·Clinical Research·

Evaluation of the Ex-PRESS® P-50 implant under scleral flap in combined cataract and glaucoma surgery

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Abstract

• AIM: To evaluate the efficacy and safety of glaucoma drainage device Ex-PRESS® P-50 for combined cataract surgery and glaucoma.

• METHODS: Patients having cataract and open angle glaucoma or patients with open advanced glaucoma which needed two or more antiglaucoma medications were included. Combined cataract surgery and glaucoma with Ex-PRESS® P-50 model placed under scleral flap was performed.

• RESULTS: Out of 40 eyes of 40 patients (55% male and 45% female) completed the study during one -year follow -up. The mean of age was 76.6 ±11.02y. The intraocular pressure (IOP) decreased significantly during the 12-month follow-up from 23.5 mm Hg to 16.8 mm Hg (Wilcoxon signed ranks test, *P*<0.001). A 59.5% of patients did not need any topical treatment, 10.8% of them needed one active principle, 27% needed two active principles, and 2.7% of them needed three active principles for successful IOP control (<21 mm Hg).

• CONCLUSION: Combined surgery of phacoemulsification with ExPRESS® P-50 lowers IOP from the preoperative baseline and reduces significantly the number of antiglaucoma active principles for IOP control after the operation.

• **KEYWORDS:** ExPRESS; combined surgery; cataract surgery; glaucoma surgery
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INTRODUCTION

Cataract and glaucoma usually affect elderly population. Both pathologies are strongly related to the aging process and may frequently affect the same individual patient. Besides age, this might be related to the possible role of antiglaucoma medications in the progression of lens opacity [1-10]. Glaucoma filtering surgery is indicated when glaucomatous damage progresses despite the lower level of intraocular pressure (IOP) obtained with pharmacological treatment. It is also required when maximun antiglaucomatous medications are insufficient to decrease IOP to targeted levels [1-11]. When cataract surgery and glaucoma surgery are required, these can be performed separately or in combination. Trabeculectomy has been the gold-standard treatment for primary open angle glaucoma (POAG) since 1968 [1]. However, the tube-shunt operations may be equally effective in controlling POAG [2-11]. While full-thickness filtration procedures considerably reduced the IOP, they were associated with early postoperative hypotony and related side effects and became progressively less popular. Glaucoma drainage implants, designed to shunt the aqueous posteriorly, represent an alternative method for lowering IOP in glaucomatous patients [2-8]. The ExPRESS® glaucoma filtration device (Alcon, Fort Worth, Texas, USA) is a stainless steel miniature glaucoma device, developed as an alternative to trabeculectomy for patients with POAG. This procedure would be theoretically more reproducible and simple to perform as well as less traumatic to the ocular tissue than traditional filtering surgery. Although the standard trabeculectomy is still the most commonly used glaucoma operation worldwide, the Ex-PRESS exhibits similar outcomes with fewer early postoperative complications [2-5]. It was initially inserted from the limbus into the anterior chamber and placed underneath the conjunctiva, the currently adopted method places it under the scleral flap to avoid overfiltration, exposure of the Ex-PRESS, and other complications [6-9]. This shunt procedure can be performed on its own or in combination with cataract surgery by phacoemulsification[2].

The combined cataract surgery by phacoemulsification and trabeculectomy has been successfully performed [10]. This combined procedure enables to lower the IOP and gain in visual acuity in one surgery, with the treatment of two

distinct disorders [10]. Combined surgery for cataract and glaucoma is associated with less long-term IOP reduction compared with trabeculectomy alone. Nevertheless, combined surgery effectively lowers IOP and reduces the long-term requirement for antiglaucoma medications without additional complications[11]. However, the early postoperative hypotony and related side effects, such as choroidal detachment, athalamia and pharmacologic midriasis by cycloplegic agents, cause slower visual recovery. The emergence of new devices in glaucoma filtering surgery may contribute these complications to be less frequent in combined cataract and glaucoma surgery[12-13]. The Ex-PRESS® glaucoma filtration device is a miniature stainless steel glaucoma device, developed as an alternative to trabeculectomy and to the other types of glaucoma filtering surgery for patients with POAG. The Ex-PRESS ® R-50 device has been successfully employed to increase outflow in glaucoma patients [2,4-5]. Some studies have shown that phacoemulsification plus Ex-PRESS® R-50 implantation are significantly more effective in reducing IOP and medication use than phacoemulsification alone [6,14]. A second generation Ex-PRESS® P-50 has recently been developed. To the best of our knowledge, the efficacy and safety of the new Ex-PRESS® P-50 device have only been evaluated in glaucoma filtering surgery [15-16] but not in combined surgery. The purpose of this study was to evaluate the mid-term efficacy and safety of the Ex-PRESS® P-50 implanted under scleral flap in combined cataract and glaucoma surgery.

