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Effectiveness of Kumar's 2nd generation stainless steel spiral Schlemm's canal expander in decreasing intraocular pressure in patients with primary open-angle glaucoma refractory to previous penetrating and non-penetrating glaucoma surgeries

Kumar V., Med.Sc.D., Professor[1], Head of Ophthalmic unit[2];
Frolov M.A., Med.Sc.D., Professor, Head of the Ophthalmology department[1];
Dushina G.N., M.D.[2], postgraduate[1];
Bozhok E.V., M.D.[2]

[1]Peoples' Friendship University of Russia, *6 Miklukho-Maklaya St., Moscow, Russian Federation, 117198;*
[2]Ophthalmic unit, Skhodnya city Municipal Hospital, *31A Michurina St., Skhodnya Microdistrict, Khimki, Moscow region, Russian Federation, 141421.*

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Резюме

PURPOSE: To evaluate effectiveness of Kumar's 2nd generation stainless steel spiral Schlemm's canal expander (SCE) in decreasing intraocular pressure (IOP) in patients with primary open-angle glaucoma (OAG) refractory to previous penetrating and non-penetrating glaucoma surgeries.

METHODS: Nine consecutive patients (9 eyes) having failed filters (failed trabeculectomy — 6 cases, failed deep sclerectomy — 2 cases and failed selective laser trabeculoplasty — 1 case), who's IOP was insufficiently controlled, were operated upon. A 2.5-3.0 mm long stainless steel spiral 2nd generation SCE made from 0.04mm thick medical grade stainless steel wire, having outer diameter of 0.2 mm and inner lumen diameter of 0.12 mm was implanted into Schlemm's canal (SC) ab externo. Two patients (2 eyes) with coexisting cataract and glaucoma underwent a combined procedure. Patients were evaluated daily during hospital stay, after 1 week, and at 1, 3, 6 and 12 months after surgery. IOP was considered a primary outcome measure. Secondary outcome measures were as follows: the number of glaucoma medications pre- and postoperatively and complications. A paired t-test was used for IOP and medication analysis. Decrease in IOP >20% or IOP from 6 to 18 mmHg without medication was considered a complete success, with medication — partial success. Failure was declared if the patient had IOP < 6 mmHg or > 18 or reduction in IOP was <20% after 3 months and if patient needed a subsequent filtering surgery. Success rates were evaluated at each follow-up visit after 3 months after surgery. Statistical analysis was performed using MS office application — Excel 2007 at each follow-up visit taking into account the change in the number of patients. Results were considered significant with p<0.05.

RESULTS: Mean (mean±standard deviation (SD)) preoperative IOP was 25.2±5.5 mmHg. At each follow-up a decrease in mean IOP was observed, resulting in 12.5±3.9 mmHg (p=.00003) at 6 months and 12.9±1.4 mmHg (p=.00009) at 12 months. This represents a reduction in IOP from baseline of 49.4±17.4 and 44.2±9.8% at 6 and 12 months respectively. Mean number of used medications decreased from baseline 2.4±1.0 to 1.4±1.0 (p=0.05) and 1.0±1.0 (p=0.03) at 6 and 12 months respectively. Complete and partial success were observed in 2 and 6 cases (n=9) at 3 months, in 2 and 7 cases (n=9) at 6 months and 2 and 3 cases (n=5) at 12 months. There was only 1 case at 3 months, who fulfilled the failure criteria. There were no failure cases at 6 and 12 months. Intraoperative microperforation of trabecular meshwork (TM) in areas other than exposed part of SC occurred in 1 case. In 7 cases the device could be inserted completely into SC lumen. In 2 cases the caudal end (0.5 mm) of the device was left in the exposed part of SC. In the early post-operative period a bleb was noticed in 3 cases at 1 week and in 1 case at 1 and 3 months each. Complications like device dislocation, inflammation at the implantation site, devices' erosion through TM, loss of device were nil. YAG laser trabeculopucture was not required in any of the cases.

CONCLUSION: Kumar's 2nd generation SCE is effective in decreasing IOP in patients with primary OAG refractory to previous penetrating and non-penetrating glaucoma surgeries. Use of medications is significantly reduced after implantation of this device.

KEYWORDS: Schlemm's canal surgery, Schlemm's canal expander, glaucoma surgery, refractory glaucoma surgery.

Для контактов:

Kumar V., e-mail: kumarvinod1955@gmail.com

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Оценка эффективности стального спирального экспандера шлеммова канала Кумара 2-го поколения в снижении внутриглазного давления у пациентов с рефрактерной глаукомой

Кумар В., д.м.н., профессор кафедры глазных болезней[1], заведующий офтальмологическим отделением[2];
Фролов М.А., д.м.н., профессор, заведующий кафедрой глазных болезней[1];
Божок Е.В., врач офтальмологического отделения[2];
Душина Г.Н., аспирант[1], врач офтальмологического отделения[2].

[1]Российский университет дружбы народов, *117198, Российская Федерация, Москва, ул. Миклухо-Маклая, д. 6;*
[2]Офтальмологическое отделение МБУЗ «Сходненская городская больница», *141421, Российская Федерация, Московская область, городской округ Химки, мкр. Сходня, ул. Мичурина, д. 31А.*

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Abstract

ЦЕЛЬ. Оценить эффективность применения стального спирального экспандера шлеммова канала (ЭШК) 2-го поколения в снижении внутриглазного давления (ВГД) у пациентов с рефрактерной глаукомой.

МЕТОДЫ. Прооперировано 9 человек (9 глаз) с рефрактерной глаукомой, у которых ВГД не контролировалось на максимальной гипотензивной терапии. Из них у 6 больных ранее была проведена трабекулэктомия, у 2 — глубокая склерэктомия и у 1 — селективная лазеропластика. Всем пациентам имплантировали ЭШК 2-го поколения наружным доступом. ЭШК изготовлен из проволоки нержавеющей стали медицинского качества толщиной 0,04 мм, длиной 2,5-3,0 мм, наружный диаметр — 0,2 мм, внутренний — 0,12 мм, кривизна соответствует кривизне ШК. В 2 случаях была произведена одномоментная комбинированная хирургия по поводу катаракты и глаукомы. Осмотр пациентов проводили ежедневно в стационаре, далее через 1 неделю, 1, 3, 6 и 12 месяцев. Критериями оценки являлись динамика ВГД, необходимость применения гипотензивных капель до и после операции и частота осложнений. Снижение ВГД >20% и 6<ВГД≤18 мм рт.ст. без применения гипотензивной терапии считали полным успехом, с применением гипотензивной терапии — частичным. Критериями неудачи являлись снижение ВГД <20% и ВГД<6 или >18 мм рт.ст., а также необходимость проведения последующей операции.

Статистический анализ проводили используя приложение Excel 2007 (Microsoft Office). Результаты считались достоверными при p<0,05.

