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Ab interno goniotomy with a Kahook Dual Blade in 6-month follow-up

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ABSTRACT

Aim of the study: Evaluation of *ab interno* goniotomy using a Kahook Dual Blade in combination with phacoemulsification in patients with primary open angle glaucoma during a 6-month follow-up.

Material and methods: 75 patients with mild and moderately advanced primary open angle glaucoma, who had phacoemulsification combined with *ab interno* goniotomy using a Kahook Dual Blade (New World Medical, USA), were included in this analysis. The average age was 68.4 ±8.9 years. Mean pre- and postoperative intraocular pressure, number of antiglaucoma medications, complications of the surgery and need for another procedure were analysed in the 6-month follow-up.

Results: Before the surgery, mean intraocular pressure was 21.9 ±3.9 mmHg and the number of antiglaucoma medications was 2.2 ±1.2. A reduction in intraocular pressure of 17.53% and a decrease in number of antiglaucoma medications of 60% ($p < 0.001$) were observed in the 6-month follow-up. There was slight intra-operative bleeding into the anterior chamber from the incision in all cases. On the first days after surgery there were diffuse blood cells or a clot in the anterior chamber in 38% of eyes. Increase in intraocular pressure above 25 mmHg on the first day after surgery was observed in 30.6% of eyes. In one eye there was no postoperative intraocular pressure stabilisation and laser cyclodestruction was performed.

Conclusions: *Ab interno* goniotomy performed simultaneously with phacoemulsification results in a significant reduction in intraocular pressure and a decrease in the number of anti-glaucoma drugs used. The treatment is characterized by a good safety profile and does not require intensive postoperative management.

KEY WORDS: *ab interno* goniotomy, MIGS, minimally invasive glaucoma surgery, Kahook Dual Blade, glaucoma.

INTRODUCTION

An ophthalmologist treating a patient with glaucoma has a choice between several therapeutic modalities including pharmacotherapy, laser therapy, and surgery. Treatment with glaucoma eye drops, which often need to be administered more than once a day, requires the patient's strict compliance with the prescribed regimen and a systematic approach. Another aspect to consider is the fact that in a number of cases glaucoma eye drops are associated with local and systemic side effects. Selective laser trabeculoplasty (SLT) has similar efficacy in lowering intraocular pressure (IOP) as single-drug pharmacotherapy [1]. A definite advantage of this treatment modality is the fact that the therapeutic outcome does not depend on patient compliance. It also has a good safety profile. However, the beneficial effect of treatment does not occur in all patients, and if it does, it declines with time [1]. Laser cyclodestruction has a greater efficacy [2], but the risk of complications is higher than in SLT [3]. Conventional glaucoma procedures, such as trabeculectomy and drainage implants, despite being highly effective, are associated with a considerable risk of potential complications [4, 5]. In addition, patients undergoing such procedures require close postoperative monitoring. Consequently, the so-called micro-invasive glaucoma surgery (MIGS) has been gaining an increased interest in the last few years [6]. MIGS procedures are an ideal therapeutic solution for patients with early or moderate open-angle glaucoma who do not require intensive and aggressive treatment [4]. Surgical procedures included in this group are performed from the inside, via the transparent part of the cornea (*ab interno*). They offer a high safety profile, and have a short healing period. Contrary to classic procedures, they do not require intensive patient monitoring in the postoperative period. The conjunctiva is spared, which does not limit the possibility to perform other procedures in the future [7]. The decision to qualify a patient for this type of surgery can be made at an earlier stage of glaucoma damage than in classic surgical glaucoma procedures. Minimally invasive techniques can be divided into modalities improving

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the trabecular, suprachoroidal and subconjunctival outflow, and reducing aqueous humor production. They can be performed as an isolated procedure or in combination with cataract surgery [6]. The assumption is that the efficacy of MIGS procedures should be comparable to conventional treatments or lower but with fewer potential complications.

The aqueous humor is believed to drain out of the eye via two pathways: conventionally, i.e. through the trabecular meshwork into Schlemm's canal, then passing through the aqueous veins and entering the epidural veins; and unconventionally, i.e. via the uveoscleral pathway. The latter pathway drains up to 45% of the aqueous humor in young people. However, the importance of this pathway decreases with age, especially in individuals with glaucoma [8]. Another age-related process, attributed to changes in the trabecular meshwork, is an increase in outflow resistance, particularly in glaucoma patients [8, 9]. Consequently, it appears reasonable to perform procedures aimed at reducing resistance at the trabecular level in patients with primary open-angle glaucoma (POAG), as well as pigmentary or pseudoexfoliation glaucoma.