MATERIALS AND METHODS

This noncomparative, nonrandomised, nonmasked prospective interventional trial was conducted to assess the efficacy and safety of the Ex-PRESS® P-50 device combined with cataract surgery. The enrolled patients had an open angle glaucoma or pseudoexfoliative glaucoma and were sent to our department for cataract surgery. This study was approved by the Ethics Committee of the Universitary Hospital Arnau de Vilanova (CEIC) and was conducted according to the tenets of the Declaration of Helsinki. After information of the procedure a written informed consent for combined Ex-PRESS ® P-50 implantation and cataract surgery was obtained from each patient.

Materials Subjects were recruited prospectively at the Department of Ophthalmology, Universitary Hospital Arnau de Vilanova (Lleida, Spain). All patients underwent a complete ophthalmic evaluation including: best corrected visual acuity (BCVA), slit-lamp biomicroscopy, Goldmann applanation tonometry IOP measurement, gonioscopy, dilated fundus examination. Posteriorly, an automated perimetry (Humphrey, Carl Zeiss, Germany) and retinal nerve fiber layer study by optical coherence tomography (OCT) (Stratus, Carl Zeiss, Germany) to assess the stage of the glaucoma were performed.

The inclusion criteria were patients with cataract and coexisting medically uncontrolled open angle glaucoma or pseudoexfoliative glaucoma. Clinical indication for combined cataract surgery and glaucoma filtering surgery was patients with BCVA ≤0.3 logMAR scale and IOP > 21 mm Hg with topical antiglaucomatous eyedrops. Patients with advanced glaucoma with IOP betwen 17 and 22 mm Hg who needed two or more antiglaucoma medications and had to be operated on for cataracts were also included. Patients with neovascular glaucoma, primary angle-closure glaucoma, congenital or juvenile glaucoma, normal-tension glaucoma or prior filtering surgery were excluded. The number of preoperative and postoperative antiglaucoma active principles was processed for statistical analysis.

Surgical Technique The surgical procedures were performed under peribulbar anesthesia and sedation. Topical 5% povidone-iodine was applied 10min prior surgery. After a fornix-based conjunctival flap was performed, a partial thickness of scleral flap of one-half to two-thirds scleral thickness was created similar to trabeculectomy. The scleral dissection was carried forward to the clear cornea to gain adequate exposure of the scleral spur. Cataract surgery with a standard sutureless temporal or nasal clear corneal phacoemulsification and posterior chamber foldable acrylic IOL implantation was performed, prior to the Ex-PRESS ® P-50 implantation, in order to ensure stability and deepen the anterior chamber. After IOL is inside the bag, acetylcholine 1% was injected into the anterior chamber to constrict the pupil. The anterior chamber was refilled with a viscoelastic substance to maintain the anterior chamber pressure during implantation maneuvers of the Ex-PRESS. Then, a puncture wound by a 25 G needle was performed under the scleral flap opening the anterior chamber for successful placement of the implant. The Ex-PRESS® P-50 device comes preloaded on an injector system. The injector device was rotated 90 degrees prior to the insertion. It was finally rotated again to its final position inside the eye. Posteriorly, the device was released until the tip of its introducer and the appropriate planned scleral flap provided good coverage of the Ex-PRESS. All Ex-PRESS implants employed in the study were model P-50. Scleral flap closure was achieved placing at least two 10-0 nylon sutures at the two posterior corners of the sclerotic block. Only one suture was used in the triangular flaps. Conjunctival closure was achieved using an 8-0 polyglactin (Vicryl®) running suture. The viscoelastic was cleared at the end of the operation.