РЕЗУЛЬТАТЫ. До операции среднее ВГД составляло 25,2±5,5 мм рт.ст. Спустя 6 и 12 мес. после операции среднее ВГД снизилось до 12,5±3,9 мм рт.ст. (p=0,0003) и 12,9±1,4 мм рт.ст. (p=0,00009) соответственно. В процентном отношении это составило снижение ВГД от исходного на 49,4±17,4 и 44,2±9,8% соответственно. Среднее число лекарств сократилось от 2,4±1,0 до 1,4±1,0 (p=0,05) и 1,0±1,0 (p=0,03) через 6 и 12 мес. соответственно. Полный и частичный успех был достигнут в 2 и 6 случаях (n=9) через 3 мес., в 2 и 7 случаях (n=9) через 6 мес. и в 2 и 3 случаях (n=5) спустя 12 мес. Во время операции микроперфорация трабекулы внутри шлеммова канала произошла в 1 из 9 случаев. В 7 случаях ЭШК полностью удалось имплантировать внутрь канала, в 2 случаях хвостовая часть экспандера (0,05 мм) оставалась во вскрытом канале. В раннем послеоперационном периоде фильтрационная подушка сформировалась у 3 больных через 1 неделю и в 1 случае через 1 и 3 мес. Осложнения, такие как наличие воспалительной реакции на месте имплантации ЭШК, его дислокация и прорезывание через трабекулярную ткань, не наблюдались. Проведение ИАГ-лазерной трабекулопунктуры не потребовалось ни в одном случае.

ВЫВОДЫ. Имплантация ЭШК Кумара 2-го поколения эффективно снижает ВГД у больных с рефрактерной глаукомой. Достоверно сокращается число используемых гипотензивных лекарств в отдаленные сроки.

КЛЮЧЕВЫЕ СЛОВА: хирургия шлеммова канала, экспандер шлеммова канала, хирургия глаукомы, хирургия рефрактерной глаукомы.

Glaucoma affects over 60 million people and is one of the leading causes of irreversible blindness [1]. The objective of glaucoma management is to preserve visual function by decreasing intraocular pressure (IOP). External filtration procedures result in excellent long-term IOP control in open-angle glaucoma (OAG) but have a high profile for intra- and postoperative complications and are not free from future morbidities [2-7]. To make glaucoma surgery more safe and effective with low potential for adverse effects new minimally invasive and microincisional glaucoma surgical (MIGS) techniques have been developed [8, 9].

Elevated IOP in glaucoma is due to an increased resistance to outflow, and majority of resistance is present in the juxtacanalicular connective tissue of the

trabecular meshwork (TM) including the inner wall of SC [10-13]. An ideal intervention for uncontrolled glaucoma would result in restoration of the natural outflow system. Theoretically, a moderate dilation of SC and the collector canal in conjunction with a trabecular bypass would reduce the IOP level significantly [14, 15]. A number of devices have been developed for the purpose. The iStent and iStent inject («Glaucos corporation Laguna Hills», CA) are Trabecular Micro-Bypass Stents, which are inserted through trabecular meshwork ab interno [16, 17]. Hydrus microstent («Ivantis Inc», Irvine, CA) is a SC scaffold, which is also inserted into canal lumen ab interno [18, 19]. These ab interno procedures are difficult to master, technically difficult to perform. Need to change the positioning of the patient's head, the microscope, and use of gonioprism during procedure make the procedures more challenging. Sometimes it is difficult visualizing the anterior chamber angle through the gonioprism, especially if blood refluxes into TM. To date MIGS procedures have been studied only in cases with mild to moderate OAG [16-22].

Ab externo procedures do not require mastering of other unfamiliar to surgeon techniques and maneuvers. Surgery is performed by using usual settings of the operating microscope. No tilting of optical head of the microscope and of patient is required.

Canaloplasty is an ab externo procedure, which uses natural aqueous outflow pathways to reduce IOP and is reported to have fewer complications compared with standard trabeculectomy surgery [23-26]. But the procedure is difficult to master and learning curve is long. The most difficult steps in canaloplasty surgery are dissection of Descemete's membrane, circumferential viscodilation of Schlemm's canal (SC), placement of 10-0 suture, proper tensioning of SC and watertight suturing of flaps. Combining canaloplasty with phacoemulsification is a more challenging. Another disadvantage of this technique is that placement of 360° 10-0 suture disturbs intracanalicular structures (Johnstone's transparent tubules), whose function is not yet fully studied and understood in fluid outflow [27].

A novel stainless steel spiral Schlemm's canal expander (SCE) (Kumar's 1st generation SCE) was developed to distend a segment of SC ab externo. Its safety and efficacy in decreasing IOP in primary OAG cases has been proved and reported elsewhere [28, 29]. The 5-6 mm long spiral device was made from medical grade stainless steel Vanadium wire of 0.05 mm thickness and its external diameter was 0.3 mm. The diameter of the device was selected depending upon the findings of SC size from studies, which measured SC in enucleated bank eyes. As per results of these studies SC size varied between 0.181 to 0.350 mm [30, 31]. Recent studies showed that SC size in vivo differs from that of bank eyes [32, 33]. Average SC diameter as measured by 80 MHz ultrasound biomicroscopy in vivo is 0.121±0.045 mm [32]. J. Hong et al. (2013) measured SC diameter and its size by using Spectral – Domain Optical Coherence Tomography (OCT) in Chinese population and reported that SC size varied from 0.042±0.007 mm to 0.045±0.004 mm [33]. Taking into consideration these findings, certain modifications were made in 1st generation SCE size to make its insertion into SC lumen less traumatic. Overall length was reduced from 5-6 to 2.5 to 3.0 mm and outer diameter from 0.3 to 0.2 mm. The device was termed as Kumar's 2nd generation SCE. A pilot study was undertaken to evaluate its safety and effectiveness in decreasing IOP in OAG cases. Results were compared with that of 1st generation SCE and it was concluded that both 1st and 2nd generation SCE were equally effective in decreasing IOP in OAG, though, after 2nd generation SCE implantation, YAG laser trabeculopuncture as a second step procedure was more frequently needed [34]. The present study was undertaken to evaluate effectiveness of 2nd generation SCE in decreasing IOP in patients with primary OAG refractory to previous penetrating and non-penetrating glaucoma surgeries.

Materials and Methods

In this prospective, non-comparative, uncontrolled, non-randomised, interventional case series study the clinical evaluation of the efficacy of Kumar's 2nd generation SCE in decreasing IOP in 9 consecutive patients (9 eyes) having failed filters, who's IOP was insufficiently controlled was carried out. After getting approval from the ethical committee of the institution, this study was conducted in accordance with the tenets of the World Medical Association Declaration of Helsinki and an informed consent was obtained from all subjects after the experimental nature of the procedure had been fully explained. Study period: July, 2013 – May, 2014.

