in this surgical technique; it decreases complication rate and inflammation; and more controllable filtration can be achieved fixed lumen diameter and implantation beneath scleral flap.[2] However, Ex-PRESS implantation is a penetrating glaucoma surgery, and complications similar to trabeculectomy can be seen. Also, it has specific complications such as dislocation of the implant into the anterior chamber, lumen tip occlusion, contact of implant tip to iris, metal reaction and mechanical irritation to the lens in case anterior chamber shallowing, accelerated cataract development, and endothelial cell loss.[2,11,12] There is no significant variation in complications according to shunt type in cases underwent Ex-PRESS® Mini Glaucoma Shunt implantation in the literature; this may be because both P200 and P50 were implanted beneath scleral flap. Scleral flap may have a more important role in reduction of excessive filtration when compared to lumen diameter.[7] In our study, no implant occlusion or dislocation was observed; this may be due to the fact that our patients were pseudophakic; thus, there was no contact of implant tip to iris. In the literature, there is a limited number of studies with contradictory outcomes regarding complications of P50 and P200.[6,12] In our study; it was observed that there was a delayed hypotonia with resultant choroid effusion in one patient and anterior chamber shallowing in 2 patients. No apparent hyphema, tube occlusion or dislocation, blebitis, or endophthalmitis was observed in our patients. Complications can differ based on glaucoma type. In our study, the severe complication rate was 14% (3/21) in agreement with literature.[2-5,14-17] In the studies by Seider et al.,[18] Türkoğlu et al.[19] and Buran et al.,[20] complication rates were higher than our study. This may be due to fact that Ex-PRESS surgery was performed in other complex glaucoma types including neovascular glaucoma in those studies. In the literature, there are prospective and retrospective studies and a limited number of meta-analyses comparing effectiveness, safety, cost, and complications by trabeculectomy. Although it has been reported that Ex-PRESS implantation is as successful as trabeculectomy with fewer complications,[4,14,16,17,21-23] comparable success and complications were reported less frequently[8,24,25,] and comparable success but higher complication rate was reported rarely.[18] In the literature, the CS rate for Ex-PRESS surgery ranged from 43% to 80%, while QS rates from 65% to 100%. The IOP reduction rate was reported as 35-59%.[3, 5, 8, 9, 12, 17, 18, 21-23,25] Our results are in agreement with the literature. In the literature, there is no study comparing trabeculectomy and Ex-PRESS implantation in pseudophakic cases. Only study using Ex-PRESS shunt implantation in only pseudophakic patients with open-angle glaucoma was reported from Turkey by Karakurt et al., which included 11 eyes of 8 cases.[26] In the study, Ex-PRESS P50 and 5-FU were used in the study and authors reported that IOP was decreased by 52% and that no patient required anti-glaucomatous agent at postoperative period and no severe complication was observed during a mean follow-up of 15.3 months (6-26 months). The study seemed to be more successful than our study and those reported in the literature. To best of our knowledge, our study is the most extensive series assessing Ex-PRESS (P200) shunt surgery in only pseudophakic eyes in the literature.

In a study, comparing Ex-PRESS (P200) shunt surgery and trabeculectomy, Liu et al.[2,3] found that Ex-PRESS had comparable success rates (CS: 43% and QS: 75%) and IOP decrease based on results at year one. Interestingly, a higher hypotonia rate was reported in the Ex-PRESS group (37%). There is a limited agreement with our results regarding both success and complication. These differences might be due to ethnicity and phakic eyes.

The study by Netland et al.[14] is among largest Ex-PRESS series. In the study, Ex-PRESS mini shunt (P50) was implanted in 59 patients (34 phakic and 25 pseudophakic eyes). In the Ex-PRESS group, IOP was decreased by 41% in year one. The mean number of drugs was reported as 0.91±1.3 at year one. Based on success criteria similar to our study, the authors reported CS as 90% at year one and 83% at year 2. Overall complication rate was reported as 18.6%.[14] These results are in agreement with our study.