Postoperative treatment consisted of topical application of mixed eyedrops of tobramycin and dexamethasone 4 times a day followed by gradual tapering after the first week over approximately 4wk. During the first week moxifloxacin eyedrops 3 times a day were also administered.

Follow-up Postoperative visits were scheduled for 1, 7, 15d, 1, 3, 6 and 12mo. Every visit included BCVA, slit-lamp biomicroscopy of the anterior segment, Goldmann applanation tonometry, gonioscopy and fundus examination. Additional topical antiglaucoma medications were added if IOP was higher than 21 mm Hg. Side effects during the first postoperative week were recorded. For analysis of the data only preoperative values and at 24h, 7, 15d, 1, 3, 6 and 12mo were recruited for the study. Patients with a follow-up lower than 12mo were not included in the study. Success rate was determined by IOP between 5 and 21 mm Hg for a year of follow-up, with or without medication, and without requiring further filtering surgery. Early hypotony was defined as IOP ≤5 mm Hg during the first two weeks.

Statistical Analysis Data are expressed as the mean±SD (minimum and maximum values). Statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS 19.0 for Windows, SPSS Inc., Chicago, IL, USA). Kolmogorov-Smirnov test was performed to check normal distribution of variables in the sample. The Wilcoxon signed-rank test was used to compare changes from baseline IOP and to compare the number of antiglaucoma drugs used by the patient. For stablishing if BCVA improved following the surgical procedure we used the Student's *t*-test for paired data. Results were considered statistically significant when $P<0.05$.

RESULTS

A total of 40 eyes of 40 patients with both cataract and glaucoma completed the study for one year. Their mean age was 76.60±11.02y. Table 1 contains the demographic data. BCVA improved significantly from 0.40±0.54 to 0.20±0.54 (logMAR scale) (Student's *t*-test for paired data; $P<0.001$), and the IOP decreased significantly during the 12mo of follow-up from 23.53±6.54 to 16.08±4.59 mm Hg (Wilcoxon signed-ranks test; $P<0.001$) (Table 2). Figure 1 illustrates the trends in IOP changes from baseline preoperative values. The diminution of IOP is maintained during the observation period. Table 3 shows the successful outcomes after 12mo of follow-up. Thus, 57.5% of patients did not need any adjunctive topical treatment, 10% of them needed only one active principle, 27.5% of eyes needed two active principles, and 5% of them needed three active principles. The mean time for adding antiglaucomatous medications when was necessary was 2mo (range 15d-11mo). Table 4 shows the success rate when we considered IOP ≤21 mm Hg. In 92.5% of eyes IOP was ≤21 mm Hg. After a follow-up of 12mo, 59.5% of patients remained without any additional medication, while 40.5% needed additional topical treatment (Table 4).

Complications in the early period included two cases of ocular hypotony and uveal effusion (5%), which were solved during the first two weeks. In two cases (5%) of triangular flap, a suturolisis with argon laser was performed. Finally, one case needed reintervention after a year of follow-up due to uncontrolled IOP (2.5%).

Table 1 Demographic description of the population of the study

Parameters	Patients
No. of subjects	40 (40 eyes)
Sex (M/F)	18 (45%)/22 (55%)
Age (a)	76.60±11.02
Race	Caucasian
Types of glaucoma	
Primary open angle glaucoma	38
Pseudoexfoliative glaucoma	1
Traumatic open angle glaucoma	1

Table 2 IOP and BCVA after 12mo of follow-up *n*=40

Parameters	Preoperative		Postoperative		*P*
	Mean	SD	Mean	SD	
IOP	23.53	6.54	16.08	4.59	<0.001[a]
BCVA	0.40	0.54	0.20	0.54	0.001[b]

[a]Wilcoxon signed-ranks test; [b]Paired samples statistics.

