Национальный журнал глаукома
2015, Т. 14, № 2, стр. 45-55

Russian journal of glaucoma
2015, Vol. 14, № 2, pp. 45-55

УДК 617.7-007.681-089:617.741-004.1

Safety and effectiveness of Kumar's Schlemm's canal expander in management of open-angle glaucoma in cataract patients

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Conflicts of Interest and Source of Funding: none declared. No financial support was received by any of the authors for this study.

Abstract

PURPOSE: To evaluate safety and effectiveness of Schlemm's canal expander (SCE) in management of open-angle glaucoma (OAG) in cataract patients.

METHODS: A total of 9 cases (9 eyes) having visually significant cataract and insufficiently controlled by their current ocular hypotensive medication(s) glaucoma were operated upon. There were 5 cases of pseudoexfoliation syndrome, rigid pupils and weakening of Zinn's ligaments resulting in instability of native lens and requiring implantation of a capsule tension ring (CTR) into the capsular bag to stabilize it. A one-stage combined surgery — phacoemulsification with in-the-bag implantation of a foldable acrylic hydrophilic intraocular lens (IOL) and implantation of SCE in Schlemm's canal (SC) was performed in all cases. A 4-5 mm long SCE made from 0.05mm thick medical grade vanadium stainless steel wire was implanted into the SC lumen by ab externo approach. Primary outcome measure was intraocular pressure (IOP) change, secondary — number of glaucoma medications pre- and postoperatively and complications. A paired t-test was used for IOP and medication analysis. 25% decrease in IOP or IOP of 18 mm Hg or less without medication was considered a complete success, with medication — partial success. The need for subsequent filtering surgery was qualified as failure. Success was evaluated on the basis of Kaplan-Meier cumulative probability at each follow-up visit. Results were considered statistically significant with $p<0.05$. Minimum postoperative follow-up was 18 months.

RESULTS: Out of 9 operated cases a total of 7 cases (7 eyes) were included for analysis. 1 patient who died of natural causes 3 months after the surgery and another case with incomplete follow up were excluded from the study. Mean preoperative IOP was 26.1±4.6 mm Hg (range: 19.0-30.9; 95% CI 22.7-29.5) and mean number of preoperative medications was 2.1±0.4 (range: 2–3; 95% CI 1.9-2.4). At each follow-up a decrease in mean IOP was observed, resulting in 11.3+3.0 mmHg (range: 7.1-15.3; CI 9.1-13.5) at 18 months ($p=0.0000015$). This represents a reduction of 56.3±11.6% from the baseline IOP. A reduction in glaucoma medications use was observed at each follow up visit and was 0.9+1.2 (range: 0-3; 95% CI 0.0-1.8) at 18 months ($p=0.016$). Complete and partial success was observed in 4 and 3 cases at the 18-month point, respectively. Microperforation of the trabecular meshwork (TM) in areas other than the exposed part of SC occurred in 1 case. In 5 cases the device could be pushed into SC completely. In 2 cases one end (0.5 to 1.0 mm in length) of the device was left in the exposed part of SC. No specific complications related to the device were noted. A filtration bleb was noticed in 5 cases on day one, 2 cases at 1 week and 1 case at 1 month. At 3 months and afterwards no filtration bleb was noticed in any of the cases. In 1 case laser capsulotomy for secondary cataract was performed to restore vision. Gonioscopically the device was in the lumen of the SC in all cases except the case with intra-operative microperforation, where one end of the device was lying in the anterior chamber (AC) without any contact with intraocular structures.

CONCLUSION: Eighteen months results of the SCE implantation in surgical management of OAG in cataract patients show significant reduction in IOP from the baseline and in hypotensive medication(s) use.

KEYWORDS: Schlemm's canal surgery, Schlemm's canal expander, stainless steel spiral Schlemm's canal expander, glaucoma surgery, open angle glaucoma, mini invasive glaucoma surgery, combined surgery for cataract and glaucoma.

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Поступила в печать: 15.01.2015

Received for publication: January 15, 2015

Оценка эффективности и безопасности применения экспандера шлеммова канала Кумара в лечении открытоугольной глаукомы у больных с сопутствующей катарактой

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Авторы не получали финансирование при проведении исследования и написании статьи.
Конфликт интересов: отсутствует.

Резюме

ЦЕЛЬ. Оценить эффективность и безопасность применения экспандера шлеммова канала (ЭШК) Кумара в лечении открытоугольной глаукомы (ОУГ) у больных с катарактой.

