

Long-term Evaluation of the Efficacy and Safety of the EX-PRESS® Glaucoma Drainage Device in the Treatment of Primary Open-Angle Glaucoma: A Five-Year Retrospective Study

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SUMMARY

Aim: To evaluate the long-term efficacy and safety of the EX-PRESS glaucoma drainage device implantation in patients with primary open-angle glaucoma over a five-year follow-up period.

Materials and Methods:

The retrospective analysis included 77 eyes of 58 patients (28 women, 30 men) who underwent EX-PRESS glaucoma drainage device implantation between 2011 and 2020. The follow-up period was 60 months for all eyes. The evaluated parameters included intraocular pressure (IOP), the need for and type of antiglaucoma medication, best-corrected visual acuity (BCVA), optic nerve head findings, mean deviation (MD) of visual field testing, and the incidence of postoperative complications. The indication for surgery was primary open-angle glaucoma which was insufficiently controlled despite maximally tolerated medical therapy.

Results: Mean intraocular pressure (IOP) was reduced from 23.55 ± 9.54 mmHg preoperatively to 12.61 ± 6.83 mmHg at 3 months, 13.04 ± 3.95 mmHg at 12 months, 13.39 ± 3.33 mmHg at 24 months, 13.48 ± 3.75 mmHg at 36 months, 13.53 ± 3.23 mmHg at 48 months, and 13.52 ± 2.96 mmHg at 60 months. After surgery, a marked reduction in antiglaucoma medication was observed. A total of 84.4% of eyes required no medication at 3 months, decreasing to 72.7% at 12 months, 49.4% at 24 months, 42.9% at 36 months, 42.9% at 48 months, and 42.9% at 60 months. The mean number of antiglaucoma medications decreased from 3.19 to 1.09, representing a 66% reduction. No intraoperative complications were observed. Early postoperative complications included hypotony in 6 eyes, choroidal detachment in 14 eyes, subconjunctival hemorrhage in 5 eyes, iris incarceration in 2 eyes, and conjunctival suture loosening in 6 eyes. Late postoperative complications included filtration failure in 1 eye, endophthalmitis in 1 eye, and implant obstruction in 2 eyes. In one case, PRESERFLO™ MicroShunt implantation was performed 5 years after EX-PRESS implantation.

Conclusion: EX-PRESS glaucoma drainage device implantation is an effective surgical method for the treatment of glaucoma, which provides long-term stability. It enables a significant reduction of intraocular pressure with a concurrent decrease in the need for antiglaucoma medication, and demonstrates an acceptable safety profile over a five-year follow-up period.

Key words: primary open-angle glaucoma, filtration surgery, EX-PRESS implant, intraocular pressure, antiglaucoma medication

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INTRODUCTION

Glaucoma is a multifactorial, chronic and progressive disease characterized by damage to the optic nerve and corresponding loss of the visual field [1]. In pathophysiological terms it involves a loss of retinal ganglion cells and their axons, which leads to progressive atrophy of the optic nerve and an irreversible deterioration of visual functions

[1]. The disease is clinically manifested in a deterioration of visual sensitivity, blind spots in the visual field, and in the advanced stages in blindness [1]. The most common form of glaucoma is primary open-angle glaucoma [1].

The chief demonstrably modifiable risk factor of glaucoma is intraocular pressure (IOP), the reduction of which constitutes the fundamental therapeutic principle [2]. At present, pharmacological treatment is the method of first

choice, though its long-term effect may be limited by insufficient adherence to therapy on the part of patients [3]. In the case of insufficient compensation of the disease or progression of glaucoma despite the maximum tolerated treatment, laser or surgical intervention is indicated [1,2].

Classic trabeculectomy and tubular implants represent effective but invasive surgical methods, the results of which are burdened by a substantial degree of variability and the risk of complications [4,5].

In recent years, less invasive surgical procedures have been developed, the aim of which is to increase the safety and predictability of the procedure while maintaining a sufficient hypotensive effect [6]. Implantation of an EX-PRESS drainage device (Alcon, Fort Worth, TX, USA; originally Optonol Ltd., Israel) represents a modification of filtration surgery [7]. It is a miniature device with a length of approximately 2–3 mm, which is implanted beneath the scleral flap and ensures controlled drainage of the chamber fluid from the anterior chamber to the sub-scleral space by means of a standardized lumen [7]. The implant is produced from surgical stainless steel (316L). The available variants (P50, P200) differ in terms of the size of the lumen, in which the choice of the correct type depends on the target value of intraocular pressure and the character of the ocular finding [7,10]. The device is implanted with the aid of a single-use application system, which enables precise orientation during the implantation. Implantation of an EX-PRESS drainage device is indicated primarily for patients with primary open-angle glaucoma which is insufficiently controlled by the maximum tolerated pharmacological treatment, or following the failure of laser therapy [8,9].

Suitable candidates are patients with progression of the disease documented on perimetry or on imaging methods, in which the aim is to attain lower values of intraocular pressure while at the same time reducing antiglaucoma medication [2,8]. The procedure is indicated especially for patients with an intact, freely motile conjunctiva in the place of the planned implantation, and may be performed either separately or in combination with cataract surgery [10,11].