Table 3 Successful outcomes after 12mo and needed of additive topical treatment after the follow-up *n* (%)

Treatments	Frequency	
	Preoperative	Postoperative
Without treatment	0 (0)	23 (57.5)
One active principle	9 (22.5)	4 (10.0)
Two active principles	27 (37.5)	11 (27.5)
Three active principles	4 (10.0)	2 (5.0)
Total	40 (100)	40 (100)

Table 4 Success rate after 12mo of follow-up ***n* (%)**

Active principles	With treatment	Without treatment	Total
1	4 (10.8)	0	4 (10.8)
2	10 (27)	0	10 (27)
3	1 (2.7)	0	1 (2.7)
Total	15 (40.5)	22 (59.5)	37 (92.5)

Success IOP ≤21 mm Hg.

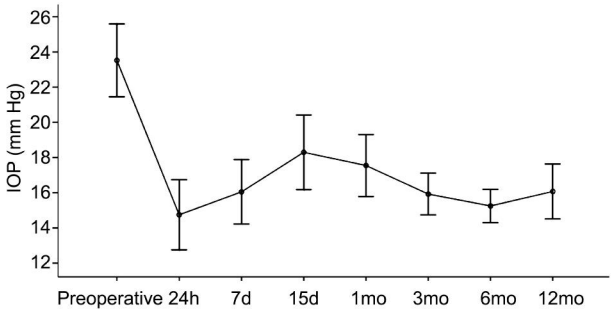

Figure 1 Change from preoperative baseline IOP (mm Hg) in eyes treated with phacoemulsification and Ex-PRESS Mean± standard deviation.

DISCUSSION

The Ex-PRESS mini glaucoma shunt is a stainless steel miniature shunt developed for using as an alternative

procedure to trabeculectomy [2,17]. The Ex-PRESS glaucoma filtration device was designed to drain aqueous fluid from the anterior chamber to the subconjunctival space, forming a filtration bleb, akin to a trabeculectomy. It was currently available in two models: R-model and P-model. The Ex-PRESS R-model has a beveled tip, an external diameter of 400 μm (27-gauge), an internal lumen of 50 μm, a total device length of 2.96 mm and a uniform back plate. The Ex-PRESS® P-50 model has a decreased bevel angle, an external diameter of 400 μm, a total device length of 2.64 mm and a vertical channel back plate. It is available in both a 50-μm and 200-μm internal lumen size [17]. The P-model features vertical channels in the plate, designed to enhance posterior flow of aqueous and formation of a more diffuse posterior bleb. The devices also contain a relief port designed to provide an alternative pathway for aqueous should the axial lumen become occluded by iris, fibrin or blood [16]. Four studies have published results of the Ex-PRESS® R-50 implant combined with phacoemulsification cataract extraction, two of them under conjuntival flap[6,14] and the other ones under scleral flap [2,18]. Thus, Traverso *et al* [14] included 26 eyes of 25 patients. The overall success rate (IOP ≤21 mm Hg), with or without medications, was 94.4% at two years. Serious complications as conjunctival erosion were reported in three cases (11.5%). The main limitation of this study was the relatively small number of patients. However, its strengths were the length of follow-up and excellent IOP control. The second trial of the Ex-PRESS® R-50 shunt under conjunctival flap combined with cataract extraction was implanted in 35 eyes of 35 patients who were followed for up to 48mo[6]. Conjunctival erosion was reported in four cases (11.4%). Ten patients (32.7%) remained without medicatons after the follow-up. The study showed that, despite a good IOP control, Ex-PRESS® R-50 implantation under the conjunctiva was associated with a relatively high number of complications. The authors concluded that a refinement in the tube design and implantation technique would increase the success rate. Maris *et al* [2] implanted under scleral flap the Ex-PRESS® R-50 device combined with phacoemulsification in a subgroup of 15 patients of a comparative series between trabeculectomy and Ex-PRESS® R-50 implant. Overall surgical success was not different in eyes treated with combined surgery compared with those treated only with the Ex-PRESS device. No special complications for this subgroup were reported. The limitations of this study were the small subgroup of combined surgery and a follow-up of 10.8 months. Kanner *et al* [18] reported 231 eyes treated with ExPRESS® R-50 alone and 114 eyes operated with ExPRESS® R-50 filtering surgery and phacoemulsification with a follow-up of 21.9mo. Compared with baseline values, the IOP and number of glaucoma medications were significantly lowered in both grops. However, the change of IOP from baseline was lower after the ExPRESS® R-50 implant alone.