МЕТОДЫ. Прооперировано 9 человек (9 глаз) с катарактой и ОУГ, у которых внутриглазное давление (ВГД) не компенсировалось на максимальной гипотензивной терапии. У 5 больных был диагностирован псевдоэксфолиативный синдром, у этих пациентов имели место узкие зрачки и выраженный факодонез, нуждающийся в имплантации капсульного кольца для стабилизации капсульного мешка. Всем пациентам проведена одномоментная комбинированная хирургия — факоэмульсификация с имплантацией складывающейся гидрофильной интраокулярной линзы (ИОЛ) в капсульный мешок и имплантация ЭШК в просвет шлеммова канала (ШК). ЭШК длиной 4-5 мм изготовлен из проволоки нержавеющей ванадиевой стали медицинского качества толщиной 0,05 мм, имплантирован в просвет ШК ab externo. Критериями оценки являлись динамика ВГД, необходимость применения гипотензивных капель до и после операции и частота осложнений. Для статистического анализа использовали двухвыборочный t-тест. Снижение ВГД более чем на 25% или ВГД равное 18 и меньше без применения гипотензивной терапии считалось полным успехом, с применением гипотензивной терапии — частичным. Необходимость в проведении последующей операции считалась неудачей. Успех оценивали при каждом посещений пациента с использованием кривой выживаемости Каплана – Мэйэра. Результаты считались достоверными при p<0,05. Минимальное послеоперационное наблюдение — 18 месяцев.

РЕЗУЛЬТАТЫ. Из 9 прооперированных больных в анализ были включены 7 пациентов. 1 пациент скончался спустя 3 месяца после операции, в 1 случае послеоперационное наблюдение было прервано, эти пациенты были исключены из анализа. До операции среднее ВГД составляло 26,1±4,6 мм рт.ст. (19,0-30,9; 95% доверительный интервал (ДИ) 22,7-29,5) среднее количество используемых гипотензивных препаратов — 2,1±0,4 (2-3; 95% ДИ 1,9-2,4). Спустя 18 месяцев после операции среднее ВГД снизилось до 11,3+3,0 мм рт.ст. (7,1-15,3; ДИ 9,1-13,5) (p=0,0000015) и среднее количество гипотензивных препаратов сократилось до 0,9+1,2 (0-3; 95% ДИ 0,0-1,8). В процентном отношении снижение ВГД от исходного составляло 56,3±11,6%. Полный и частичный успех был достигнут в 4 и 3 случаях соответственно. Во время операции микроперфорация трабекулы внутри ШК произошла в 1 случае. В 5 случаях полностью удалось имплантировать ЭШК в просвет ШК. В 2 случаях один конец устройства оставлен во вскрытом ШК. Осложнения, связанные с ЭШК и техникой его имплантации, не наблюдали. Фильтрационную подушку различной выраженности наблюдали через 1 день после операции у 5 пациентов, через 1 неделю — у 2-х и через 1 месяц — у 1 пациента. Спустя 3 месяца после операции пациентов с фильтрационной подушкой не было. В 1 случае понадобилось выполнение лазерной капсулотомии по поводу вторичной катарактой. Спустя 18 месяцев после операции устройство находилось в просвете ШК у всех пациентов. У пациента с микроперфорацией один конец устройства находился в углу передней камеры, не контактируя с внутриглазными структурами.

ВЫВОДЫ. Анализ результатов имплантации ЭШК при хирургическом лечении глаукомы у больных с катарактой показывает достоверное снижение ВГД от исходного, что в свою очередь приводит к сокращению используемых гипотензивных препаратов.

КЛЮЧЕВЫЕ СЛОВА: хирургия шлеммова канала, экспандер шлеммова канала, спиральный экспандер шлеммова канала, хирургия глаукомы, открытоугольная глаукома, миниинвазивная хирургия глаукомы, комбинированная хирургия при катаракте и глаукоме.

