



Long Term Results of the Ex-PRESS P-200 Miniature Glaucoma Filtration Device in Primary and Secondary Glaucoma

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Abstract

Purpose: To report the efficacy and safety of the Ex-PRESS P-200 glaucoma filtration device implanted under a partial-thickness scleral flap in white adult patients affected by uncontrolled primary or secondary glaucoma, and to evaluate the ability of clinical variables to predict the success of the Ex-PRESS implant.

Design: clinical, retrospective, non-comparative case series study.

Study Population: Chart review of patients of 18 to 90 years of age affected by uncontrolled glaucoma with intraocular pressure (IOP) ≥ 18 mmHg and ≤ 45 mmHg on maximum tolerated medical therapy, who had undergone implantation of the Ex-PRESS P-200 miniature glaucoma shunt as first-line glaucoma filtration surgery, and had a minimum of 12-month postoperative follow up.

Intervention: The Ex-PRESS P-200 device was implanted under a scleral flap pre-treated with Mitomycin C as a single procedure or combined with phacoemulsification cataract extraction and in the bag IOL implantation when necessary.

Main Outcome Measures: IOP, number of anti-glaucoma drugs, intra- and post-operative complications. Success was defined as complete if postoperative IOP was 6 mmHg to 18 mmHg without medication, and qualified if IOP was within the same range with anti-glaucoma medication. Failure was defined as postoperative IOP <6 or >18 mmHg, prolonged hypotony or loss of light perception.

Results: A total of 132 eyes of 132 patients (mean age of 75.5 years \pm 10 years) with a mean follow-up of 31.6 months \pm 24 months (range: 12-96) were included in the study. Mean preoperative IOP and number of anti-glaucoma medications significantly decreased at all postoperative follow-ups ($P < 0.001$), with a mean postoperative reduction of 42% and 59%, respectively ($P < 0.001$). Kaplan-Meier analysis determined a complete and qualified success rate of respectively 34% and 74% at 3 years after surgery. The most frequent postoperative complications included hypotony (10 eyes), hyphema (10 eyes) and flat anterior chamber (9 eyes). The best predictor of qualified success at 3-year follow-up was combined cataract extraction surgery (univariate Cox model; hazard ratio [HR] 3.2; $P = 0.001$).

Conclusion: The Ex-PRESS P-200 implant is an effective IOP-lowering procedure in white adults affected by primary or secondary glaucoma, both alone and combined with cataract surgery. The best predictor of success of the Ex-PRESS P-200 implant was simultaneous cataract extraction surgery.

Keywords: Ex-PRESS glaucoma filtration device; Glaucoma; Glaucoma filtration surgery; Intraocular pressure; Success rate; Risk factors

Introduction

Glaucoma surgery is performed when, in order to prevent optic nerve damage or visual field deterioration, further intraocular pressure (IOP) reduction is needed despite the use of maximum tolerated medical therapy and appropriate laser treatment.

Since 1968, trabeculectomy is the most widely utilized procedure for glaucoma filtration surgery and it is still considered as the standard procedure for adult glaucoma surgery [1]. Although it has been demonstrated to provide good results in terms of postoperative IOP lowering [2],

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Figure 1: The Ex-PRESS P-200 glaucoma filtration device.

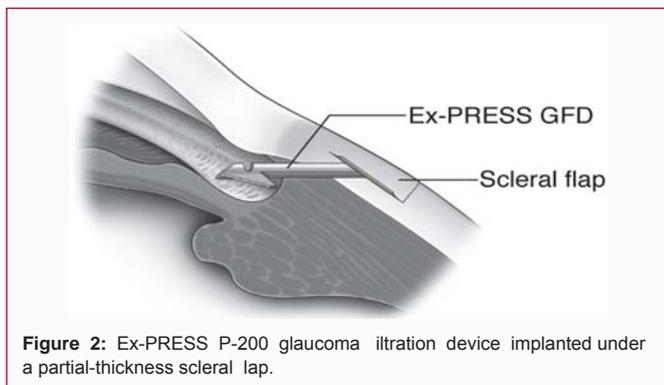


Figure 2: Ex-PRESS P-200 glaucoma filtration device implanted under a partial-thickness scleral flap.

trabeculectomy is associated with postoperative complication in approximately 50% of cases [3], with the most frequent complications being hyphema (25%), shallow anterior chamber (24%), hypotony (24.3%), bleb leak (17.6%), visual acuity decrease, mainly due from cataract development (18.8%), and irreversible visual loss (3.7% to 4.4%) [3,4].