Relative contraindications include conditions with an increased risk of failure of filtration, in particular conjunctival scarring following previous operations, active inflammatory ocular pathology, or neovascular glaucoma [8,12]. Another contraindication is a narrow or closed chamber angle, upon which safe implantation of the device into the anterior chamber is not possible [7,9]. It is not suitable for patients with a significant healing deficiency, severe pathology of the ocular surface or insufficient cooperation in the postoperative period [3,13].

The correct indication of the procedure and the selection of patients represent a key factor influencing the long-term success of EX-PRESS implantation and the minimization of postoperative complications [5,8].

The aim of our study was to evaluate the long-term efficacy and safety of implantation of the EX-PRESS drainage device in patients with primary open-angle glaucoma over a five-year follow-up period, focusing on the development

of intraocular pressure, the need for antiglaucoma medication, and the incidence of postoperative complications.

COHORT AND METHOD

The retrospective analysis included 77 eyes of 58 patients, of whom 28 were women and 30 men, with a mean age of 72.9 ± 11.02 years (median 74.5 years; range 44–93 years). The follow-up period for all patients was set at 60 months, at intervals of 3, 6, 12, 18, 24, 36, 48, and 60 months for evaluating intraocular pressure and the need for antiglaucoma medication, and at intervals of 6, 12, 24, 36, 48, and 60 months for evaluating retinal nerve fiber layer thickness, visual field, optic nerve disc excavation and corneal pachymetry.

The mean observation period for glaucoma before implantation of an EX-PRESS device was 105.8 ± 57.39 months (median 100 months; range 7–258 months), with a mean frequency of checks before surgery of once every three months. In all cases, progression was demonstrated preoperatively on perimetry or on OCT. The operations were performed from February 2011 to December 2020 at the VISUS, spol. s.r.o. eye center in Náchod. The P50 model was implanted in 45 eyes, and the P200 implanted in 32 eyes. In 55 eyes, implantation of the EX-PRESS device was preceded by cataract surgery, on average 46.3 ± 42.96 months before the procedure. Conversely, in 12 eyes cataract surgery was performed after implantation of the EX-PRESS device, on average 29.1 ± 21.89 months after the procedure. In all cases, implantation of the EX-PRESS drainage device was performed as a separate procedure.

The indication for implantation of an EX-PRESS drainage device was advanced primary open-angle glaucoma which was insufficiently compensated by the maximum tolerated antiglaucoma medication, with demonstrated progression of the disease on perimetry or OCT, or following the failure of previous surgical antiglaucoma treatment. Before surgery, all 77 eyes were being treated with antiglaucoma medication (Table 1). The mean number of preoperatively used antiglaucoma active agents was 3.19 per eye. A total of 48 eyes had undergone previous antiglaucoma surgery (Table 2). The mean period between the previous antiglaucoma operation and implantation of the EX-PRESS device was 34.5 ± 33.02 months.

Surgical procedure

The procedures were performed under subconjunctival anesthesia with articaine hydrochloride and epinephrine 1 ml (Supracain, Zentiva, Prague, Czech Republic). After incision and preparation of the conjunctiva, the sclera was exposed and a scleral flap created of approximately one half of the thickness of the sclera, with a size of 4×3 mm to 5×5 mm, depending on the anatomical proportions of the eye. Mitomycin C was applied to regulate healing in a concentration of 0.2 mg/ml for a period of 1–2 minutes subconjunctivally and beneath the scleral flap, if applicable the collagen implant Ologen was used, or alternatively adjuvant therapy was not applied, based on the individual judgement of the operating surgeon. Subsequently the

operating field was thoroughly rinsed with a physiological solution. Puncture into the anterior chamber was performed using a 25G needle in the region of the corneal limbus, in parallel with the iris. The EX-PRESS drainage device was then implanted, in which its position and functionality was carefully monitored, and also verified with the aid of paracentesis. The scleral flap was then fixed using individual nylon sutures 10/0. The conjunctiva was closed with absorbable suturing material 8/0, on the limbus or in the fornix according to the type of preparation. At the end of the procedure, betamethasone dipropionate and betamethasone disodium phosphate (Diprophos, Merck Sharp & Dohme, Kenilworth, NJ, USA) were applied subconjunctivally, and a cream containing tobramycin and dexamethasone (Tobradex, Novartis, Basel, Switzerland) was applied into the conjunctival sac. The eye was covered with a bandage. In all cases, one EX-PRESS drainage device was implanted into the upper half of the eyeball. The procedures were performed by two experienced surgeons using identical surgical techniques (MV 70 eyes, PR 7 eyes) (Table 3).

Postoperative care

In the postoperative period, a combination of the antibiotic tobramycin with the corticosteroid dexamethasone (Tobradex, Novartis, Basel, Switzerland) was applied locally in the form of eye drops 5x per day for a period of approximately 1–2 weeks. Therapy subsequently continued in the form of the local corticosteroid alone, with progressive reduction of the dose depending on the clinical finding, the character and vascularization of the filtration cushion, and the character of filtration.

The antiglaucoma medication in the operated eye was discontinued after surgery and reapplied only in the case of insufficient compensation of intraocular pressure, or upon progression of glaucoma. In the early postoperative period, the patients were monitored at regular intervals, as a rule more frequently in the first month after surgery, with the aim of timely identification and resolution of any ensuing complications.