Inclusion criteria: patients having insufficiently controlled IOP with failed filters from previously performed glaucoma surgeries for primary OAG.

Exclusion criteria: conditions interfering with reliable applanation tonometry by Maklakov's method, minimum follow-up period less than 6 months and cases having macro perforation of TM in exposed SC area during surgery. Cases having micro perforation of TM in areas other than exposed SC were not excluded. Earlier intraocular surgery like phacoemulsification with intraocular lens implantation (IOL) was not considered as exclusion criteria.

Observation procedure: a complete ophthalmological examination was performed before surgery including visual acuity evaluation, applanation tonometry measurement by Maklakov's method, slit lamp biomicroscopy, 78 D ophthalmoscopy, perimetry and gonioscopy.

The device: 2nd generation SCE was made from 0.04 mm thick medical grade soft Vanadium stainless steel wire by winding it on a 0.12 mm thick stainless

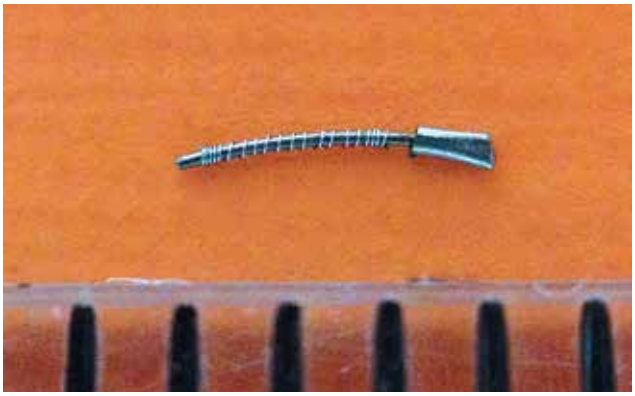

Figure 1. Kumar's 2nd generation Schlemm's canal expander mounted on the conductor/inserter along with measuring scale (minimum division 1 mm)

steel microprobe, having curvature as of SC. The device is 2.5-3.0 mm long, outer diameter is 0.2 mm, inner lumen diameter - 0.12 mm. The wire loops of end parts are closely located, in the central part they are apart from each other by 0.1- 0.2 mm *(Figure 1)*.

Surgical technique: after creating a fornix based conjunctival flap away from the previous surgery site, 1/2 thickness superficial flap and deep scleral flap upto ciliary body were dissected. Redissection of previous surgery site was avoided in all cases. No diathermy was carried out in any of the case to preserve any patent collector channels. The SC was exposed without creating a window in Descemete's membrane. Further channelography was performed to trace out collector channel — aqueous vein system and transtrabecular passage. For the purpose a small quantity of off label diluted solution of fluorescein (1 drop of 10% fluoresceine sodium; AK-fluor, "Akorn, Inc." Lake Forest, Il, was diluted in 4-5 ml of balanced salt solution, Industria Farmaceutica Galencia Senese, Monteroni d'Arabia, Italy) was injected into SC lumen using a special viscocanalostomy canula (34 G) (Pricon Visco canalostomy cannula, "Iscon surgical Ltd.", India). Further a 2-3 mm segment of SC (temporal segment in left eyes and nasal in right eyes) was dilated with cohesive viscoelastic device (high viscosity viscoelastic solution 1.4% Sodium Hyaluronate, BVI, "Beaver Visitec International, Inc.", Waltham, MA, USA) and microprobe of 0.3mm diameter. The SCE mounted on 0.12 mm thick inserter was inserted into dilated SC with the help of a forceps and held there with second instrument (Pearse style straight corneal fixation forceps — working part with groove 0.2 mm, Titan medical, Russian Federation) followed by careful removal of the inserter. The superficial, deep scleral flaps and conjunctiva were sutured back water tightly with 10-0 nylon interrupted sutures. During combined surgery, first phacoemulsification with implantation of a hydrophilic IOL was performed. After irrigation of viscoelastic out of anterior chamber and hydration of corneal wounds, glaucoma surgery was carried out.

Follow-up evaluation: no washout of the patient's ocular hypotensive medications was done. Patients discontinued their IOP-lowering medications one day before surgery and oral acetozolamide 0.25 gm (Diacarb, "Polpharma", Poland) twice daily was prescribed for one day and were instructed to resume IOP-lowering medications only if the investigator determined that additional IOP lowering was needed. Patients were evaluated daily during hospital stay, after 1 week, and at 1, 3, 6 and 12 months after surgery. Postoperative assessment included visual acuity evaluation, tonometry measurement by Maklakov method, biomicroscopy and ophthalmoscopy. SCE location and TM condition were evaluated gonioscopically and wherever possible were photo- and video documented. Adverse events if any and number of glaucoma medications were noted.

Outcome measures and statistical analysis: The primary outcome measure was IOP. The IOP was measured by Maklakov's applanation tonometer and converted to P_0 using special conversion table for the purpose [35]. The secondary outcome measures were number of glaucoma medications pre- and postoperatively and complications. A paired t-test was used for IOP and medication analysis. Decrease in IOP >20% or IOP 6-18 mmHg without medication was considered as a complete success, with medication — partial success. Failure was considered if the patient had IOP <6 mmHg or >18 mmHg or reduction is <20% after 3 months and if patient needed a subsequent filtering surgery. Success rates were evaluated at each follow-up visit after 3 months after surgery. Statistical analysis was performed using MS Office application — Excel 2007 at each follow-up visit taking into account the change in the number of patients. Results were considered significant when $p<0.05$.

Results

There were 5 male and 4 female patients with an average age of 68.8±8.1yrs. The demographic characteristic of the cases is presented in *table 1*.

There were 4 right and 5 left eyes. Two cases (2 eyes) with coexisting pathology underwent combined two site procedure (phacoemuclification with implantation of a foldable IOL followed by SCE implantation), and the remaining 7 eyes had SCE implantation only. In all cases anterior chamber angle was open.

Mean IOP at each follow-up visit. Mean preoperative IOP was 25.2±5.5 mmHg (range: 18.1-36.9; 95% confidence interval (CI) 21.6-28.9). At each follow-up a decrease in mean IOP was observed, resulting in 14.7±3.0 mmHg (n=9, range: 11.9–19; 95% CI 12.7-16.7; p=0.0001) at 1 month; 13.7±4.4 mmHg (n=9, range: 8.3–23.7; 95%CI 10.8-16.6; p=0.0001) at 3 months; 12.5±3.9 mmHg (n=9, range: 7.1-19.0; 95%CI 9.9-15.0; p=0.00003) at 6 months and 12.9±1.4 mmHg (n=5, range: 11.9-15.3; 95% CI 12.0-13.9; p=0.00009) at 12 months *(Figure 2)*.