The high complication rate associated with trabeculectomy has driven the development of alternative approaches in glaucoma surgery.

The Ex-PRESS glaucoma filtration device (Alcon Laboratories, Inc., Fort Worth, TX, USA) was developed in 2001 with the aim to mimic the IOP control by trabeculectomy and to offer easier, faster, less invasive and more standardized glaucoma surgery [5-7]. It is a miniature, biocompatible, non-valved, medical-grade stainless steel device approved by the US Food and Drug Administration (FDA) to divert aqueous humour from the anterior chamber into a subconjunctival space. Six Ex-PRESS models with different structural characteristics (R-50, T-50, X-50, X-200, P-50 and P-200) obtained the FDA-approval; only models P-50 and P-200 are actually available on the market [8]. The Ex-PRESS glaucoma filtration device model P-200 is shown in Figure 1.

The Ex-PRESS device was initially designed to be implanted through full-thickness sclera near the limbus under the conjunctiva, but this approach demonstrated high rate of post-operative complications, including persistent hypotony, flat anterior chamber, choroidal detachment, conjunctival erosion, shunt extrusion [6,7,9-12].

In 2005, Dahan and Carmichael described an alternative surgical technique in which the device was implanted under a scleral flap [13] (Figure 2). This approach was associated with satisfactory IOP control [7,12-15] and reduced postoperative complication rates [9,13-17].

The aim of the present study was to provide the results of the implant of the Ex-PRESS P-200 device as first-line glaucoma incisional surgery in patients affected by uncontrolled primary or secondary glaucoma. To the best of our knowledge, this is the first study reporting the results of the model P-200 in a large cohort of

patients.

Methods

This retrospective, non-comparative case series included 287 Caucasian patients over 18 years who had undergone implantation of the Ex-PRESS P-200 glaucoma filtration device under a partial-thickness scleral flap from March 2010 to May 2017. The study was in compliance with the tenets of the Helsinki's Declaration and with Institutional Review Boards (IRBs) and HIPAA requirements, and it was approved by the IRB of the Azienda per l'Assistenza Sanitaria "Friuli Occidentale", Pordenone, Italy.

The inclusion criteria were age \geq 18 years and Ex-PRESS P-200 device implantation with or without associated cataract extraction with phacoemulsification and at least 12 months of follow up after shunt implantation.

Main outcome measures were IOP (measured by calibrated Goldmann applanation tonometers), number of anti-glaucoma medications, and intra- and post-operative complications. Variables recorded from medical records included demographics, glaucoma diagnosis, glaucoma stage based on the Glaucoma staging system classification [18], previous intraocular procedures or laser treatments, additional procedures required, duration of the follow-up, and time to failure.

For the postoperative IOP outcomes, success was defined as complete if the postoperative IOP was 6-18 without IOP-lowering medication on two consecutive follow-up visits, and qualified if IOP was within the same range with or without medications on two consecutive follow-up visits. Failure was qualified as IOP $<$ 5 mmHg or $>$ 18 mmHg despite medications, persistent hypotony, progression to no light perception vision or any further glaucoma surgeries to control high IOP. An IOP value of $<$ 5 mmHg on two consecutive follow-up visits after 3 months was defined as persistent hypotony. Laser suture lysis, bleb needling and 5-fluorouracil injection (5 mg in 0.1 mL) inside the bleb were not considered as failures of the procedure.

All surgeries were performed by a single expert surgeon (GB) at the Department of Ophthalmology of the S. Maria degli Angeli Hospital, Pordenone, Italy, between March 2010 and May 2017. All patients over 17 years old who required glaucoma surgery were considered candidates for the procedure of Ex-PRESS implant and informed consent was obtained before the surgical procedure by all patients. Ex-PRESS implant was combined with cataract surgery in patients with visually significant cataract.