The association of glaucoma with cataract has become more frequent because of increase in life expectancy and is a common finding in clinical setups. There has been much published in recent years on how best to manage these subjects but no consensus has been reached yet [1-3]. For cataract extraction, phacoemulsification is the golden standard. But what should be the safest and effective glaucoma surgery is still a debatable question. Cataract extraction by phacoemulsification alone can decrease IOP by 1.8–4.5 mmHg, hence phacoemuslification is the most widely performed glaucoma surgery in cases of mild glaucoma and visually significant cataract [4-13]. But evidence has shown that IOP tends to return to baseline levels with time after initial significant reduction. Therefore IOP-lowering effect of primary cataract extraction in OAG is insufficient to achieve adequate IOP control [11-13]. In a meta-analysis, Friedman D.S. and colleagues (2002) reported that good evidence supports the finding that long-term IOP is lowered more by a combined procedure than by cataract extraction alone [1]. Results of studies conducted by Casson R.J. et al (2001) and Rosdahl J.A. et al (2010) are also in favor of combined procedure [14, 15].

High rate of intra- and postoperative complications in conventional filtration surgeries are well documented [16, 17]. Non-penetrating filtration procedures have fewer risks for early postoperative complications than traditional filtering surgery [18-22]. But these surgeries are bleb dependent. To make glaucoma surgery more safe and effective with low potential for adverse effects new minimally invasive and microincisional techniques to address IOP control have been developed [23-32]. These surgeries are bleb independent and are aimed to restore natural aqueous outflow through SC and the collector channel.

An original stainless steel spiral SCE has been proposed [33]. A pilot study was undertaken to evaluate its safety and effectiveness during combined surgery for coexisting cataract and glaucoma.

Purpose. To evaluate safety and effectiveness of SCE in management of OAG in cataract patients.

Materials and Methods

Within a period from October, 2012 till April, 2013 a total of 9 cases (9 eyes) having visually significant cataract and insufficiently controlled by their current ocular hypotensive medication(s) glaucoma were operated upon. A one stage two site surgery — phacoemulsification with implantation of a foldable acrylic hydrophilic IOL and implantation of SCE in SC was performed in all cases.

Design of the study:

This is an interventional case series. 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.

Inclusion criteria: Patients having concomitant visually significant cataract and OAG.

Exclusion criteria: Conditions interfering with reliable applanation tonometry by Maklakov's method, peripheral anterior synechia or insufficient gonioscopic visualization of the trabeculum and minimum follow-up period less than 18 months. Cases having macro perforation of TM in exposed SC area during surgery were excluded from the study, whereas cases having micro perforation of TM in areas other than exposed SC were included.

Observation procedure: A complete ophthalmological examination was performed before surgery including best corrected visual acuity (BCVA) measurement converted to the logarithm of the minimum angle of resolution (logMAR), applanation tonometry measurement by Maklakov's method, slit lamp biomicroscopy of the anterior segment, 78 D ophthalmoscopy, perimetry and angle grading by gonioscopy.

The device: The design and making of the SCE has been described in detail elsewhere [33]. Briefly, the device is made from 0.05mm thick medical grade soft vanadium stainless steel wire by winding it on a 0.2 mm thick stainless steel microprobe, having curvature as of SC. The device is 4-5 mm long, outer diameter is 0.3 mm, inner diameter — 0.2 mm. The wire loops of end parts are closely located, in the central part they are apart from each other by 0.5 to 1mm *(figure 1 A-C)*.

Surgical technique: After creating a 8 mm fornix based conjunctival flap, 1/2 thickness superficial (5×5 mm) and deep (3×3 mm) scleral flaps up to ciliary body were dissected. The deep scleral flap was dissected till SC was reached. Without opening the canal, the flaps were replaced back and a standard phacoemulsification was performed through a clear corneal incision (2.75 mm) away from the glaucoma surgery site and a foldable IOL was implanted in the capsular bag. At the end AC was irrigated with balanced salt solution and all of the viscoelastic was removed and wounds were sealed by hydration. In absence of red reflex anterior capsule was dyed using trypan blue dye. Capsulorhexis in hypermature swollen cataracts was performed using the following technique: first a small rhexis was created followed by aspiration of swollen masses using Simcoe's cannula, after decreasing pressure in capsular bag, capsulorhexis was extended and phacoemulsification was performed. In cases with rigid pupils and absence of red reflex, anterior capsule was dyed using our modified technique and pupils were dilated either with the help of four iris retractors inserted through parasynthesis or by making several sphinctrotomies at the pupil margin followed by its stretching with two IOL manipulators [34]. Unstable capsular bags were stabilized by insertion of a CTR into bag's fornix prior to IOL implantation. The CTR were either inserted using a special injector or with the help of forceps.