In 2015, the Food and Drug Administration (FDA) approved the single-use surgical instrument called the Kahook Dual Blade (KDB, New World Medical) for use in minimally invasive glaucoma surgery. The KDB operates by reducing the aqueous humor outflow resistance at the trabecular level. The instrument is equipped with a bent, pointed tip with two side blades (Figure 1).

Kahook Dual Blade is designed to allow surgeons to excise a portion of the trabecular meshwork by making a precise incision and continuing it along Schlemm's canal. The tissue to be excised is lifted on an appropriately profiled ramp and removed from its original position, so that it can be removed from the eye after the procedure is completed. Such controlled excision of the trabecular meshwork establishes a direct connection of the anterior chamber with Schlemm's canal and then communication with the aqueous veins [10, 11]. Through this sequence, the procedure increases the aqueous humor outflow via the conventional pathway. Based on the observations to date, the procedure leads to a reduction in IOP at a level comparable to the effect of treatment with one glaucoma medication. In addition, it allows a decrease in the number of topically administered medications [11].

The aim of the present study is to evaluate the therapeutic outcomes obtained by performing *ab interno* goniotomy using the KDB in conjunction with phacoemulsification cataract surgery in patients with early and intermediate open-angle glaucoma during a 6-month follow-up. The analysis also included the safety profile of the procedures, and the need for additional treatments.

Figure 1. Design of the Kahook Dual Blade

MATERIAL AND METHODS

The retrospective study included a total of 75 eyes diagnosed with cataract and POAG which did not require aggressive glaucoma treatment. The mean age of patients was 68.4 ±8.9 years. Women accounted for 56% of the study group, while 44% were men. The inclusion criteria were: age over 18 years, early and intermediate POAG coexisting with age-related cataract, and insufficiently effective and/or poorly tolerated pharmacotherapy. The diagnosis of glaucoma was confirmed by detecting characteristic abnormalities in the visual field and RNFL deviations. The study excluded patients with glaucoma types other than POAG, including, but not limited to, patients with pigmentary glaucoma and pseudoexfoliation syndrome, advanced changes in the visual field [MD (absolute value) > –12 dB, number of points for which $p < 5\%$ is greater than 37, number of points for which $p < 1\%$ is greater than 20, absolute defect within the central 5° of the visual field and presence of points with a sensitivity of < 15 dB within the central 5° in both halves of the visual field], patients after laser trabeculoplasty and other surgical glaucoma procedures, failing to report for postoperative follow-up, and patients with advanced systemic conditions.

All patients underwent cataract phacoemulsification with intracapsular implantation of intraocular lens in conjunction with *ab interno* goniotomy using the Kahook Dual Blade (New World Medical, USA). The indication to extend cataract phacoemulsification was the need to lower IOP or reduce the number of glaucoma medications because of drug intolerance. The procedures were performed by the same surgeon. The patients had follow-up evaluations on the first day after the procedure, after 5-7 days, and then after 1, 3 and 6 months. Intraocular pressure was measured with a Goldman applanation tonometer.

The procedures were conducted under drip anesthesia combined with intrachamber administration of 1% lignocaine. Goniotomy was performed following the insertion of the intraocular lens into the lens capsule. The opening of Schlemm's canal with a disposable KDB was performed at 100-120°. A direct gonioscope (Volk Surgical ACS Gonio Lens) was used to visualize the filtration angle. In some patients, it was necessary to inject Miostat into the anterior chamber in order to constrict the pupil and pull the iris out of the filtration angle. The anterior chamber was filled with a viscoelastic (2% methylcellulose). The operating microscope was tilted approximately 45°, and the patient's head was rotated approximately 40° away from the treated eye. The Kahook blade was inserted via a side port with a width of 1.4-1.6 mm (Figure 2).