Table 1

The demographic characteristic of the study population

Case №	Gender	Age (yrs.)	Eye	Previous glaucoma surgery	Other intraocular surgery	Concomitant pathology
1	F	68	OS	SLT	–	–
2	F	73	OD	DS	–	Cataract
3	F	61	OS	Trab	–	–
4	M	61	OS	Trab	Phaco + IOL	–
5	M	78	OS	Trab	–	–
6	F	67	OD	Trab	–	Cataract
7	M	74	OD	DS	Phaco + IOL	–
8	M	57	OS	Trab	–	–
9	M	80	OD	Trab	Phaco + IOL	–

Notice: M — male; F — female; OD — right eye; OS-left eye; SLT — selecetive laserplasty; DS — deep sclerectomy; Trab — trabeculectomy; Phaco — phacoemulsification; IOL — intraocular lens.

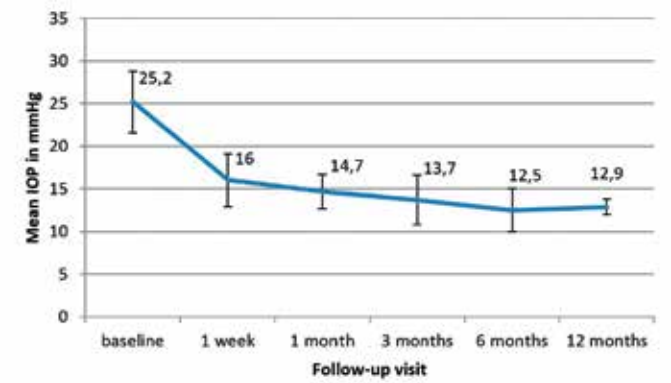

Figure 2. Mean IOP at each follow-up visit

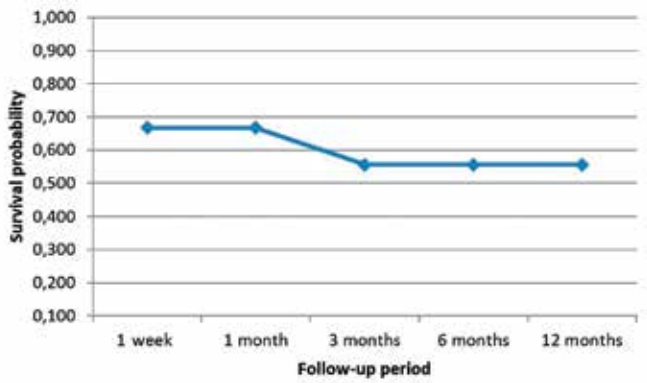

Figure 3. Kaplan-Meier survival plot for cumulative probability of success after implantation of 2nd generation SCE. Success was defined as an IOP ≤18 mmHg or decrease in IOP >20% from the baseline with or without medication

This represents a reduction in IOP from baseline of 40.7±11.3, 45.3±20.7, 49.4±17.4 and 44.2±9.8% at 1 month, 3 months, 6 months and 12 months respectively *(Figure 2)*.

Success rate. Complete and partial success were observed in 2 and 6 cases (n=9) at 3 months, in 2 and 7 cases (n=9) at 6 months and 2 and 3 cases (n=5) at 12 months. There was only 1 case at 3 months, who fulfilled failure criteria. The IOP in this case was controlled medically after 4 months after surgery. There were no failure cases at 6 and 12 months *(Figure 3)*.

Mean number of preoperative medications was 2.4±1.0 (range: 1-4; 95% CI 1.8-3.1). After surgery mean number of glaucoma medications reduced at each follow up visit and was 0.9±0.9 (n=9, range: 0-2; 95%CI 0.3-1.5; p=0.004), 1.3±1.0 (n=9, range: 0-3; 95% CI 0.7-2.0; p=0.03), 1.4±1.0 (n=9, range: 0-3; 95% CI 0.8-2.1; p=0.05) and 1.0±1.0 (n=5, range: 0-2; 95%CI 0.3-1.7; p=0.03) at 1,3,6 and 12 months respectively *(Figure 4)*.

Mean best corrected visual acuity before surgery was 1.1±0.9 logarithm of the minimum angle of resolution (logMar). Mean logMar at 1, 3, 6 and 12 months was 1.1±1.0, 0.8±0.8, 0.9±0.8 and 0.6±0.8 respectively.

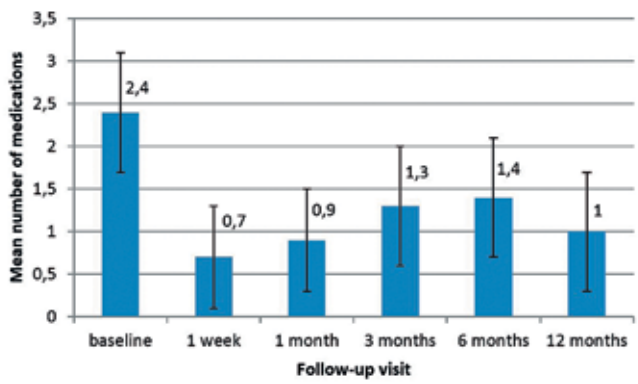

Figure 4. Mean number of medications used at each follow-up visit

Observations during surgery: nearly in all cases because of superior location of previous surgery site, it was difficult to create scleral flaps, especially deeper ones and in right eyes. Blood regurgitation from SC ostium after SC exposure was noticed in 2 cases. Patency of collector channel – aqueous vein system was further confirmed by channelography in 3 cases. Only

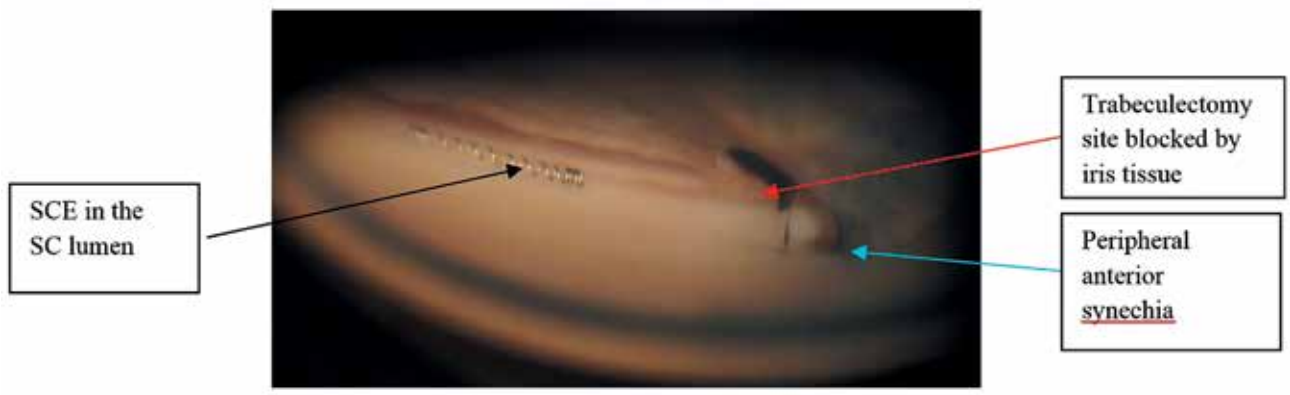

Figure 5. Implantation of Kumar's 2nd generation SCE in a case of failed trabeculectomy. Gonioscopic view: the device is completely in the SC lumen (black arrow), away from the previous trabeculectomy site. Previous trabeculectomy site is blocked by iris tissue (red arrow). A thick peripheral anterior synechia can also be noted (blue arrow)

in 1 case some dye entered into anterior chamber, indicating partial patent transtrabecular passage. In other cases trabecular passage was non functional.