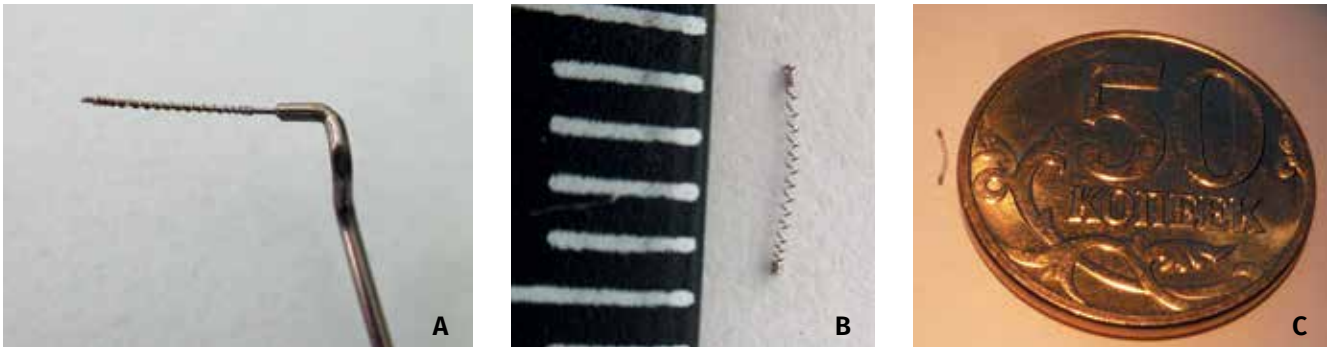

Figure 1. The SCE. **A:** Device is mounted on 0.2 mm thick microprobe having curvature as of SC. **B:** Actual size of SCE. **C:** Device size in comparison to 50 kopeek coin.

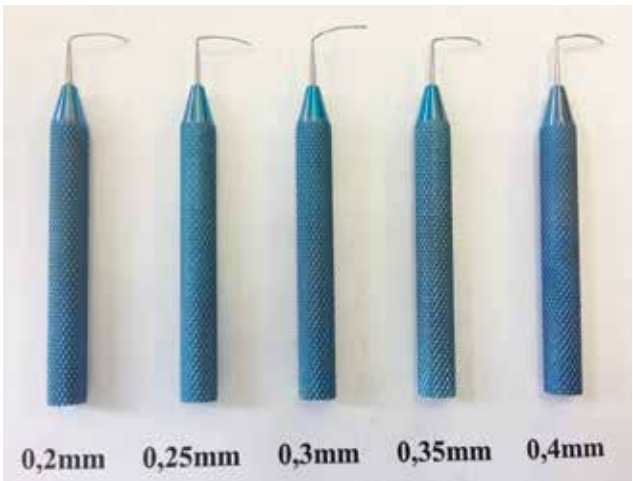

Figure 2. Microprobes of varying diameters from 0.2 mm to 0.4 mm for dilation of canal of Schlemm.

After completion of cataract extraction part, glaucoma operation site was revisited. The SC was exposed without creating a window in Descemete's membrane. Further 5-6 mm of SC (temporal side in left eyes and nasal side in right eyes) was dilated with cohesive viscoelastic device (1.2 or 1.4% hyaluronic acid, whichever was available in operation theatre) and microprobes of varying diameters from 0.2 mm to 0.4 mm *(fig. 2)*. The SCE mounted on 0.2 mm thick microprobe was inserted into dilated SC and held there with second instrument (Hoskin corneal forceps — working part with groove of 0.2 mm) followed by careful removal of microprobe. The superficial and deep scleral flaps and conjunctival flap were sutured back water tightly. IOP was evaluated at the end of surgery and if needed AC was refilled with balanced salt solution. In case of leakage from the main incision instead of increasing pressure in the globe to make the incisions watertight an interrupted 10-0 suture was applied, which was removed next day or whenever assessed necessary. Surgical steps of device insertion are illustrated in *figure 3 A-H*.

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 — 250 mg, 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, 12 and 18 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 measured by Maklakov's method was further converted to P_0 using special conversion table [35]. The secondary outcome measures were visual acuity, number of glaucoma medications pre- and postoperatively and complications. A paired t-test was used for IOP and medication analysis. Decrease in IOP >25% or IOP 18 mmHg or less without medication was considered as a complete success, with medication — partial success. Failure was considered if the patient needed subsequent filtering surgery. Success was evaluated on the basis of Kaplan-Meier cumulative probability at each follow-up visit starting after 1 week after surgery. Statistical analysis was performed using Microsoft office application — Excel 2007 at each follow-up visit. A maximum two-tailed p value of <.05 indicated statistical significance.