The surgical technique used in the present study has been extensively reported elsewhere [14]. Briefly, after peribulbar anesthesia, a fornix-based conjunctival flap and a partial thickness 4.0 mm x 3.0 mm scleral flap were created in an upper quadrant. Mitomycin C (0.4 mg/mL) was applied under the scleral flap and the conjunctiva for 2 minutes and copiously irrigated with balanced salt solution. After that, a nasal or temporal clear corneal paracentesis port was made. A 27-gauge needle was used to make an entry track into the anterior chamber parallel to the iris plane under the scleral flap at the grey line, which corresponds to a location just anterior to the trabecular meshwork. The Ex-PRESS P-200 shunt was introduced into the ostium with a disposable injector, placing the shunt with its tip in the anterior chamber and the plate flush on the scleral bed. The Ex-PRESS P-200 model is 2.64 mm in length, with a 400-micron external diameter and a 200-micron internal core, with a beveled

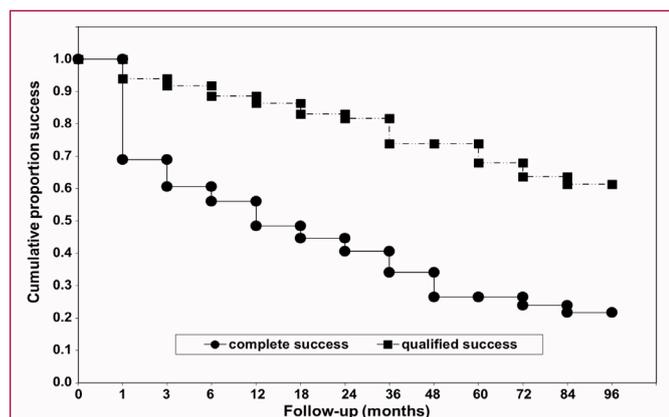


Figure 3: Results of the Kaplan-Meier survival analysis showing the cumulative probability of success over time following the Ex-PRESS P-200 glaucoma filtration device implant. Success was defined as complete if the postoperative IOP was ranging between 6 and 18 mmHg without IOP-lowering medications, and as qualified if the postoperative IOP was within the same range with or without anti-glaucoma medications.

tip shape and a vertically split plate surface [19] (Figure 1). The scleral flap was sutured using four permanent 10-0 nylon sutures. Shunt flow was tested by injecting balanced salt solution into the anterior chamber through the paracentesis port. The conjunctiva was sutured with 8-0 vicryl sutures. When required, a supero-temporal or supero-nasal clear cornea phacoemulsification cataract extraction with “in the bag” intraocular lens insertion was performed. Postoperative local therapy included 0.1% dexamethasone sodium phosphate and ofloxacin (Alcon Laboratories, Inc. Fort Worth, TX, USA) eye drops, which were administered 4 times daily for 1 week. The antibiotic drops were discontinued 1 week after surgery, and dexamethasone eye drops were tapered for 1 month in all patients.

Each patient underwent postoperative examinations at 1 day, 1 week, 1, 3, 6 months and every 6 months. The examination at each follow-up included: best corrected visual acuity evaluation, tonometry with Goldmann applanation tonometer, slit-lamp anterior segment examination and fundus biomicroscopy with a 90-diopter lens.

Statistical analysis

Data distribution was analyzed using the Kolmogorov-Smirnov test. Comparisons between pre-and post-operative data were assessed using the paired Student *t* test for continuous variables and the Friedman test for non-continuous variables. Success rate was assessed using Kaplan-Meier survival analysis. Univariate and multivariate Cox proportional hazard models were used to identify the factors that were predictive of success of the Ex-PRESS P-200 implant. Variables with *p*<0.1 in the univariate model were considered in a multivariate model. Cox proportional hazards multivariate model was performed using a backward strategy, with a statistical significance cutoff for variable screening of 0.05. The statistical analysis was performed using SPSS 11.0 for Windows (SPSS Inc, Chicago, IL). Statistical significance was defined as *p*<0.05.

Results

The study included 132 eyes of 132 Caucasian patients (mean age of 75.5 years ± 10 years) who met the inclusion criteria from a total of 287 eyes who had undergone Ex-PRESS P-200 shunt implantation between March 2010 and May 2017. In patients who had surgery in both eyes, the eye with longer follow-up was selected.