Present study is evidently the first report of mid-term postoperative results in combined surgery with the Ex-PRESS® P-50 device under scleral flap. Our success rate was similar to Traverso *et al* [14] article and better than Rivier *et al* [6] study. Kanner *et al* [18] did not observe in the combined group of phacoemulsification and catarat with the R-50 model. Nevertheless, the same study reported conjunctival erosion in 0.43% of cases with the Ex-PRESS® R-50 device alone without phacoemulsification. The most common device-related complication described by Kanner *et al* [18] was blockage of the lumen of the implant, which was effectively treated with Nd: Yag laser. The causes of occlusion were the presence of pigment or vitreous in the lumen. We did not observe this complication. It may be because we had no patients with any complication during the operation, such as capsular bag failure and vitreous loss. In the first week, Kanner *et al* [18] reported a 7.9% of hypotony cases. We observed this complication in only 5% of cases, which is not really significant. Two cases of our series needed suture lysis (5%) for lowering the IOP after the procedure.

In our study the BCVA significantly increased. This improvement is a direct benefit of cataract surgery as in previous reports [6,14]. No high improvement of the visual acuity occurred in our serie due to the advanced stage of the glaucoma. Nevertheless, the additional IOP reduction associated to cataract surgery may contribute to the maintenance of BCVA during the 12-month follow-up. IOP significantly decreased from preoperative baseline values in all follow-up exams. Regarding the success rate, 57.5% of patients did not need additional antiglaucoma medications and the percentage of patients which reduced the number of topical medications was also significant. This fact is in accordance with previous studies[6,13-14,18]. If we take as success an IOP ≤21 mm Hg, we obtained a 92.5% of success. 59.5% of them did not need any treatment and 40.5 % of them needed topical treatment for IOP control. Our success rate of 92.5% would be in agreement with the success rate reported in the literature, which is approximately 60% -100% for the trabeculectomy[8,19-20].

Although the percentage of success may be decresased after the first year of the implantation of the Ex-PRESS® P-50 device, similar rates have been described following trabeculectomy [4]. Many trabeculectomies start failing in the second year as do Ex-PRESS shunt implantations[11]. The main risk factors for failure of the Ex-PRESS device are diabetes, non-Caucasian race, and previous glaucoma surgery[4].

The advantage against trabeculectomy is that there is no iridectomy and no sclerectomy during the implantation of the Ex-PRESS device. Thus, the postoperative inflammation and anterior chamber reaction may be similar to the phacoemulsification alone in cases of combined surgery with the advantage that it is possible to diminish additionally the

IOP. In the postoperative period the Ex-PRESS device do not need additional treatment with cycloplegic agents. This fact makes more rapid the visual recovery. Some of these advantages make its use in special cases as patients with only one useful eye[21].

The criticism to the use of Ex-PRESS is the significant increased cost of the surgery [22]. However, recent published studies conclude that visual recovery is more rapid with the Ex-PRESS device than trabeculectomy [5]. Furthermore, the IOP variation was lower during the early postoperative period, and postoperative complications were less frequent after Ex-PRES implantation compared with the classic trabeculectomy. These results added to the caratact surgery have an important advantage for a more rapid visual recovery. As we have demonstrated in our study the combined phacoemulsification with Ex-PRESS® P-50 has a few early complications, improves significantly BCVA, reduces significantly the IOP from preoperative baseline values and also reduces the number of antiglaucoma active principles which are necessaries for IOP control. All of this may be cost effective in the cases affected of cataract and glaucoma.

The limitation of this study may be the number of cases; nevertheless, it is similar or even higher than other studies[6,13-14]. The lack of a control group in which only cataract surgery performed may be considered as a limitation since cataract surgery alone has an impact in IOP control in such population[23]. All of our patients were caucasians and, unlike other studies [14], there was no racial influence in the successful rate outcomes. To the best of our knowledge, this is the first study of combined phacoemulsification with Ex-PRESS® P-50.

In conclusion, the combined surgery of phacoemulsification with the Ex-PRESS® P-50 model has few early postoperative complications, improves significantly the BCVA, lowering IOP from the preoperative baseline values and reducing the number of antiglaucoma active principles after the operation.

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