Evaluation parameters

We evaluated the degree of reduction of intraocular pressure in millimeters of mercury measured by Goldmann applanation tonometry (Haag-Streit, Bern, Switzerland) on a slit lamp CSO SL-980 (C.S.O, Scandicci-Florence, Italy), reduction of local antiglaucoma medication and its spectrum, best corrected visual acuity on a Snellen chart (NIDEK SC-1600, Gamagori, Japan), degree of stabilization on perimetry according to the mean deviation indicator (MD, mean deviation of sensitivity of all points in comparison with the norm for the corresponding age) on computer perimetry (TT 30-2) HFA 740i (Carl Zeiss Meditec AG, Oberkochen, Germany), the degree of stability of thickness of the retinal nerve fiber layer (RNFL) on OCT, excavation of the optic nerve discs on OCT (Carl Zeiss Meditec AG, Oberkochen, Germany), and the incidence of adverse effects of surgery. A pachymetry examination of the operated eyes was performed at individual follow-up intervals (on the

Table 1. Antiglaucoma medication and its frequency before surgery

Frequency of antiglaucoma medication	Number of eyes
Monotherapy	1
Double Combination	11
Triple Combination	37
Quads	28

Table 2. Types of antiglaucoma surgery performed prior to EX-PRESS implantation

Antiglaucoma surgery	Number of eyes
Trabeculectomy	16
Selective laser trabeculoplasty	14
Cyclocryocoagulation	10
Laser iridectomy	4
Ahmed implant	2
Canaloplasty	1
Deep sclerectomy	1

Table 3. Distribution of individual types of adjuvant therapy in the study group

	Number of eyes
Mitomycin C	69
Ologen	3
No adjuvant therapy	5

Auto-kerato-refractometer TRK-1P, TOPCON, Japan). The aim of the safety evaluation was to identify the incidence of all adverse effects associated with the implant during the course of surgery or the follow-up period.

Success criteria

Success of the operation was defined as complete if intraocular pressure was within the range of 6–21 mmHg and reduction of IOP from the baseline value by $\geq 20\%$ was achieved, without any reoperation for glaucoma (defined as requiring a procedure in an operating theater), no chronic hypotony defined as IOP ≤ 6 mmHg at two consecutive follow-up intervals of three months, and no use of antiglaucoma therapy. Qualified success was defined as fulfilment of the same criteria for IOP but with the use of supplementary antiglaucoma medication. The number of antiglaucoma medications was not a separate criterion of success, but was evaluated as a secondary parameter of the efficacy of the procedure. In patients who did not achieve a reduction of intraocular pressure by $\geq 20\%$ even despite the necessary administration of antiglaucoma medication or despite necessary reoperation, the operation was considered unsuccessful.

Statistics

Descriptive statistics were used for interpretation of the data (mean $\pm$ SD, median and IQR). The IOP data show

an abnormal distribution (Shapiro-Wilk test $p < 0.05$), and as a result for pair comparison nonparametric tests were used, and Wilcoxon signed-rank tests of paired data (baseline value vs. each point in time) with Bonferroni correction for multiple comparisons. A Friedman test was used for assessment of the overall trend over time. The size of the effect was expressed by Cohen's r ($r = Z / \sqrt{N}$). For secondary parameters (RNFL, MD, pachymetry) a Wilcoxon signed-rank test and Friedman test were also used. The analysis was conducted in the program IBM SPSS Statistics version 29.0.1 (IBM Corp., Armonk, NY, USA).

RESULTS

The cohort consisted of 77 eyes of 58 patients with a mean age of 72.9 years (median 74.5 years; range 44–93 years). The follow-up period of 60 months was completed in all eyes in the cohort. Preoperatively mean IOP was 23.55 ± 9.54 mmHg (median 21 mmHg; range 10–62 mmHg). All eyes had the maximum possible tolerated antiglaucoma medication administered in a mean number of 3.19 active agents per eye.

Intraocular pressure

Mean IOP was statistically significantly reduced at all the monitored points in time (Wilcoxon signed-rank test, $p < 0.05$ for all points in time). At three months after surgery, mean IOP was 12.61 ± 6.83 mmHg, which represents a reduction by 46.4% as against the baseline value. In the further course of the follow-up at 6 months after surgery, IOP was 12.64 ± 4.59 mmHg (reduction by 46.3%), 12 months after surgery 13.04 ± 3.95 mmHg (reduction by 44.6 %), 18 months after surgery 13.06 ± 4.06 mmHg (reduction by 44.5 %), 24 months after surgery 13.39 ± 3.33 mmHg (reduction by 43.1 %), 36 months after surgery 13.48 ± 3.75 mmHg (reduction by 42.7 %), 48 months after surgery 13.53 ± 3.23 mmHg (reduction by 42.5%), and 60 months after surgery 13.52 ± 2.96 mmHg (reduction by 42.6 %) as against the mean baseline value (Graph 1). The Friedman test demonstrated a statistically significant difference in the values of intraocular pressure during the course of the follow-up observation ($p < 0.05$). Intraocular pressure was already reduced in the early postoperative period, and the achieved effect remained stable throughout the entire five-year follow-up period.