Patient’s demographic and pre-operative data are summarized

Table 1: Clinical Variables.

	Variables	Number of eyes=132
Clinical data	Age (years) mean ± SD (range)	75.5 ± 9.9 (39 - 90)
	Sex (Male/Female) n (%)	82/49 (63/37%)
	Eye (Right/Left) n (%)	61/71 (46/54%)
Glaucoma Diagnosis	Primary open-angle	78 (59.1%)
	Primary chronic angle-closure	9 (6.8%)
	Pseudoexfoliative	22 (16.7%)
	Pigmentary	4 (3.0%)
	Uveitic	2 (1.5%)
	Neovascular	3 (2.3%)
	Post-traumatic	2 (1.5%)
	Corticosteroids-related	5 (3.8%)
	Other secondary glaucoma	7 (5.3%)
	Primary glaucoma	87 (66%)
Secondary glaucoma	45 (34%)	
Glaucoma stage^ n (%)	Stage 1	1 (0.8%)
	Stage 2	38 (28.8%)
	Stage 3	51 (38.6%)
	Stage 4	27 (20.5%)
	Stage 5	15 (11.4%)
Lens status n (%)	Phakic Pseudophakic	69 (52.3%)
	Pseudophakic	63 (47.7%)
Previous lasers n (%)	Trabeculoplasty	21 (15.9%)
	Peripheral iridotomy	9.0 (6.8%)
Previous ocular surgery n (%)	Cataract extraction	63 (47.7%)
	Penetrating keratoplasty	4 (3.0%)
	Via pars plana vitrectomy	3 (2.3%)
	Others	2 (1.5%)
Combined phaco + IOL	Yes n (%)	56 (42.4%)
	No n (%)	76 (57.6%)

SD: Standard Deviation; n: Number; ^: Glaucoma Staging System Classification in Table 1. The preoperative glaucoma diagnosis was primary glaucoma (open-angle or chronic angle-closure) in 66% of eyes and secondary glaucoma in the remaining 34% of cases. All patients were on maximal tolerable anti-glaucoma medications preoperatively. The Ex-PRESS P-200 device was implanted as a single procedure in 76 eyes (57.6%) and combined with cataract surgery in 56 eyes (42.4%). All 132 patients had at least 1-year follow-up; the mean follow-up duration was 31.6 months ± 24 months (range 12-96).

Postoperative interventions included bleb needling (3 cases) and bleb needling with 5-fluorouracil injection (7 cases).

Mean IOP and mean number of medications preoperatively and at all postoperative follow-up times are shown in Table 2. Mean preoperative IOP and number of anti-glaucoma medications significantly decreased at all postoperative follow-up times (*P*<0.001), with a mean postoperative reduction of 42% and 59%, respectively (*P*<0.001).

The results of the Kaplan-Meier survival analysis for the cumulative probability of complete and qualified success are shown in (Figures 3). The cumulative probability of success at 12, 36 and 60

Table 2: Pre- and post-operative intraocular pressure (IOP) values and number of medications.

		IOP (mmHg)	Pre- vs post-op differences	Number of medications	Pre- vs post-op differences
	(n of eyes)	mean ± SD (95% CI)	P value a	mean ± SE (95% CI)	P value b
Pre-op	(132)	26.8 ± 6.7 (18 - 42)	-	2.9 ± 0.7 (2 - 4)	-
Post-op	1 m (132)	15.1 ± 5.5 (6 - 27)	<0.0001	0.4 ± 0.8 (0 - 3)	<0.0001
	3 ms (132)	14.9 ± 4.7 (8 - 26)	<0.0001	0.5 ± 0.9 (0 - 3)	<0.0001
	6 ms (132)	15.7 ± 4.9 (10 - 27)	<0.0001	0.7 ± 1.0 (0 - 3)	<0.0001
	1 y (132)	15.0 ± 4.1 (6 - 25)	<0.0001	0.8 ± 1.1 (0 - 3)	<0.0001
	1.5 ys (126)	15.2 ± 3.7 (10 - 27)	<0.0001	1.0 ± 1.2 (0 - 3)	<0.0001
	2 ys (118)	15.5 ± 3.6 (9 - 24)	<0.0001	1.0 ± 1.1 (0 - 3)	<0.0001
	3 ys (101)	15.9 ± 4.2 (10 - 27)	<0.0001	1.2 ± 1.2 (0 - 3)	<0.0001
	4 ys (68)	15.6 ± 4.0 (10 - 26)	<0.0001	1.6 ± 1.4 (0 - 3)	<0.0001
	5 ys (42)	14.7 ± 3.7 (10 - 22)	<0.0001	1.7 ± 1.5 (0 - 3)	<0.0001
	6 ys (24)	15.9 ± 3.8 (10 - 23)	<0.0001	1.7 ± 1.1 (0 - 3)	<0.0001
	7 ys (10)	16.7 ± 3.2 (14 - 24)	0.005	1.7 ± 1.0 (0 - 3)	<0.0001
	8 ys (6)	16.4 ± 4.9 (14 - 24)	0.009	1.8 ± 1.3 (0 - 3)	<0.0001