Results

Baseline data

Out of 9 cases one case died by natural causes 3 months after surgery hence was excluded from the study. Another case had incomplete follow up and was also not included in the analysis. A total of 7 cases (7 eyes) were included for analysis. Among them there were 4 male and 3 female patients with an average age of 70.0+7.8 yrs. (range: 65-82 yrs.). There were 2 cases of secondary open-angle glaucoma. Out of these, 1 case was of postthrombotic secondary glaucoma and another

Figure 3. Surgical steps of glaucoma surgery. **A:** SC exposure without dissecting a window in Descemet's membrane. **B:** Canalography to identify patent collector channels. **C:** Mechanical dilation of SC lumen following viscodilation of SC ostium. **D:** The device mounted on microprobe before insertion. **E:** A second instrument — Hoskin corneal forceps is used to free the device from the microprobe. **F:** The device is inserted into SC lumen. **G:** Water-tight closure of deep scleral flap. **H:** Closure of superficial scleral and conjunctival flaps.

of postuveitic glaucoma having remission for last 1 year. Pseudoexfoliation syndrome was prevalent in 5 cases leading to marked phacodonesis in 4 cases. There was 1 case of high myopia with intumescent dense cataract. Demographic details of the cases are listed in *table 1*.

IOP results

Mean preoperative IOP was 26.1±4.6 mm Hg (range: 19.0–30.9; 95% CI 22.7-29.5). At each follow-up a decrease in mean IOP was observed, resulting in 10.8±3.6 mm Hg (range: 8.3–18.1; 95% CI 8.2-13.5) at 6 months (p=0.0000012), 11±2.7 mm Hg (range: 7.1-15.3; 95% CI 9.0-13.0) at 12 months (p=0.0000009) and 11.3+3.0 mm Hg (range: 7.1-15.3; CI 9.1-13.5) at 18 months (p=0.0000015). This represents a reduction in IOP from baseline of 58.1±12% at 6 months, 56.1±16% at 12 months and 56.3±11.6% at 18 months. IOP changes after combined surgery in each case is represented in *figure 4*, whereas mean IOP changes over time are reflected in *figure 5*, which shows stable decrease in IOP after combined surgery with implantation of SCE.

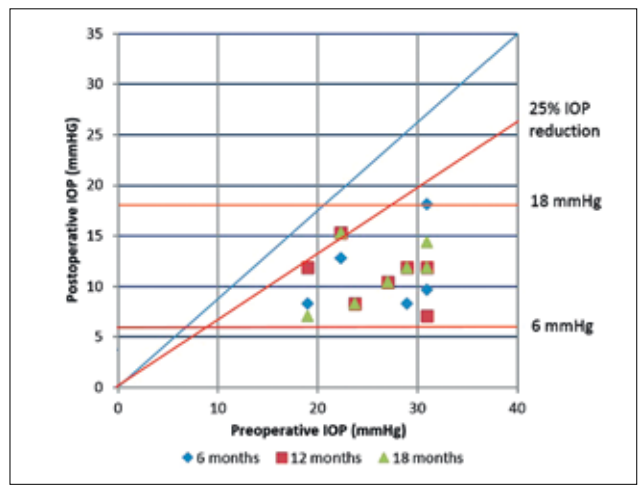

Figure 4. Scatter plot of preoperative IOP compared to postoperative IOP at 6, 12 and 18 months after surgery. Each symbol indicates a patient. Points below the oblique line define a lower IOP than a baseline.

Table 1

Patients' characteristics at baseline

Case №	Gender	Age (yrs.)	Eye	Diagnosis	Complicating factors	Previous ocular surgery
1	F	77	OD	POAG2a, IMC	–	none
2	F	72	OD	POAG2b, IMC	PEX, Phacodonesis	none
3	M	65	OS	Secondary post thrombotic OAG, HMC	PEX, high myopia, intumescent cataract	none
4	F	72	OD	POAG 3b, IMC	PEX, phacodonesis	none
5	M	60	OS	POAG 3b, IMC	PEX, phacodonesis	none
6	M	64	OS	Secondary postuveitic OAG 3c, IMC	PEX, phacodonesis	none
7	M	82	OD	POAG 3c, IMC	–	none