The incision of the filtration angle along Schlemm's canal was made at 100-120°, in two steps. The first incision was performed in the inferior quadrant from bottom to top. Next, the

blade was rotated 180°. The second incision was made in the upper quadrant, some distance from the end of the first incision, and was continued down until the two incisions met, and an excised trabecular meshwork strip was obtained. In this manner, the posterior wall of Schlemm's canal was exposed. The excised portion of the trabecular meshwork was removed from the anterior chamber. After the bleeding from the incision site had stopped, the viscoelastic was rinsed out from the anterior chamber. Figure 3 shows the gonioscopic appearance of the region of the filtration angle after the surgery.

The patient was monitored during the first postoperative day. Until the follow-up, the patient did not use any medications in the operated eye. In patients with good IOP control before the procedure and normal IOP in the follow-up examination, a decision was made to reduce the number of glaucoma medications used. In patients with elevated IOP on the first day, it was lowered, as required; while the number of drugs was left unchanged. Other postoperative recommendations were the same as in cataract surgery, including topical antibiotics, steroids, and non-steroidal anti-inflammatory drugs. At subsequent follow-ups, based on IOP values, the need for further modification of pharmacological glaucoma therapy was determined.

The study endpoints were to achieve an IOP value ≤ 18 mmHg or lower the IOP value by at least 20% and reduce the number of glaucoma medications used by patients by at least one. Intraocular pressure, the number of glaucoma medications used postoperatively, and the presence of potential complications associated with the procedure were evaluated. As the study had a retrospective observational design, no preoperative withdrawal of glaucoma medications was scheduled as the washout phase. Given the design of the study, no control group was planned, either. The degree of IOP reduction and the number of medications taken by patients after combination surgery were compared with the baseline values and examined against literature data on IOP reduction after cataract phacoemulsification alone.

The compliance of the distribution of values with normal distribution was verified with the Shapiro-Wilk normality test, and descriptive statistics were presented as arithmetic means and standard deviations (±SD). The significance of differences between the groups was assessed using Student's *t*-test (for variables with a normal distribution) or Mann-Whitney's *U* test (for non-parametric variables). The value of 0.05 ($p \leq 0.05$) was adopted as the probability threshold.

RESULTS

Intraocular pressure changes

The mean baseline IOP was 21.9 ±3.9 mmHg. A statistically significant reduction in IOP was observed as early as on the first postoperative day. The effect persisted at subsequent follow-ups. All differences are highly significant statistically in relation to the baseline examination ($p < 0.001$). Table I lists the changes in mean IOP during the follow-up of 6 months. Mean IOP was reduced by 17.53% from the baseline. The predefined IOP reduction by 20% was achieved in 38% of patients. A decrease in IOP below 18 mmHg was achieved in 58% of patients.

Figure 2. Intraoperative photograph. Kahook Dual Blade tip visible in the anterior chamber. Gonioscope placed on the eye allows visualization of the filtration angle

Figure 3. View of the filtration angle after the procedure. Site of incision of the trabecular meshwork visible in the upper part of the photograph; unchanged angle in the lower part

Changes in the number of medications used by patients

The mean number of drugs used before the procedure was 2.2 ±1.1 (Table I). Six months after the surgery, it decreased to 0.88 ±1.0, which corresponds to a reduction by 60% ($p < 0.001$). Figure 4 shows graphs representing changes in the analyzed parameters over time. In 82% of the eyes, the number of glaucoma medications was reduced by at least 1. In the group of patients with IOP reduction under 20%, the mean decrease in the number of medications was 1.73 ±0.71.

Safety profile

On the first postoperative day, there was an increase in IOP between 25 and 34 mmHg in a total of 11 eyes (14.6%),

Table I. Mean intraocular pressure (IOP) values and mean number of glaucoma medications used during 6-month follow-up

	At baseline	1 day postoperatively	1 week postoperatively	1 month postoperatively	3 months postoperatively	6 months postoperatively
Mean IOP ±SD (mmHg)	21.90 ±3.9	19.53 ±3.7	20.38 ±5.7	18.25 ±3.7	17.76 ±2.8	18.14 ±3.2
Mean number of glaucoma medications	2.2 ±1.1	0.47 ±0.7	0.8 ±0.9	0.82 ±0.9	0.76 ±0.9	0.88 ±1.0