IOP: Intraocular Pressure; SD: Standard Deviation; CI: Confidence Interval; SE: Standard Error; m: month; y: year; a: paired; t: test; b: Friedman test

Table 3: Univariate Cox proportional hazard model for development of qualified success after the Ex-PRESS device implant at 3-year follow-up.

Preoperative variables	HR	95% CI	P value
Age (per 1 year older)	1.0	0.9 - 1.0	0.88
Sex (Male)	0.8	0.4 - 1.6	0.55
Eye (Right)	0.8	0.4 - 1.2	0.55
Glaucoma type (Primary)	1.0	0.5 - 2.1	0.99
Glaucoma stage (per 1 stage higher)	1.0	0.7 - 1.5	0.89
Lens status (phakic)	0.2	0.1 - 0.5	0.005
Previous surgery (No)	0.1	0.0 - 0.9	0.04
Previous laser (No)	2.0	0.7 - 2.8	0.18
Combined phaco + IOL (Yes)	3.2	1.3 - 7.8	0.001
Preoperative IOP (per 1 mmHg higher)	1.1	0.9 - 1.1	0.09
Pre-op number of medications (per 1 unit higher)	1.3	0.8 - 2.0	0.3

HR: Hazard Ratio; CI: Confidence Interval; IOL: Intraocular Lens

postoperative months was 49%, 34% and 27% for complete success, and 86%, 74% and 68% for qualified success, respectively. The mean time for failure was 17.2 months ± 22.2 months for complete success and 29.9 months ± 24.8 months for qualified success.

Thirty-one eyes (23.5%) failed to respond to Ex-PRESS P-200 shunt implantation. The reasons for surgical failure were the development of uncontrolled IOP (>18 mmHg with anti-glaucoma medications) (30 eyes), and persistent postoperative hypotony with choroidal detachment (1 case), that required choroidal drainage. No cases of loss of light perception were recorded. Of the 30 eyes that developed postoperative uncontrolled IOP, 25 were scheduled for further surgery, including: revision of the bleb and scleral flap (16 cases), trabeculectomy (5 cases), Ahmed valve implant (3 cases) and ciliary body cryoablation (1 case). Three cases required explantation of the Ex-PRESS device for the following reasons: contact with the iris (1 case); contact with the corneal endothelium with corneal peripheral oedema (1 case); implant dislocation in the anterior chamber (1 case).

Table 3 shows the results of the univariate Cox proportional hazard model for the development of qualified success of the Ex-PRESS glaucoma filtration device implant at 3-year follow-up, with hazard ratios, 95% CIs and P values for each putative predictive

factor. Variables significantly predictive of qualified success at 3-year follow-up included: phakic lens status, absence of previous intraocular surgery, and combined cataract extraction surgery. These variables could not be included in a multivariate Cox model because they were significantly inter-dependent. The variable associated with the best ability of predicting success of the Ex-PRESS P-200 implant was the simultaneous cataract extraction surgery (hazard ratio of 3.2, P>0.001).