Antiglaucoma medication

In the evaluation of antiglaucoma therapy, complete discontinuation of all pharmaceuticals was demonstrated in 65 eyes (84.4%) 3 months after surgery, in 59 eyes (76.6%) at 6 months, in 56 eyes (72.7%) at 12 months and in 48 eyes (62.3%) at 18 months after surgery. Twenty-four months after surgery a total of 38 eyes (49.4%) were without antiglaucoma medication. In the third and fourth follow-up year, the number of eyes without medication was 33 (42.9%), and at the end of the observation period (60 months) 33 eyes (42.9%). The mean number of antiglaucoma medications was reduced from the baseline 3.19 to 1.09 at the end of the follow-up period, which re-

presents a reduction by 66% (Graph 2).

Retinal nerve fiber layer, excavation of optic nerve disc, visual field and corneal pachymetry

Mean RNFL thickness on OCT was 66.0 ± 11.7 μ m at baseline. At 6 and 12 months the differences compared with the baseline value were not statistically significant. From 24 months a statistically significant reduction was observed ($p < 0.05$), which persisted until the end of the follow-up period (60 m.: 63.7 ± 10.6 μ m). The clinical impact of the reduction by approximately 2–3 μ m in 5 years is evaluated as small (Graph 3).

Mean excavation of the optic nerve discs (C/D ratio) was 0.75 ± 0.19 at baseline (median 0.82). At 6 and 12 months the changes were not statistically significant. From 24 months a statistically significant increase was observed ($p < 0.05$). The mean MD value of the visual field before surgery was -9.8 ± 8.1 dB; at 6 and 12 months the changes were not statistically significant. From 24 months statistically significant changes were recorded ($p < 0.05$), although the mean reduction by approximately 0.7 dB over 5 years (Graph 4) is considered slight from a clinical perspective.

Mean corneal pachymetry was 539 ± 48 μ m at baseline, and during the course of the follow-up period remained practically stable (range 540–546 μ m). Statistically insignificant changes were confirmed at 6 and 12 months. From 24 months a statistically significant but clinically insignificant increase was observed (< 10 μ m; $p < 0.05$), which has no influence on the interpretation of tonometry.

Visual acuity

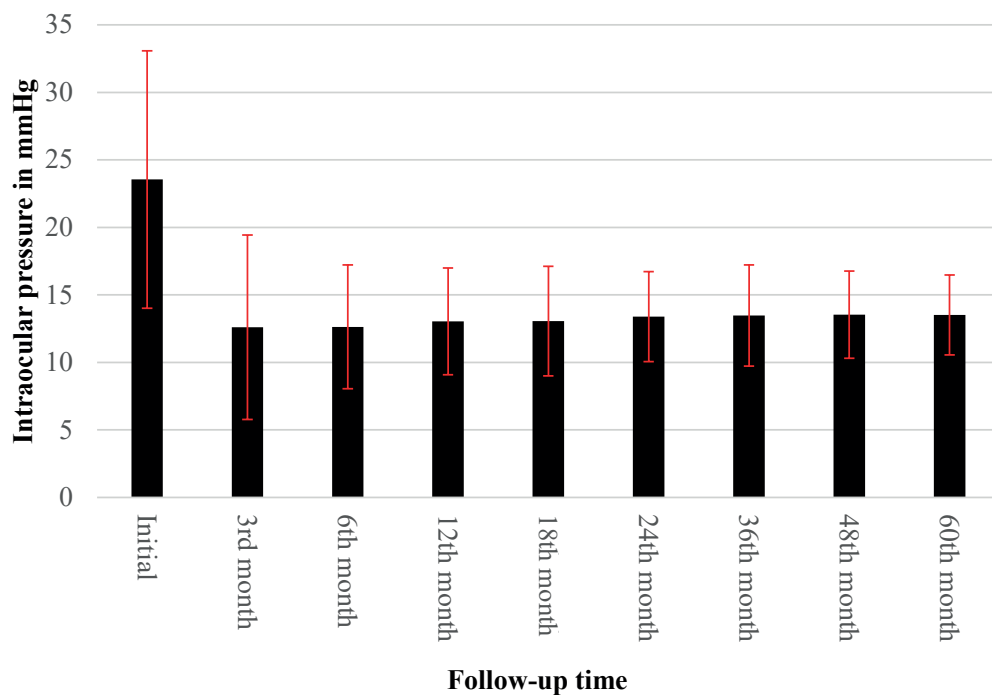
Best corrected visual acuity (BCVA) was evaluated according to a Snellen chart. The distribution of categories remained relatively stable throughout the course of the follow-up observation. Full visual acuity (BCVA 1.0) was recorded in 29 eyes at baseline, and in 27 eyes at the end of the follow up period (60 months) 37 eyes. Severely affected visually acuity (BCVA 0.16–0.1) was recorded at baseline in 5 eyes, and after 60 months in 7 eyes. Relatively stable distribution of BCVA upon progression of glaucoma is evaluated as a favorable result.