In 7 cases the device could be inserted completely into SC lumen. In 2 cases caudal end (0.5 mm) of the device was left in the exposed part of SC. In 1 case microperforation of TM inside the canal lumen occurred, resulting in excess filtration of aqueous humor from the SC with flattening of anterior chamber. Next day the anterior chamber in this case was stable, of equal depth as compared to other eye.

In early post-operative period some bleb was noticed in 3 cases at 1 week and in 1 case each at 1 and 3 months. Complications like, device dislocation, inflammation at the insertion site, devices' erosion through TM, loss of device were nil. YAG laser trabeculopucture was not required in any of the cases.

For demonstrating purpose a case is presented. Patient K.S. 57 year old male, suffering from OAG since 2005 year, had undergone trabeculectomy in 2007. After surgery IOP remained under control till 2012, when patient was started on 2 hypotensive medications (beta blocker and carbonic anhydrase inhibitor). IOP could not be controlled sufficiently and on 23.01.2014 patient had undergone operation — insertion of 2nd generation SCE into a segment of SC ab externo. Baseline IOP was 22.7 mmHg on 2 hypotensive medications. Flap dissection was difficult because of scar tissue at 12 o'clock from previous glaucoma surgery. After SC exposure, fluorescein chanellogrpahy was performed and patency of collector channel – aqueous vein system was verified. Fine collectors in the form of a meshwork were traced out. No dye entered into anterior camber, which showed non functional transtrabecular passage. After viscocanalostomy and SC dilation with microprobe of 0.3 mm the SCE was implanted into SC lumen using bimanual technique. Flaps were sutured back water-tightly. Patient was followed up for 1 year. Postoperatively, surgery site was free from bleb at any of the follow up visit. IOP decreased to 12.8 mmHg at 12 months. On an average mean reduction of IOP from the baseline was more than 46%. At the time of last follow-up: eye globe was quiet, there was no bleb formation, anterior chamber was of medium depth and pupil was centrally placed. Gonioscopically a peripheral iridectomy from the previous surgery and blockage of previous trabecular site by iris tissue could be made out. The device was in the SC lumen without any sign of inflammation or erosion *(Figure 5)*.

Discussion

Trabeculectomy is the most commonly used surgical procedure in management of OAG [36]. However, long-term cumulative failure rates of initial trabeculectomy are significant. In a study on the outcomes of initial trabeculectomy with MMC in the treatment of phakic patients with OAG, failure rates ranged from 15 to 21% at 1 year and 38 to 54% at 3 years, depending on the failure criteria applied [6]. In pseudophakic patients failure rates may vary from 13 to 24% at 1 year and 33 to 50% at 2 years [37].

In cases with failed filters, repeat trabeculectomies with use of antimetabolites or implantation of epibulbar glaucoma drainage devices have been advocated [2, 7, 38]. But because of unacceptably high failure and complication rates the therapeutic potential of repeat external filtration procedures is limited. In a multicenter randomized prospective clinical trial — The Tube Versus Trabeculectomy Study, the safety and efficacy of tube shunt surgery and trabeculectomy with MMC in eyes with prior ocular surgery were compared. Patients with uncontrolled glaucoma who had previously undergone cataract extraction with intraocular lens implantation and/or failed filtering surgery were enrolled and randomized to receive either a 350-mm^2 Baerveldt glaucoma implant ("Abbott Medical Optics", Santa Ana, California, USA) or a trabeculectomy with MMC. A total of 212 eyes of 212 patients were enrolled, including 107 in the tube group and 105 in the trabeculectomy

group. At 5 years, mean IOP was 14.4±6.9 mmHg in the tube group and 12.6±5.9 mmHg in the trabeculectomy group (p=0.12). The number of glaucoma medications was 1.4±1.3 in the tube group and 1.2±1.5 in the trabeculectomy group (p=0.23). The cumulative probability of failure during 5 years of follow-up was 29.8% in the tube group and 46.9% in the trabeculectomy group (p= -0.002; hazard ratio = 2.15; 95% CI 1.30 - 3.56). The rate of reoperation for glaucoma was 9% in the tube group and 29% in the trabe-culectomy group (p=0.025). Vision-threatening early postoperative complications occurred in 21% cases in the tube group and 37% cases in the trabeculectomy group (p=0.012). Late postoperative complications developed in 34% cases in the tube group and 36% cases in the trabeculectomy group during 5 years of follow-up (p=0.81). Urgent postoperative interventions were performed in 74% of trabeculectomies and 27% of tube shunts. The rate of reoperation for complications was 22% in the tube group and 18% in the trabeculectomy group (p=0.29). Cataract extraction was performed in 54% phakic eyes in the tube group and 43% phakic eyes in the trabeculectomy group (p=0.43) [7].

Role of MIGS in management of failed filters is debatable. It has been stated that after successful filtering procedure pathological changes occur in SC structure. After the conventional outflow tract is bypassed there are atrophic changes in the pathway. Subendothelial TM deposits and an amorphous material in the juxtacanalicular tissue narrowing the lumen were noted in human eyes following trabeculectomy, with a significant correlation between lower IOPs and smaller canals [39-41]. Successful filters also result in reduction of SC diameter [42]. D.H. Johnson, Y. Matsumoto (2000) reported smaller SC diameter after filtration surgery as measured by scanning and light microscopy of enucleated human eyes. Average reported canal diameter was 0.178 mm in postfiltration surgery eyes versus 0.276 mm in normal eyes (p<0.001). The authors theorized that in bypassing the TM and SC, successful filtration surgery caused underperfusion of these structures [41]. Irshad F.A., Mayfield M.S. et al (2010) measured variations in diameter and location of SC in vivo with 80-MHz ultrasound biomicroscopy and reported that the average canal diameter was smaller in patients with previous glaucoma surgery compared with patients without glaucoma surgery (0.098±0.020 mm vs. 0.125±0.004 mm; p<0.01) [32]. Hong J. et al (2013) using Spectral-Domain Optical Coherence tomograph reported that eyes with primary OAG have a decreased SC area compared with normal eyes [33].