No significant intraoperative complications were recorded. Postoperative complications are listed in Table 4. The more frequent complications were transient hyphema (10 cases), hypotony in the first postoperative week (10 cases), shallow anterior chamber (9 cases) and choroidal detachment (6 cases). Two eyes developed a postoperative visual acuity reduction of ≥ 2 decimal levels.

Discussion

The EX-PRESS glaucoma filtration device has been proposed at the beginning of the 20th as a less invasive, more reproducible alternative to conventional filtering surgery.

Several studies have shown that the Ex-PRESS glaucoma filtration device implant placed under a scleral-flap with adjunctive Mitomycin

Table 4: Postoperative complications.

Complications (number of eyes; percentage)	Interventions (number of eyes)
Conjunctival leakage (4; 3%)	Contact lens (2); conjunctival suturing (2)
Hyphema (10; 7.6%)	Medical therapy (10)
Hypotony in first week (10; 7.6%)	Medical therapy (3); viscoelastic in AC (7)
Flat anterior chamber (9; 6.8%)	Medical therapy (2); viscoelastic in AC (7)
Choroidal detachment (6; 4.5%)	Choroidal drainage (1); medical therapy (5)
Blocked tube (3; 2.3%)	Nd:YAG laser (3)
Device endothelial touch (1; 0.75%)	Surgical revision (1)
Device iris touch (2; 1.5%)	Surgical revision (2)
Device exposition (1; 0.75%)	Surgical revision (1)
Device dislocation in AC (1; 0.75%)	Surgical revision (1)
Dysthetic bleb (1; 0.75%)	Surgical revision (1)
Visual acuity decrease (>2 decimal levels) (2; 1.5%)	-

AC: Anterior Chamber

C is clinically safe and effective in providing postoperative reduction of the IOP, [7,9,12-15] not only as first-line surgical procedure, but also in refractory glaucoma [7,9,13,14] and in patients with prior vitrectomy or corneal graft [20,21].

When the results of the Ex-PRESS implant (X-200, X-50, R-50 or P-50 models, with a maximum follow-up of 5 years) and trabeculectomy were compared, neither prospective randomized, controlled studies [22-28] nor retrospective, case control studies [14,29-31] found significant differences between the two procedures in IOP-lowering efficacy, with some reports of lower complications with the Ex-PRESS device [8,14,22,23,28,30]. At the present, it remains unclear whether there is any long-term, clinically relevant superiority in mean IOP reduction with either technique [8,32].

Compared with trabeculectomy, the Ex-PRESS device eliminates the need for both peripheral iridectomy and removal of a deep corneoscleral tissue block, and standardizes the outlet of the aqueous humour from the anterior chamber, offering a safety advantage especially in selected patients. The Ex-PRESS seems to have indeed particular appeal when there is a small untouched mobile area of conjunctiva in eyes that have been exposed to prior surgical procedures. On the other hand, the device requires a precise alignment to avoid the contact with both the cornea and the iris, and device malposition or dislocation can be considered as specific shunt complications [8].

The present study reports the results of our intermediate-long-term experience with the implantation of the Ex-PRESS P-200 shunt under a scleral flap with adjunctive Mitomycin C as a single procedure (57.6%) or combined with cataract surgery (42.4%).

To the best of our knowledge, this is the first study reporting the results of the Ex-PRESS model P-200 implant as first-line surgical glaucoma procedure in a large cohort (132 eyes) including both primary (66%) and secondary (34%) glaucoma patients, with a long follow-up time (between 12 months and 96 months).

In our series, the Ex-PRESS shunt implant provided a mean postoperative IOP reduction of 42% (P<0.0001) and a mean postoperative decrease in number of anti-glaucoma medications of 59% (P<0.0001). Three years after surgery, the cumulative probabilities of complete and qualified success were 34% and 74%, respectively, with a mean time for failure of approximately 17 months for complete success and 30 months for qualified success. The overall

failure rate was of 23.5%.

The IOP-lowering effect obtained by the Ex-PRESS P-200 implant in our cohort of patients compares favourably with that reported in literature by previous authors. In a retrospective single-arm study of the Ex-PRESS X-200 implant in 345 patients affected by primary open-angle glaucoma with or without combined cataract surgery, Kanner et al. [33] reported a qualified success (IOP ≥ 5 mmHg and ≤ 21 mmHg) of 95% at 3 years, with a mean IOP reduction of 20% to 54% at all time points, and a mean reduction in number of IOP-lowering medications of 70% at 3 years.