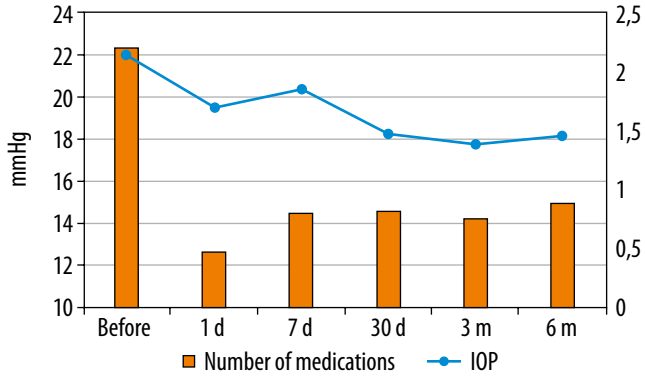

Figure 4. Changes in mean IOP values and mean number of glaucoma medications used during 6-month follow-up

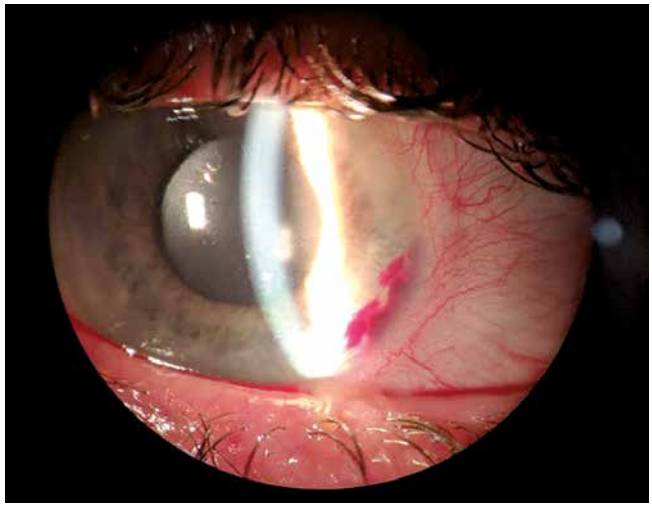

Figure 5. Blood clot in the anterior chamber in one of the patients, noted on day 1 postoperatively

and over 35 mmHg in 12 eyes (16.0%). All the patients experienced slight intraoperative bleeding at Schlemm's canal opening. On the first postoperative day, diffuse blood cells in the anterior chamber were observed in 5 eyes (6.6%), and a slight blood clot was detected in 8 (10.7%) patients (Figure 5). In one eye (1.3%), IOP could not be stabilized despite the introduction of pharmacotherapy, and laser cyclodestruction was additionally performed.

DISCUSSION

The effect of cataract phacoemulsification on the value of IOP has been evaluated in multiple studies. In healthy people undergoing cataract surgery, the average reduction in IOP was 1.0-4.0 mmHg [12-14]; in individual studies the effect was slightly higher [15]. The degree of IOP reduction has been shown to be proportional to the baseline value [13, 15, 16]. The small discrepancy between the studies can probably be attributed, among other factors, to different mean baseline IOP values. In patients with POAG, similar analyses of long-term effects showed a slightly different IOP reduction one year after the procedure: by 1.15 ±3 mmHg (6.8 ±18.1%) [17], by 1.0 ±5.5 [12], or by 13% [18]. A large metaanalysis found that the mean reduction in IOP noted at 6, 12, 24 and 36 months after the surgery was 12%, 14%, 15% and 9% from the baseline, respectively [14]. Similarly to healthy subjects, the reduction of IOP in patients with POAG was proportionally greater in patients with higher baseline IOP. It was also found that in patients with POAG the shallower the anterior chamber and the narrower the angle of filtration, the greater the hypotensive effect of the procedure [19].

The above-mentioned metaanalysis demonstrated a reduction in the number of glaucoma medications used by patients by an average of 0.66 at 6 months after cataract phacoemulsification, and by 0.58, 0.53 and 0.38 at one, two and three years after the procedure, respectively. However, the effect of reduced use of glaucoma medications appears to diminish over time [20]. In a recently published paper, a decrease in the number of medications was achieved in 17.1% of patients. A total of 7.2% patients required additional glaucoma medications, and in 75.7% of patients with POAG the number of medications remained unchanged [17]. Reducing the dependence on glaucoma medications limits their adverse effects on the ocular surface [14], leading to improved patient comfort and potentially increasing therapeutic compliance.