Complications

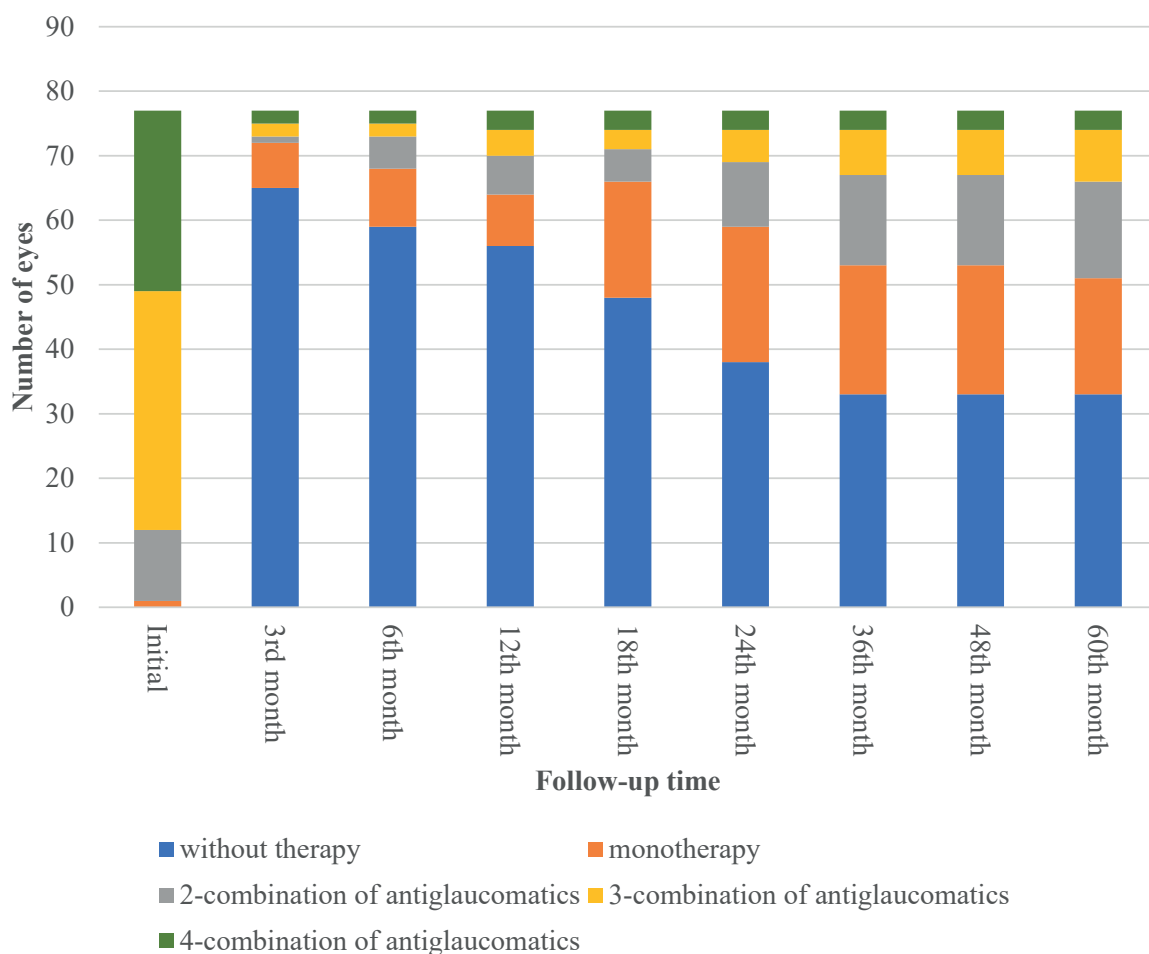
No complications were recorded intraoperatively. In the early postoperative period, we determined postoperative hypotony in 6 eyes, choroidal detachment in 14 eyes, subconjunctival hemorrhage in 5 eyes, iris incarceration in 2 eyes and conjunctival suture loosening in 6 eyes. In most cases this was a transitional condition in the early postoperative period without a long-term negative impact on the functional result of the operation.

We treated hypotony conservatively by adjusting local therapy. In all cases we achieved stabilization of intraocular pressure without the development of chronic hypotony.