Another retrospective single-arm study regarding the results of the Ex-PRESS R-50 or T-50 implant in 100 patients with previous failed cataract or glaucoma surgery, Lankaranian et al. [34] found a complete success (IOP ≥ 5 mmHg and ≤ 21 mmHg) of 80%, 64% and 56% at 1, 2 and 3 years respectively, and a qualified success of 94%, 77.5% and 67% at 1,2 and 3 years, respectively.

In a prospective single-arm study including 26 patients affected by medically uncontrolled and/or refractory glaucoma treated with the implant of Ex-PRESS X-200, Bissig et al. [35] showed a complete and qualified success (IOP 6 mmHg to 18 mmHg) at 18 months of respectively 69% and 85%, with a mean IOP reduction of >42% at all time points and a mean reduction in number of IOP-lowering medications of 79%.

In another prospective single-arm study reporting the results of the implant of the Ex-PRESS R-50 in 24 eyes affected by medically uncontrolled and/or refractory glaucoma, Gindroz et al. [36] found, 4-year follow-up, a complete and qualified success (IOP 6 mmHg to 21 mmHg) of 46% and 85% respectively, with a mean IOP and number of IOP-lowering medications reduction of 25% and 74%, respectively.

The lack of uniformity of the study design, population included, model of Ex-PRESS device used for implantation, definition of success, and reporting of efficacy endpoints, make it difficult to compare our results with those provided by previous authors. In general, the success rate of the Ex-PRESS shunt implant in lowering IOP of the present study seem to be definitely satisfactory, especially considering the glaucoma types included (both primary and secondary uncontrolled glaucoma) and the more stringent cut-offs used for the definition of success (IOP 6 mmHg to 18 mmHg). Considering that the IOP has

been widely demonstrated to be the main risk factor for progression of glaucoma [37,38], the achievement of a postoperative IOP \leq 18 mmHg has been indeed suggested by previous authors in order to prevent optic nerve damage or visual field deterioration, especially in advanced glaucoma stages [39].

The univariate Cox proportional hazard model showed that variables significantly predictive of the qualified success at 3-year follow-up included: phakic lens status, absence of previous intraocular surgery and, with the highest hazard ratio, combined cataract extraction surgery (hazard ratio of 3.2, $P > 0.001$). In disagreement with previous authors [33] that showed a significantly greater reduction in IOP postoperatively in eyes treated with the Ex-PRESS implant alone compared with combined cataract surgery, we found a higher overall success rate probability in combined procedure than in the single one. Our results are in accordance with several previous studies demonstrating the IOP-lowering effect of the phacoemulsification cataract extraction itself [40,41], so that an additive effect of both procedure could be supposed.

In our study, we found postoperative complication rates similar to those found by previous studies where the Ex-PRESS implant was placed under a partial thickness scleral flap [5,9,14-17] and lower than that reported when the implant was placed directly under the conjunctiva [6,7,9-14]. The most common device-related complication were transient hyphema, early postoperative hypotony, and choroidal detachment, which resolved spontaneously in the majority of cases. Even if in our series only a single case of localized corneal oedema due to the Ex-PRESS device contact with the corneal endothelium was observed, the issue of the potential effect of the Ex-PRESS device on the corneal endothelium has been raised by previous authors [42] and requires long-term longitudinal studies in order to be better clarified.

A limitation of our study was the retrospective, non-randomized design. However, including a large number of patients followed for a long follow-up time, and performing all surgeries by one surgeon and with a single model of Ex-PRESS device (P-200) increases the credibility of our results.

In conclusion, Ex-PRESS glaucoma shunt implanted under a partial-thickness scleral flap with adjunctive Mitomycin C seems to be a safe, well-tolerated and effective surgical procedure for both primary and secondary uncontrolled glaucoma patients, with an overall success rate of 74% at 3-year follow-up. Long-term, multicentre, prospective studies would clarify whether the EX-PRESS glaucoma filtration device offers superior safety and efficacy compared with trabeculectomy for a broader population of surgeons and patients.

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