In this study, the mean reduction in IOP was 17.53%. In 38% of patients, the decrease in IOP during a follow-up of 6 months was over 20%, while in 52% of patients it was below 18 mmHg. The relatively small reduction in IOP can be attributed to the fact that IOP in the study cohort was well-controlled preoperatively with eye drops. However, these values are significantly higher compared to the outcomes of cataract surgery alone, especially considering that the number of glaucoma medications used by patients was reduced by at least 1 in 82% of patients, by an average of 60%. In addition, the analysis showed that in the group of patients with IOP reduction not exceeding 20%, the mean decrease in the number of medications was higher than in patients with greater IOP reduction: –1.73 ±0.71 and –1.4, respectively. Both endpoints, i.e. IOP reduction by at least 20% or less than 18 mmHg and a decrease in the number of medications by at least one, were achieved in 24% of patients. Our findings do not differ significantly from data reported in studies published to date, evaluating the efficacy of KDB goniotomy performed in conjunction with cataract surgery [21-24]. In these studies,

IOP decrease achieved after the KDB procedure combined with cataract phacoemulsification was 26.4-33.4% (2.1-6.93 mmHg). The effect depended on the baseline IOP value (17.1 ±4.8-20.75 ±8.15 mmHg). In these studies, the reduction in IOP was slightly higher than in our observation, but the decrease in the number of glaucoma medications was smaller (by an average of 0.7-1.1).

Following isolated KDB goniotomy, a mean decrease in IOP by 3.8-13.7 mmHg (21-46%) and a reduction in the number of glaucoma medications by 0.9-1.3 were reported. A greater reduction in IOP and decrease in the number of medications were noted in the eyes with higher baseline IOP values [25].

The efficacy of reducing IOP shown in studies evaluating traditional trabectome surgery performed with a trabectome designed specifically to remove the trabecular meshwork and the inner wall of Schlemm's canal by electric cauterization with irrigation and aspiration was in the range of 35-48%, with the size of the effect depending on baseline IOP [27-30]. The reduction in the number of medications used was maintained in the range of 0.8-1.7 [29]. KDB goniotomy is based on the same concept as trabectome surgery, but in principle the instrument allows for greater precision of excising the trabeculum, without leaving superfluous tissue that might induce inflammation or cause adhesions. For comparison, non-invasive SLT reduces IOP by more than 20% below baseline values in 66.7-75% of patients at 6 months after the surgery [1, 26, 31]. However, in a 5-year follow-up, the effect persists in only 11.1-31% of patients, and declines over time [1, 26]. In some of the studies, the number of glaucoma medications used by patients was maintained at a constant level throughout the entire follow-up period [31] or other medications were added to the regimen, as needed [26]. In other studies, the number of medications was reduced as far as possible (on average by –0.162 (SD 1.21) [32].

A metaanalysis of 5 studies (248 patients) evaluating the efficacy of the iStent device – a micro-bypass stent connecting the anterior chamber with Schlemm's canal – showed a 22% reduction in IOP over an 18-month follow-up in patients with one iStent, a 30% reduction in IOP during 6 months after the procedure in patients with two iStents, and a 41% reduction in IOP over a 6-month follow-up in patients with three iStents. The studies consistently demonstrated a greater reduction in the use of glaucoma medications in patients with more iStents (by an average of –1.68 for one implant, –1.88 for two, and –2.0 for three implants), but the exact degree of reduction varied significantly between studies and hence requires further observation [33]. However, an increase in the number of implants raises the cost of the procedure. An analysis of costs associated with the implantation of a single [34, 35] or even a double [36] iStent compared to laser trabeculoplasty and pharmacotherapy showed that during the first year after the surgery the latter two options were more cost-efficient. However, the iStent seems to be a more cost-efficient approach after 5 years, especially in patients using more expensive glaucoma medications. The cost of a single disposable KDB accounts for approx. 50% of the iStent price. Studies comparing the efficacy of the iStent treatment and KDB goniotomy (both procedures performed in conjunction with cataract phacoemulsification) showed that the degree of IOP reduction was similar for both modalities [37] or KDB goniotomy was superior to a single iStent [38, 39].

The HYDRUS II study compared IOP following cataract surgery and after the combined procedure with the implantation of a Hydrus stent – an implant placed in Schlemm's canal to improve the outflow of aqueous humor. In the second group, IOP was reduced by at least 20% in 80% of patients, but only in 46% of patients who underwent cataract surgery alone [40]. For patients with POAG who underwent GATT (gonioscopy-assisted transluminal trabeculotomy), a 30 ±20% reduction in IOP and a decrease in the number of glaucoma medications by 0.9 ±1.3 was achieved in a 12-month follow-up [41].