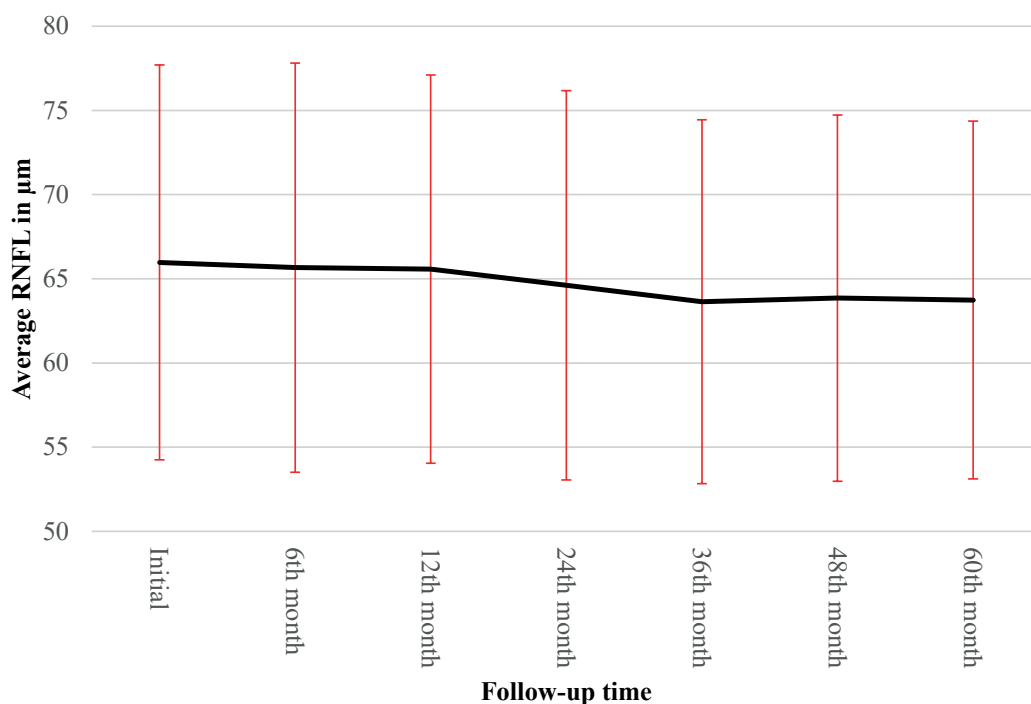
We treated choroidal detachment conservatively, with the result that it regressed spontaneously. Subconjunctival hemorrhage did not require specific therapy. We treated iris incarceration by surgical repositioning of the iris. We removed the loose conjunctival sutures in outpatient



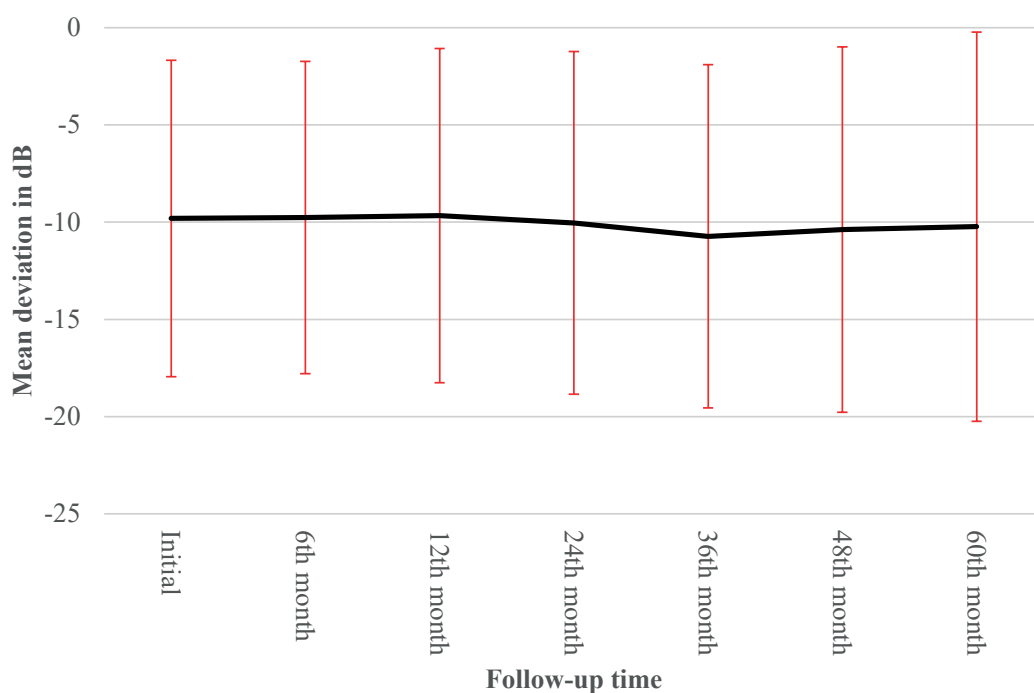
Graph 1. Mean intraocular pressure (IOP) in mmHg during the follow-up period (mean $\pm$ SD and median). The dashed red line indicates the upper limit of normal (21 mmHg)



Graph 2. Antiglaucoma therapy during the follow-up period – distribution of the number of medications at individual time points



Graf 3. Mean retinal nerve fiber layer (RNFL) thickness measured by optical coherence tomography (OCT) during the follow-up period (mean $\pm$ SD). The vertical dotted line indicates the time point of statistically significant change (from month 24, $p < 0.05$)



Graph 4. Mean visual field mean deviation (MD) during the follow-up period (mean $\pm$ SD). The vertical dotted line indicates the time point of statistically significant change (from month 24, $p < 0.05$)

care without any further impact on healing.

In the late postoperative period, we determined failure of filtration as a consequence of fibrosis of the filtration cushion in one eye, which we treated by needling of the filtration cushion. Endophthalmitis in one eye upon

a background of the general complicating skin complaint lichen planus was treated according to standard therapeutic approaches. Obturation of the implant was determined in two eyes, in one case by vitreous fiber with the need for replacement of the implant and in one case in

association with loosening of the implant, which we treated by surgical repositioning. In one case, implantation of PRESERFLO™ MicroShunt was performed five years after the EX-PRESS operation.