In a retrospective study on 70 cases, Good and Kahook[21] performed Ex-PRESS (P50) implantation in 35 patients and compared with trabeculectomy group during a mean follow-up of 28 months. The IOP was decreased by 45%, as well as the number of drug use was also decreased. Based on success criteria similar to our study, authors reported CS of 77%, QS of 83% and complication rate of 8.5% with two hypotonia and 1 hyphema in agreement with our study.[21]

The study by De Jong et al.[3] is the Ex-PRESS series reporting the longest follow-up time and most successful results in the literature[3]. In the study, Ex-PRESS and trabeculectomy were recorded in 78 patients at 5 years of follow-up. Ex-PRESS (P50) was implanted to 39 patients. The mean IOP reduction was 48% at year one and 50% in year 5 in the Ex-PRESS group. The mean number of drugs was <1 at year one and five while it was signifi cantly lower than trabeculectomy group at both time points. The CS and QS were reported to be 87% and 100% in year 1, whereas 59% and 97% at year 5, respectively. The results reported are in agreement with our study. Authors reported lower complication rate when compared to trabeculectomy but details were not specified. Authors declared a financial relationship with manufacturer.[3]

In a study on 63 cases with 3-years follow-up, Gonzalez-Rodriquez et al.[15] implanted Ex-PRESS to 32 cases, which were compared with trabeculectomy. The authors reported CS and QS as 42% and 59% at year 2, whereas 35% and 52% in year 3, respectively.[15] Although comparable results were reported for Ex-PRESS and trabeculectomy, they had the lowest success rate together with those reported by Seider et al.[11] and Liu et al.[23] These low success rates were inconsistent with our results.

In a study on 32 cases with a mean follow-up of 6.3±3 months (3-16 months) from Turkey, based on Ex-PRESS (P50) implantation outcomes, Okka et al.[27] reported that there was a decrease in mean IOP by 56% and a marked decrease in drug use on postoperative month 6. Using 5 ≤ IOP ≤ 21 mmHg as success criteria, authors reported CS and QS as 81% and 100% at the last follow-up, respectively. This might be due to success criteria ≤ 21 mmHg and short follow-up period.[27]

Buran et al.[20] reported Ex-PRESS (P50) implantation outcomes in a series including 30 eyes. At a mean follow-up of 12.4±7 months (1-30 months), the authors reported mean IOP reduction by 59% and CS of 57%, QS of 80%, and a failure rate of 20%; however, follow-up periods were heterogeneous. Complication rate was found to be higher due to complex glaucoma types, but it was in agreement with our study.[20]

In a study by Türkoğlu et al.,[19] results of Ex-PRESS implant were reported in a case series of 30 patients (received MMC) with different glaucoma types and lens status at a mean follow-up of 9.5±7.6 months (6-24 months). The mean IOP was decreased by 31%, and success rate defined as 6 ≤ IOP ≤21 mmHg was reported as 70% on month 6. Drug use was significantly reduced at last visit. Authors reported hyphema, hypotonia-choroid effusion, dehiscence over implant and corneal decompensation as complication.[19] Although success and complication rates were lower than our study, this may be explained by surgeries in more complicated cases.

The majority of studies were conducted on heterogeneous groups regarding one or more characteristics such as glaucoma type, ethnicity, Ex-PRESS implant model, preoperative lens status (phakic, pseudophakic, aphakic), preoperative anti-metabolite use, and type of anti-metabolite and whether it is combined with cataract surgery.

In our study, it was intended to rule out effects of lens status and lens complications related to surgery and tube implant on surgical success by including only pseudophakic patients with uncomplicated posterior chamber IOL and standardization of anterior chamber depth in patients with similar ethnic characteristics. Implantation in similar glaucoma types (such as open angle glaucoma and pseudoexfoliation), identical concentration, and duration of MMC using Ex-PRESS P200 implant alone allowed us to assess surgical outcomes in a more homogeneous group.

This study has some limitations including the retrospective design, lack of comparison, small sample size and relatively shorter follow-up. However, its strength includes

being the largest series evaluating Ex-PRESS implant in only pseudophakic eyes with similar characteristics using the same surgical technique and implant at 12-months follow-up. However, further randomized trials with larger sample size and longer follow-up will provide a better understanding.

CONCLUSION

Based on our results at year one, Ex-PRESS® Mini Glaucoma Shunt (P200) surgery is highly effective (IOP decreased by 55%) in long-term control of glaucoma and successful (QS: 90.5%) with low complication rate (14%) in pseudophakic eyes with open-angle glaucoma. It achieved IOP control without medication in the majority of patients (CS: 57%), and the mean number of drugs used was significantly decreased.

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