A study comparing Trab 360 with KDB goniotomy found no significant differences in terms of mean IOP reduction. Trab 360 – a procedure involving the insertion of a microcatheter in Schlemm's canal, followed by breaking through the anterior wall of the canal and trabecular meshwork with the microcatheter – successfully reduced IOP in 84.6% of patients. For KDB goniotomy, the corresponding figure was 81.7% ($p = 0.737$). However, IOP ≤ 18 mmHg was achieved in more eyes in the KDB group (80.0% [56/70] vs. 59.3% [16/27], $p = 0.040$) and ≤ 15 mmHg (61.4% [43/70] vs. 25.9% [7/27], $p = 0.003$) [42]. At 12 months' follow-up, *ab interno* canaloplasty (ABiC (Ellex)) led to post-surgery reduction in mean IOP from 18.6 ±6.4 mmHg to 14.1 ±3.7 mmHg after 6 months, and 12.9 ±2.0 mmHg after 12 months. The mean number of glaucoma medications was reduced from 2.0 to 1.0 [43].

For trabeculectomy with mitomycin C, a reduction in IOP exceeding 30% was shown in up to 39.4% of patients during a 4-year follow-up [44]. The efficacy of filtering valves determined by studies was similar to trabeculectomy, but the method was associated with a greater number of glaucoma medications used by patients after the surgery, both at 6 months and 5 years after the procedure [45].

In the reported study, all patients successfully underwent combined trabectome surgery with cataract phacoemulsification. There was slight intraoperative bleeding at the site of Schlemm's canal opening in all eyes. One patient (1.3%) required another glaucoma procedure. There were no severe complications associated with the procedure. Intraoperative bleeding, which occurred in all patients, is a natural consequence of the surgical technique applied for the procedure. Our observations do not differ from complications described in the literature after similar combined procedures [21]. The most commonly reported complications developing after KDB treatment combined with phacoemulsification include eye irritation (2.8-11.4%), discomfort and pain (1.4-8.6%), blurred vision (1.4-17.1%), and postoperative IOP increases (2.8-17.1%). Most of them resolve within 2-3 days after the procedure. Some patients developed cystic macular edema

(1.4-5.7%) [21, 22, 46]. Cyclodialysis was reported in one patient [47]. In other MIGS procedures increasing trabecular outflow, the most commonly reported were minor complications such as hyphema (23%) and irritation, which resolved during the first 14 days after the procedure. Short-term increases in IOP were observed in 7.4% of patients, and macular edema in 11.1%. The rate of complications does not vary significantly between the different types of procedures [21, 41, 42, 48]. Peripheral focal anterior adhesions with no significance for the hypotensive effect were reported in 12% of patients treated with Hydrus implants [40].

A considerably higher rate of complications, especially of severe nature, is noted after trabeculectomy [49]. An increased risk is observed not only for intraoperative but also postoperative complications related to the filtration bleb, including infectious and metabolite-associated complications, or the development of malignant glaucoma. There is also an elevated risk of hypotony and related complications such as maculopathy, choroidal detachment or the development of cataract in phakic eyes [50]. With drainage implants there is a risk of complications related to the implant itself. Excessive filtration during the postoperative period may cause the anterior chamber to become shallow, in which case the tube may contact the endothelium. In addition, dislocations of the implant under the conjunctiva or inside the eyeball have been reported. Also, there have been cases of conjunctival perforation by the implant [4].

CONCLUSIONS

Ab interno goniotomy using the Kahook Dual Blade performed in conjunction with cataract surgery leads to a significant IOP reduction and a decrease in the number of glaucoma medications used. It is a safe therapeutic modality in patients with early and intermediate glaucoma who do not require intensive treatment. The procedure should be considered in patients who fail to comply with the recommendations regarding pharmacological glaucoma treatment or are allergic to glaucoma medications. A major advantage of the procedure is the fact that it does not significantly change the anatomy of the eye, and does not limit the possibility of performing other procedures in the future. The data obtained so far are promising, however, further observation of patients is necessary in order to reliably evaluate the long-term effects.

DISCLOSURE

The authors declare no conflict of interest.

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