High IOP in failed filter cases will result in attenuation or even collapse of the SC. Collapsed SC will further contribute to a reduction of aqueous outflow and hence to a further marked increase in IOP. The increased IOP compresses the inner wall against the outer wall of the canal and over a prolonged period this may even result in adhesions between these structures [12, 13]. Theoretically a distended SC with patent collector channel – aqueous vein system and patent transtrabecular passage may result in decrease in IOP in failed filter cases.

Smaller size of SC can influence the efficacy of a device such as the iStent (Glaucos corporation "Laguna Hills", CA, USA), which requires patent posttrabecular channels to function. There are not many studies which studied effectiveness of MIGS procedures in cases refractory to previous glaucoma surgery. In a single case report, Fea et al. (2008) demonstrated successful IOP lowering in a pseudophakic eye after implantation of a single iStent [43]. In another case successful trabecular bypass surgery with implantation of 2 iStents was performed in a 77-year-old woman with primary OAG after failing to achieve target IOP despite previous combined phacotrabeculectomy and Ahmed valve implantations. The IOP prior to surgery was 28 mmHg on topical dorzolamide-timolol, latanoprost, and brimonidine. The IOP decreased by 11 mmHg to 17 mmHg after surgery and remained stable for 2 years [44].

In a recent prospective study Bussel I.I. et al. (2014) studied outcomes of ab interno trabeculectomy with the trabectome after failed trabeculectomy. Seventy-three eyes of 73 patients with 1 year follow-up were included and at 1 year, mean IOP significantly decreased by 28% from 23.7±5.5 mmHg and medications from 2.8±1.2 to 2±1.3 (n=58). In combined phaco and ab interno trabeculectomy cases, the mean IOP decreased by 19% from 20±5.9 mmHg and medications from 2.5±1.5 to 1.6±1.4 (n=15). Among complications authors noted transient hypotony in 7%, and further surgery was necessary in 18% [45].

Marc T.O. et al. (2013) in a randomized, interventional case series retrospectively assessed the effect of selective laser trabeculoplasty (SLT) following failed phacoemulsification cataract extraction combined with ab interno trabeculectomy using the Trabectome (phaco-trabectome) ("NeoMedix Corporation", Tustin, CA, USA). Fourteen eyes of 13 subjects were included. Mean follow-up after SLT was 12.9±8.7 months. All SLT procedures failed. Median time to failure after SLT was 3.6±0.8 (range 2.1-5.1) months. Authors concluded that in eyes in which the IOP was no longer controlled following phaco-trabectome, SLT had a limited duration of significant IOP-lowering effect [46].

Canaloplasty is usually indicated for eyes that have not undergone previous filtrating surgery for glaucoma. Brusini P., Tosoni C. (2014) reported 6 cases with previous failed trabeculectomy and elevated IOP despite maximum tolerated medical therapy who underwent canaloplasty. The preoperative IOP was 32.2±9.6 mmHg, ranging from 25 to 48 mmHg. In this group of patients, canaloplasty could be correctly completed in 5 cases; in 1 case, however, SC could not be cannulated for the

entire 360-degree circumference, thus surgery was converted into viscocanalostomy. The mean IOP at 6, 12, 18, and 24 months was 17.3, 15.4, 14.7, and 16.3 mmHg, respectively. The number of medications used before and at the 2-year follow-up was 3.2±1.2 and 2.3±0.5, respectively. Authors suggest that canaloplasty can be considered as a possible surgical option in eyes with failed trabeculectomy showing undamaged SC from previous filtrating surgery [47].

It is plausible that in at least some advanced failed filter cases, there could be patent post-trabecular outflow [48]. In the presented case series a permanent segmental distension of the SC was achieved by inserting SCE device into its lumen in 9 eyes, who had failed to achieve the target IOP after various penetrating, non-penetrating and laser surgeries. Majority of the eyes previously had trabeculectomy procedure (6/9). Fluorescein channelography, performed in 6 eyes showed patent collector channel – aqueous vein system in 3 eyes. Out of 2 cases, where complete success could be achieved, in one case no collector channels were identified during channelography, where as in the other case a fine meshwork of fine collector channels was traced out. In absence of functional transtrabecular passage, patency of collector channel – aqueous vein system plays a little role in reestablishment of natural outflow. To reestablish natural pathway, trabecular resistance has to be overcome either by trabecular bypass or by viscocanalostomy.

Cannulation of SC and injection of viscoelastic beyond the cannula result in marked dilation of SC and associated collector channels. Lateral walls, inner wall endothelium, and bridging structures of SC are frequently disrupted by cannulation and sometimes by injected viscoelastic. These findings suggest that viscocanalostomy may actually cause a direct communication between SC and the juxtacanalicular space, and so may initially enhance conventional aqueous outflow [49]. In the presented series it can be hypothesized that viscocanalostomy, which was performed in each case to ease the SCE insertion, created a direct communication between anterior chamber and SC, where as the inserted device keeps the SC segment distended which further enhanced the natural outflow.

In this cases series success (complete as well as partial) was achieved in all cases after 3 months. Use of medications after surgery also significantly reduced from 2.4±1.0 to 1.0±1.0 (p=0.03) at 12 months. Intraoperative as well as post operative complications were negligible and easily manageable. The explanation to some bleb formation after surgery in 3 cases at 1 week and in 1 case each at 1 and 3 months could be that during dissection of scleral flaps some of the collectors are severed and after natural outflow pathway is reestablished, aqueous drained from SC through these collectors and accumulates under conjunctiva. As soon as fibrosis occurs, the blebs disappeared. There were no blebs noticed after 3 months.

Shortcomings of this study are small sample size, uncontrolled, non-randomized and non-comparative nature. Randomized, controlled and comparative studies with longer follow-up and larger groups are required in order to confirm the safety and efficacy of this device in cases with failed filters. Another disadvantage of this technique is that it requires extensive dissection of conjunctiva and scleral flaps, which make future surgeries more difficult if required.

Conclusion: it can be concluded that Kumar's 2nd generation SCE is effective in decreasing IOP in patients with primary OAG refractory to previous penetrating and non-penetrating glaucoma surgeries. Use of medications is significantly reduced after 3 months after implantation of this device.