M=male, F=female, OD=right eye, OS=left eye, POAG=primary open-angle glaucoma, IMC=immature cataract, HMC=hypermature cataract, PEX=pseudoexfoliation

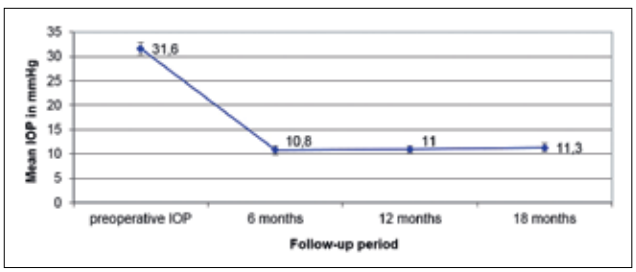

Figure 5. Mean IOP at follow-up visits.

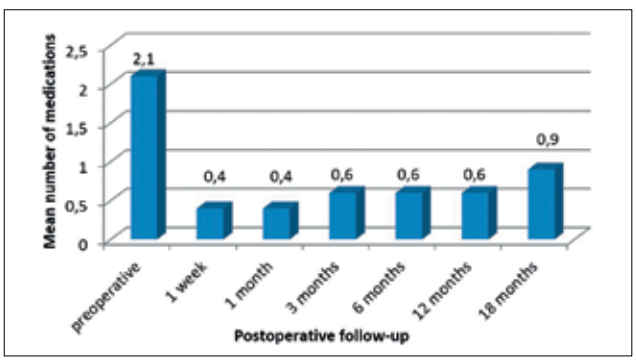

Figure 6. Mean number of hypotensive medications used at each follow up visit.

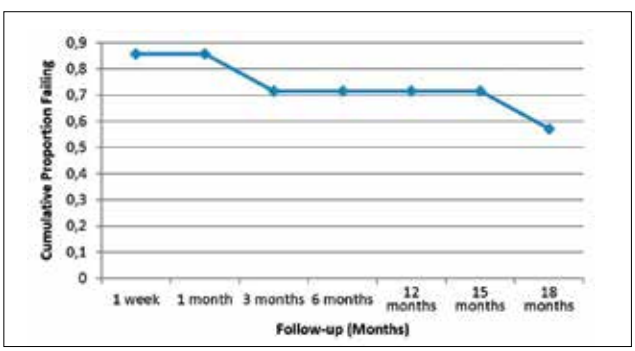

Figure 7. Kaplan-Meier survival plot for cumulative probability of complete success. Complete success was defined as an IOP 18 mmHg or less without medication or decrease in IOP >25% from the baseline.

Glaucoma medication changes

Mean number of preoperative medications was 2.1±0.4 (range: 2–3; 95% CI 1.9-2.4). After surgery mean number of glaucoma medications reduced at each follow up visit and was 0.6±1.1 (range: 0-3; 95% CI – 0.3-1.4) at 6 and 12 months (p=0.005) and 0.9+1.2 (range: 0-3; 95% CI 0.0-1.8) at 18 months (p=0.016) *(fig. 6)*.

Visual acuity results

Mean BCVA before surgery was 2±1 logMar (range: 0.7–3.0). Except 2 cases (case N 3 and 7) BCVA improved in all other cases. The reasons for poor visual outcome were dystrophic changes in retina. Mean logMar at 6, 12 and 18 months was 1.1±1.3, 1.1±1 and 0.9±0.8 respectively.

Success rate

Complete and partial success was observed in 5 and 2 cases at 6 and 12 months and in 4 and 3 cases at 18 months, respectively. Kaplan-Meier survival plot for cumulative probability of complete success is shown in *figure 7*.

Intra-operative observations

During phacoemulsification the following was observed — rigid pupils — 5 cases, weakening of Zinn's ligaments resulting in instability of native lens — 5 cases. In later cases before IOL implantation a CTR was implanted in the fornix of capsule sac to stabilize it. In all cases in the bag implantation of IOL was done. Though it was tried to complete the dissection of flaps without using any diathermy, minor diathermy was required in 2 cases. Cautery at limbal area was avoided in all cases to preserve collectors. Microperforation of TM in areas other than exposed part of SC occurred in 1 case. In this case excess filtration of aqueous humor after SCE insertion and shallowing of AC was noticed. Next day the AC in this

case was stable, of equal depth as compared to other eye. In 5 cases the device was completely inserted into SC. In 2 cases the device was pushed into SC till it meets some resistance leaving one end (0.5 to 1.0 mm in length) in the exposed part of SC. Some blood oozes out from SC after its opening in all cases, showing patency of collector channels and their openings in SC.