Success of operation

Success of the operation was evaluated in all 77 eyes at the end of the follow-up period (60 months). Complete success, defined as intraocular pressure within the range of 6–21 mmHg with a concurrent reduction by $\geq 20\%$ as against the baseline value, was achieved in 33 eyes (42.9%). Qualified success, i.e. fulfilment of the same IOP criteria with the use of supplementary antiglaucoma therapy, was achieved in 35 eyes (45.5%). Overall success (complete and qualified success together) was achieved in 68 eyes (88.3%). The operation was considered unsuccessful in 9 eyes (11.7%), in which a sufficient reduction of intraocular pressure was not achieved even with the administration of antiglaucoma medication.

DISCUSSION

Trabeculectomy has long been considered the gold standard in the surgical treatment of glaucoma. Nevertheless, its use is associated with a significant risk of postoperative complications, which has led to the development of alternative filtration techniques, including the implantation of the EX-PRESS drainage device [4,5,8,10].

In our cohort, EX-PRESS implantation led to a significant reduction of intraocular pressure from 23.55 ± 9.54 mmHg to 13.52 ± 2.96 mmHg over the 60-month follow-up period, which corresponds to a reduction by approximately 43%. Comparable results are also presented by long-term studies, in which the reduction of IOP reaches approximately 40–50%, and remains stable even after several years of observation [9,12,14].

In a direct comparison with trabeculectomy, Dahan et al. [9] state that IOP was reduced from 28.1 mmHg to 15.7 mmHg in the EX-PRESS group, compared with a reduction from 31.1 mmHg to 16.2 mmHg in the trabeculectomy group, in which the difference between the two methods was not statistically significant. These results correlate very well with our cohort, where comparable values of target pressure were achieved, which confirms that EX-PRESS provides a similar hypotensive effect as trabeculectomy.

Similarly, a multicentric randomized trial conducted by Netland et al. [14] demonstrated that after two years, average IOP was 14.7 mmHg in the case of EX-PRESS and 14.6 mmHg in the case of trabeculectomy, with a comparable success rate of 83% vs. 79%.

Another extensive study conducted by Kanner et al. [10] confirmed a high success rate of EX-PRESS implantation, which reached approximately 95% after three years of observation, both in the case of a separate procedure and in combination with phacoemulsification.

With regard to the need for antiglaucoma medication, in our cohort we recorded a reduction from 3.19 to 1.09 pharmaceuticals, in which 42.9% of eyes remained without any

medication. In the study conducted by Dahan et al. [9], a reduction from 3.7 to 0.3 pharmaceuticals was achieved in the case of EX-PRESS implantation, compared with 0.9 in the case of trabeculectomy. These results indicate that the EX-PRESS implant may lead to a pronounced reduction of medication, which is also supported by further studies [5,11,12].

As concerns the success rate, in our cohort we achieved target IOP in 88.3% of eyes. Upon differentiation of the type of success, complete success was achieved in 42.9% of cases and qualified success in 45.5%, which corresponds to the trend of progressive increase in the need for supplementary medication over time. De Jong et al. [11] present a higher proportion of eyes with achieved control of IOP without medication in comparison with trabeculectomy. A meta-analysis conducted by Wang et al. [5] confirms comparable efficacy of both methods, but with a better safety profile of EX-PRESS.

Further long-term data are presented by Mariotti et al. [12], who described a reduction of IOP from 27.63 ± 8.26 mmHg to 13.95 ± 2.70 mmHg after five years of observation, which corresponds to a reduction of approximately 50%. From the perspective of long-term success, Mariotti et al. [12] present a progressive reduction of complete success from 83% in the first year to 57% after five years of observation, which corresponds to the natural development of filtration efficacy over time.

Another comparison was presented in a study conducted by Puerto et al. [15], which compared EX-PRESS with non-penetrative deep sclerectomy and demonstrated a reduction of IOP, with a similar success rate of both methods.

In the case of combined procedures, it is necessary also to take into account postoperative inflammatory reaction. Graffi et al. [16] demonstrated a higher incidence of early postoperative inflammatory reaction upon a combination of EX-PRESS implantation with phacoemulsification (27.3% vs. 6.7%). Another randomized trial conducted by Konopińska et al. [17] confirmed a comparable hypotensive effect of the EX-PRESS implant and trabeculectomy in combined operations, without any difference in the visual and refractive results. Combined procedures were not performed in our cohort.

A specific group of patients for whom the effectiveness of EX-PRESS implantation has also been evaluated are patients with normotensive glaucoma. Aihara et al. [18] demonstrated a reduction of IOP by approximately 31%, accompanied by a pronounced reduction of medication. Although our cohort included only patients with primary open-angle glaucoma, these results indicate that the hypotensive effect of the EX-PRESS implant may also be maintained in patients with lower baseline values of intraocular pressure.

The safety profile in our cohort was favorable, in which most of the complications were of a transitory character without any long-term impact on the functional result. It has been repeatedly demonstrated in the literature that the EX-PRESS implant is associated with a lower frequency of complications, especially hypotony and the need for reintervention [5,9,14].

However, in recent years increased attention has been focused on the impact of filtration functions on the corneal endothelium. A study conducted by Abd El Rehim et al. [19] presents a loss of density of the endothelial cells by 5.7% at 12 months after EX-PRESS implantation in comparison with 8% following trabeculectomy. Similarly, Ren et al. [20] did not demonstrate a greater loss of endothelial cells in comparison with the unoperated eye, in which the mean reduction was approximately 5%.