References

1. Quigley H.A., Broman A.T. The number of people with glaucoma worldwide in 2010 and 2020. *Br J Ophthalmol* 2006; 90(3):262-267. doi: 10.1136/bjo.2005.081224.
2. Gedde S.J., Herndon L.W., Brandt J.D., Budenz D.L., Feuer W.J., Schiffman J.C. Surgical complications in the tube versus trabeculectomy study during the first year of follow-up. *Am J Ophthalmol* 2007; 143(1):23-31. doi:10.1016/j.ajo.2006.07.022.
3. Scott I.U., Greenfield D.S., Schiffman J., Nicolela M.T., Rueda J.C., Tsai J.C., Palmberg P.F. Outcomes of primary trabeculectomy with the use of adjunctive mitomycin. *Arch Ophthalmol* 1998; 116(3):286-291.
4. Edmunds B., Thompson J.R., Salmon J.F., Wormald R.P. The National Survey of Trabeculectomy. III. Early and late complications. *Eye* 2002; 16(3):297-303.
5. Jampel H.D., Musch D.C., Gillespie B.W., Lichter P.R., Wright M.M., Guire K.E. Collaborative Initial Glaucoma Treatment Study Group. Perioperative complications of trabeculectomy in the the collaborative initial glaucoma treatment study (CIGTS). *Am J Ophthalmol* 2005; 140(1):16-22. doi:10.1016/j.ajo.2005.02.013.
6. Fontana H., Nouri-Mahdavi K., Lumba J., Ralli M., Caprioli J. Trabeculectomy with mitomycin C: outcomes and risk factors for failure in phakic open-angle glaucoma. *Ophthalmology* 2006; 113(6):930-936. doi:10.1016/j.ophtha.2006.01.062.
7. Gedde S.J., Herndon L.W., Brandt J.D., Budenz D.L., Feuer W.J., Schiffman J.C. Tube Versus Trabeculectomy Study Group. Postoperative Complications in the Tube Versus Trabeculectomy (TVT) Study during five years of follow-up. *Am J Ophthalmol* 2012;153(5):804-814. doi:10.1016/j.ajo.2011.10.024.
8. Saheb H., Ahmed K. II. Micro-invasive glaucoma surgery: current perspectives and future directions. *Curr Opin Ophthalmol* 2012; 23(2):96-104. doi: 10.1097/ICU.0b013e32834ff1e7.
9. MIGS: advances in glaucoma surgery/ edited by Kahook M.Y.; associate editors: Sarwat S., Leonard K. Seibold. USA. SLACK Incorporated 2014. 122 p.
10. Grant W.M. Experimental aqueous perfusion in enucleated human eyes. *Arch Ophthalmol* 1963; 69(6):738-801.
11. Johnson D.H., Johnson M. How does nonpenetrating glaucoma surgery work? Aqueous outflow pathway morphology. *Invest Ophthalmol Vis Sci* 1999; 40(8):1676-1680.
12. Nesterov A.P. Role of the blockade of Schlemm's canal in pathogenesis of primary open-angle glaucoma. *Am J Ophthalmol* 1970; 70(5):691-696.

13. Нестеров А.П. Глаукома. М.: 1995; 33-46, 103-130. [Nesterov AP. Glaukoma [Glaucoma]. Moscow, 1995; 33-46, 103-130. (in Russ.)].
14. Zhou J., Smedley G.T. A trabecular bypass flow hypothesis. *J Glaucoma* 2005; 14(1):74-83.
15. Zhou J., Smedley G.T. Trabecular bypass; effect of Schlemm canal and collector channel dilation. *J Glaucoma* 2006; 15(5):446-455.
16. Samuelson T.W., Katz L.J., Wells J.M., Duh Y.J., Giamporcaro J.E. US iStent Study Group. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology* 2011; 118(3):459-467. doi: 10.1016/j.ophtha.2010.07.007.
17. Arriola-Villalobos P., Martinez-de-la-Casa J.M., Diaz-Valle D., García-Vidal S.E., Fernández-Pérez C., García-Sánchez J., García-Feijoó J. Mid-term evaluation of the new Glaukos iStent with phacoemulsification in coexistent open-angle glaucoma or ocular hypertension and cataract. *Br J Ophthalmol* 2013; 97(10):1250-1255. doi: 10.1136/bjophthalmol-2012-302394.
18. Samuelson T., Tetz M., Pfeiffer N., Ramirez M., Scharioth G., Vass C. One year results of a nickel–titanium Schlemm's canal microstent for IOP reduction after cataract surgery in open angle glaucoma. Paper presented at: 117th annual meeting of American Academy of Ophthalmology. November, 2012; Chicago, Il.
19. Camras L.J., Yuan F., Fan S., Samuelson T.W., Ahmed I.K., Schieber A.T., Toris C.B. A novel Schlemm's canal scaffold increases outflow facility in a human anterior segment perfusion model. *Invest Ophthalmol Vis Sci* 2012; 53(10):6115-6121. doi: 10.1167/iovs.12-9570.
20. Francis B.A., Minckler D., Dustin L., Kawji S., Yeh J., Sit A., Mosaed S., Johnstone M. Trabectome Study Group. Combined cataract extraction and trabeculotomy by the internal approach for coexisting cataract and open–angle glaucoma: initial results. *J Cataract Refract Surg* 2008; 34(7): 1096-1103. doi: 10.1016/j.jcrs.2008.03.032.
21. Иванов Д.И., Никулин М.Е., Струков В.В. Способ одномоментного хирургического лечения катаракты и глаукомы путем трабекулотомии ab interno и инструмент для ее выполнения. Патент РФ на изобретение № 2389456. Опубликовано 20.05.2010. Бюлл. 14 [Ivanov D.I., Nikulin M.E., Strukov V.V. Combined surgical treatment of cataract and glaucoma by ab interno trabeculotomy and an instrument for it. Patent of Russian Federation № 2389456. Published on 20.05.2010. Bull. 14 (In Russ.)].
22. Иванов Д.И. Трабекулотом ирригационный. Патент РФ на полезную модель № 109662. Опубликовано 27.10.2011. Бюлл. 30. [Ivanov D.I. Irrigating trabeculotome. Patent of Russian Federation № 109662. Published on 27.10.2011. Bull. 30. (In Russ)].
23. Shingleton B., Tetz M., Korber N. Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract: one-year results. *J Cataract Refract Surg* 2008; 34(3):433-440. doi: 10.1016/j.jcrs.2007.11.029.
24. Ayyala R.S., Chaudhry A.L., Okogbaa C.B. et al. Comparison of surgical outcomes between canaloplasty and trabeculectomy at 12 months' follow-up. *Ophthalmology* 2011; 118(12):2427-2433. doi: 10.1016/j.ophtha. 2011.05.021.
25. Grieshaber M.C., Pienaar A., Olivier J., Stegmann R. Canaloplasty for primary open-angle glaucoma: long-term outcome. *Br J Ophthalmol* 2010; 94(11):1478-1482. doi: 10.1136/bjo.2009.163170.
26. Grieshaber M.C., Fraenkl S., Schoetzau A., Flammer J., Orgül S. Circumferential viscocanalostomy and suture canal distension (canaloplasty) for Whites with open-angle glaucoma. *J Glaucoma* 2011;20(5):298-302. doi: 10.1097/IJG.0b013e3181e3d46e.
27. Johnstone M., Curtis K., Passin D. et al. New imaging techniques to study transparent tobules (TT) spanning Schlemm's canal structures subject to disruption by SC surgery. AGS 21st annual meeting 2011, poster abstracts, poster N 32.
28. Кумар В., Фролов М.А., Душина Г.Н., Божок Е.В., Беззаботнов А.И. Сегментарная дилятация шлеммова канала с помощью стального спирального стента собственной конструкции в хирургии открытоугольной глаукомы. *Медицинский вестник Башкортостана* 2014; 2:58-62. [Kumar V., Frolov M.A., Dushina G.N., Bozhok E.V., Bezzabotnov A.I. Segmental dilation of Schlemm's canal with the help of an original stainless steel spiral stent in open angle glaucoma surgery. *Meditsinskii vestnik Bashkortostana* 2014; 2:58-62 (In Russ.)].
29. Kumar V., Frolov M.A., Bozhok E.V., Dushina G.N., Bezzabotnov A.I. A new stainless steel spiral Schlemm's canal expander in surgical treatment open-angle glaucoma. *Национальный журнал глаукома* 2014; 3:43-51. [*Natsional'nyi zhurnal glaukoma* 2014; 3:43-51].
30. Sampaolesi R., Argento C. Scanning electron microscopy of the trabecular meshwork in normal and glaucomatous eye. *Invest Ophthalmol Vis Sci* 1977; 16(4):302-314.
31. Ramos R.F., Hoying J.B., Witte M.H., Daniel Stamer W. Schlemm's canal: endothelia, lymphatic, or blood vasculature? *J Glaucoma* 2007;16(4):391-405.
32. Irshad F.A., Mayfield M.S., Zurakowski D., Ayyala R.S. Variation in Schlemm's canal diameter and location by ultrasound biomicroscopy. *Ophthalmology* 2010; 117(5):916-920. doi: 10.1016/j.ophtha.2009.09.041.
33. Hong J., Xu J., Wei A., Wen W., Chen J.,Yu X., Sun X. Spectral-Domain Optical Coherence tomographic assessment of Schlemm's canal in chinese subjects with primary open-angle glaucoma. *Ophthalmology* 2013;120(4):709-715. doi: 10.1016/j.ophtha.2012.10.008.
34. Кумар В., Фролов М.А., Душина Г.Н., Божок Е.В., Беззаботнов А.И. Результаты снижения внутриглазного давления у пациентов с открытоугольной глаукомой при сегментарном расширении шлеммова канала с помощью интраканального экспандера второго поколения собственной конструкции. *Альманах клинической медицины* 2015; 36: 29-33. [Kumar V., Frolov M.A., Dushina G.N., Bozhok E.V., Bezzabotnov A.I. Results of intraocular pressure decrease in open angle glaucoma patients after segmental dilation of Schlemm's canal with the help of 2nd generation original intracanalicular expander. *Al'manakh klinicheskoi meditsiny* 2015; 36, January: 29-33 (In Russ.)].
35. Краснов М.М. Микрохирургия глауком. М.: 1980; 235-236. [Krasnov M.M. Mikrokhirurgiya glaukom [Microsurgery of glaucoma]. Moscow, 1980; 235-236. (In Russ.)].
36. Ramulu P.Y., Corcoran K.J., Corcoran S.L., Robin A.L. Utilization of various glaucoma surgeries and procedures in Medicare beneficiaries from 1995 to 2004. *Ophthalmology* 2007; 114(12):2265-2270. doi: 10.1016/j.ophtha.2007.02.005.
37. Fontana H., Nouri-Mahdavi K., Caprioli J. Trabeculectomy with mitomycin C in pseudophakic patients with open-angle glaucoma: outcomes and risk factors for failure. *Am J Ophthalmol* 2006; 41(4): 652-659. doi: 10.1016/j.ajo.2005.11.039.