Incidence of post operative complications

Early post operative period. All cases completed 18 months follow-up. Specific complications related to device were none. Though water tight suturing of scleral flaps was attempted in all cases, there were cases with some blebs on follow-up visits — 5 cases on day one, 2 cases at 1 week and 1 case at 1 month. At 3 months and afterwards no filtration bleb was noticed in any of the cases. In 1 case while performing goniocopy during second visit postoperatively, due to small eye fissure undue pressure was put on eye globe while inserting goniolens, which led to mechanical disruption of TM and dislocation of device body into AC not touching iris or corneal endothelium. The ends of the device were embedded in SC. In absence of inflammation at SCE site the case was kept under observation. At 18 months follow up there has not been any change in device condition. Patient required instillation of 2 glaucoma medications to control IOP starting after 3 months of follow up.

Late post operative period. In 1 case there was decrease in visual acuity due to secondary cataract and patient had undergone laser capsulotomy with restoration of vision. The case having secondary postuveitic glaucoma had relapse of iridocyclitis after 6 months after surgery. The inflammation was controlled with medications. Though gonioscopically the device site in this case was free from any inflammation the case had high IOP, which required instillation of glaucoma medication. There was no anterior synechiae noticed. Gonioscopically in all cases except the case with intra-operative microperforation the device was in the lumen of the SC free from any inflammation *(fig. 8)*. In microperforation case half of the device was lying in the AC angle without any contact with intraocular structures.

Discussion

Lately, a significant shift towards the performance of combined surgeries is seen among eye surgeons; the reason being that combined surgery is effective both in terms of IOP lowering and visual rehabilitation [14, 15]. Combined approach aims at reducing the surgical trauma resulting from two surgeries. Other advantages of combined procedures are faster rehabilitation and reduced cost associated with surgery. Performing the procedures together reduced the risk of postoperative IOP spikes as well [36].

Till last the commonest combined procedure performed was phacoemulsification with implantation of a foldable IOL and trabeculectomy using different approaches: one site, two sites, using antimetabolites and different implantable materials to enhance its IOP lowering

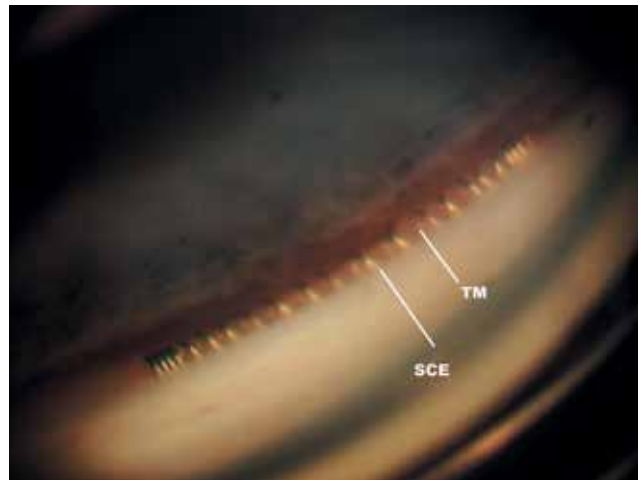

Figure 8. SCE in SC. The insertion site is free from inflammation. The device is in the lumen of SC. There are no changes in TM noticed.

effect [36]. Both penetrating as well as non-penetrating glaucoma surgeries are not free from future morbidities. These may be loss of IOP control and procedure failure. The later may be as high as 84% at 3 years [37]. Bleb related complications can occur years after [38]. Blebitis and bleb related endophthalmitis can occur in as many cases as 1.5% and 1.1% or higher [38-40].

Trabecular bypass surgery. Presently, there is an increased interest in so termed minimally invasive glaucoma surgery (MIGS) [30]. This interest is motivated by evidence that the elevated IOP in glaucoma is due to an increased resistance to outflow, and that the majority of resistance is present in the juxtacanalicular connective tissue of the TM including the inner wall of SC [41, 42]. Theoretically, a moderate dilation of SC and the collector canal in conjunction with a trabecular bypass would reduce the IOP level significantly. The iStent, iStent inject, trabectome and Hydrus Microstent are some of the procedures, which enhance trabecular outflow [43-49].