On the other hand, some studies point to a potentially negative impact of the EX-PRESS device on the corneal endothelium. Arimura et al. [21] demonstrated a greater loss of endothelial cells following EX-PRESS implantation in comparison with trabeculectomy in certain regions of the cornea. Tojo et al. [22] presented a loss of endothelial cells by approximately 7% after 2 years, in which a significant risk factor was the incorrect position of the implant, especially its implantation into the cornea. This problem is also highlighted in another case report by Tojo et al. [23], which describes the development of corneal decompensation in connection with the incorrect position of the implant. More recent data from Yamazaki et al. [24] also indicate a more rapid loss of endothelial cells in pseudoexfoliative glaucoma in comparison with primary open-angle glaucoma. Density of the corneal endothelium was not monitored in our cohort.

In most cases, antimetabolic treatment with mitomycin C (MMC) was applied in our cohort, specifically in a dose of 0.2 mg/ml for two minutes (69 eyes), while implantation with the use of the collagen implant Ologen was performed only in three eyes, and without adjuvant therapy in five eyes. The results were not statistically compared between the individual procedures. The use of MMC is currently considered a standard component of filtration surgery, since it significantly reduces the risk of scarring reaction and increases the long-term success rate of the procedure [13]. This effect has also been described in studies evaluating EX-PRESS implantation, in which antifibrotic treatment was a component of the surgical procedure [10,11].

An alternative to antimetabolites is the use of the biodegradable collagen implant Ologen, the aim of which is to modulate healing without the need for a cytotoxic effect. A study conducted by Cillino et al. [25] evaluated the long-term results of the use of a collagen implant in comparison with MMC, in which the resulting effect may be influenced by the character of healing and the individual response of the tissue. Based on our results, upon the predominant use of MMC it is possible to expect that the achieved stable hypotensive effect is influenced to a considerable degree by effective regulation of postoperative healing in the early postoperative period.

In our cohort a type P50 EX-PRESS drainage device was used in 45 eyes (58.4%), while the P200 variant was implanted in 32 eyes (41.6%). The choice of lumen size was adapted in individual cases to the individual clinical finding and target intraocular pressure value. Published studies show that in terms of long-term efficacy, differences between the individual variants of the EX-PRESS

implant have not been unequivocally demonstrated, in which the choice of lumen size is often based on the experience of the operating surgeon and the character of the disease [7,10]. Some studies suggest that lumen size may influence the dynamics of early postoperative drainage of the chamber fluid, and thereby also influence the risk of early hypotony [14]. With reference to the fact that no direct statistical comparison between the individual types of implant was conducted in our cohort, it is not possible to unequivocally evaluate the impact of lumen size on the end results.

The results of our study also follow on from our previous publication relating to the use of the EX-PRESS implant in glaucoma surgery [26]. However, the current study presents an expanded set of evaluated parameters, a longer structured follow-up and more detailed statistical processing, thereby supplementing the previous results and providing a more comprehensive view of the long-term efficacy and safety of this method.

Implantation of an EX-PRESS drainage device brings a number of advantages, in particular including standardized drainage of chamber fluid thanks to the defined lumen, the absence of any need for peripheral iridectomy, and lesser surgical trauma. The procedure is technically more reproducible and associated with a favorable safety profile. On the other hand, it is necessary to mention that the long-term effect is influenced by the healing process, as well as by potential fibrosis of the filtration cushion, and by adequate postoperative management. The result is dependent upon the surgical technique, especially on the correct position of the implant and adequate regulation of healing. A potential risk remains the influence on the corneal endothelium, especially in the case of inappropriate insertion of the implant.

A limitation of this study is its retrospective character, which means there are limited options for monitoring the observed parameters. The study also was not conceived as a comparative study, and therefore does not enable a direct comparison of the effectiveness of the EX-PRESS drainage device with other surgical methods, especially with trabeculectomy. Another certain limitation is the absence of a detailed sub-analysis of the influence of individual types of adjuvant therapy and the results of treatment. Although mitomycin C was used in the majority of cases, a smaller proportion of procedures were performed with the use of the collagen implant Ologen or without adjuvant therapy, while these groups were not statistically compared with each other. The variability of the results may also have been partially influenced by the individual approach to the choice of type of implant (P50 vs. P200) and adjuvant therapy in regular clinical practice. A strength of the study is its relatively large cohort of patients, standardized surgical technique performed by two experienced operating surgeons, and the long-term five-year follow-up period, which enables a comprehensive evaluation of the efficacy and safety of EX-PRESS implantation in actual clinical practice.

CONCLUSION

Implantation of an EX-PRESS drainage device represents an effective and safe method for the surgical treatment of open-angle glaucoma. In our cohort it led to a significant reduction of intraocular pressure which was stable over the long term, in which this effect persisted throughout

the entire five-year follow-up period. At the same time, a pronounced reduction of the need for antiglaucoma medication was achieved. Upon correct indication and with the use of the appropriate technical version, EX-PRESS implantation can be considered a reliable alternative to conventional filtration surgery in patients with insufficiently compensated glaucoma.

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