38. Saheb H., Gedde S.J., Schiffman J.C., Feuer W.J. Outcomes of glaucoma reoperations in the Tube versus Trabeculectomy (TVT) study. *Am J Ophthalmol* 2014; 157(6):1179-1189. doi: 10.1016/j.ajo.2014.02.027.
39. Ainsworth J.R., Lee W.R. Effects of age and rapid high-pressure fixation on the morphology of Schlemm's canal. *Invest Ophthalmol Vis Sci* 1990; 31(4):745-750.
40. Allingham R.R., de Kater A.W, Ethier C.R. Schlemm's canal and primary open angle glaucoma: correlation between Schlemm's canal dimensions and outflow facility. *Exp Eye Res* 1996; 62(1):101-109.
41. Johnson D.H., Matsumoto Y. Schlemm's canal becomes smaller after successful filtration surgery. *Arch Ophthalmol* 2000; 118(9):1251-1256.
42. Lütjen-Drecoll E. Functional morphology of the trabecular meshwork in primate eyes. *Prog Retin Eye Res* 1999; 18(1): 91-119. PMID: 9920500.
43. Fea A.M., Dogliani M, Machetta F., Lale-Lacroix G., Brogliatti B., Grignolo F.M. The trabecular bypass stent in a pseudophakic glaucoma patient: a 1 year follow-up. *Clin Ophthalmol* 2008; 2(4):931-934. Available at: http: //www.ncbi.nlm.nih.gov/pmc/articles/PMC2699816/pdf/co-2-931.pdf. Accessed February 1, 2015.
44. Roelofs K., Arora S., Dorey M. W. Implantation of 2 trabecular microbypass stents in a patient with primary open-angle glaucoma refractory to previous glaucoma-filtering surgeries. *J Cataract Refract Surg* 2014; 40(8):1322-1324. doi: 10.1016/j.jcrs.2014.06.017.
45. Bussel I.I., Kaplowitz K., Schuman J.S., Loewen N.A. Outcomes of ab interno trabeculectomy with the trabectome after failed trabeculectomy Trabectome Study Group. *Br J Ophthalmol* 2015; 99(2):258-262. doi: 10.1136/bjophthalmol-2013-304717.
46. Teberg-Harms M.T.O., Rhee D.J. Selective laser trabeculoplasty following failed combined phacoemulsification cataract extraction and ab interno trabeculectomy. *Am J Ophthalmol* 2013; 156(5):936-940. doi: 10.1016/j.ajo.2013.05.044.
47. Brusini P., Tosoni C. Canaloplasty after failed trabeculectomy: a possible option. *J Glaucoma* 2014; 23(1):33-34. doi: 10.1097/IJG. 0000000000000188.
48. Stamer W.D., Acott T.S. Current understanding of conventional outflow dysfunction in glaucoma. *Curr Opin Ophthalmol* 2012; 23(2):135-143. doi: 10.1097/ICU.0b013e32834ff23e.
49. Smit B.A., Johnstone M.A. Effects of viscoelastic injection into schlemm's canal in primate and human eyes. Potential relevance to viscocanalostomy. *Ophthalmology* 2002; 109(4):786-792.

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