Among all devices Glaucos iStent is the most studied one. In a prospective case series of ten eyes (eight patients), Vandewalle E. et al (2009) studied results of iStent implanation in reduction of IOP [43]. Out of these six eyes underwent combined surgery: cataract surgery followed by iStent implantation. Mean IOP dropped from 19.6 mmHg preoperatively to 15.8 mmHg after one year ($p=0.03$). There was a significant reduction in number of hypotensive medications between baseline and 12 months postoperatively from 2.7 to 1.7 medications. Authors concluded that trabecular bypass results in significant mid-term reduction of IOP as well as the number of medications. If target IOP is lower, then one stent is not enough to achieve desired reduction of IOP. Belovay GW, et al (2012) studied 53 eyes (47 patients) with OAG who had implantation of 2 or 3 micro-bypass stents with concurrent cataract surgery and follow-up through 1 year [44]. Overall mean 1-year postoperative IOP was 14.3 mm Hg, which was significantly lower than preoperative IOP ($P<.001$).

The target IOP was achieved in a significantly higher proportion of eyes at 1 year versus preoperatively (77% versus 43%; P<.001). Authors concluded that using multiple micro-bypass stents with concurrent cataract surgery led to a mean postoperative IOP of less than 15 mm Hg and allowed patients to achieve target pressure control with significantly fewer medications through 1 year. Potential complications of the iStent may include chronic inflammation, clogging of the stent's lumen, migration of the stent into other parts of the eye, and the poor function if the device is not placed directly into SC [27, 43, 44]. Learning curve is steep.

Hydrus (Ivantis Inc., Irvine, CA, USA) is a new SC scaffold made from nitinol intended to be placed through the TM into SC. Window features of the device face the TM, and the structure of the device opens and dilates the TM and SC. The posterior side is open and provides an unobstructed path to the collector channels. The implant is pre-loaded onto a delivery system. After corneal incision and positioning the patient's head for use of direct gonioprism lens, the TM is accessed and the device is delivered into SC. Once in place, the microstent provides a scaffold for SC thereby allowing access to multiple collector channels that drain the aqueous humour from TM [45-47]. The implantation of the device may be used as a stand-alone procedure or in conjunction with cataract surgery [46, 47]. In cases, which had undergone combined phacoemulsification cataract surgery with Hydrus Microstent implantation, 12-months mean IOP was reduced by 33% and medications were reduced by 85% compared to baseline levels [47]. The reported complications of this device are blood reflux and iritis [30, 47]. Long term adverse effect was peripheral anterior synechiae observed in approximately 10% cases. Advantages of this device include short duration of device implantation, a low-risk safety profile and protection of the conjunctiva which enables later trabeculectomy if required.

Ab interno trabeculotomy. There are various procedures proposed to reduce the resistance at the inner wall of SC by removing a part or whole of it. The purpose is to lower the IOP by enhancing trabecular outflow without external filtration. The trabectome (Neomedix Inc., Tustin, CA) is a device designed to excise and cauterize the inner wall of the trabeculum ab interno. This procedure also can be easily combined with phacoemulsification. Combined procedure can give an IOP decrease of around 5 mm Hg [23, 25, 48]. Early IOP spikes (5.4%), failed procedure (2.7%), blood reflux (100%), peripheral anterior synechiae (24.3%), goniosynechiae (focal iris adhesion to spur or posterior meshwork) (13.6%), transient Descemet's membrane heme (2.7%) and transient Descemet's membrane scroll (2.7%) are some of the reported complications of this procedure, though the later complication is considered as physiological [49].

Various instruments, modifications of existing instruments have been proposed to perform ab-interno trabeculotomy [29, 31, 32, 50, 51]. Not every proposed instrument is suitable for performing ab-interno trabeculotomy procedure. Seibold L.K. et al (2012) conducted a comparative study to evaluate the effects of different devices on human TM [52]. The TM from human cadaveric corneal rim tissue was incised using 3 instruments: (1) novel dual-blade device, proposed by the author; (2) microvitreoretinal (MVR) blade; and (3) Trabectome. Tissue samples underwent histologic processing and comparative analyses. Subsequently, human eye perfusion studies were also performed to evaluate IOP-lowering effects of each device. Authors came to conclusion that the MVR blade exhibited minimal removal of TM and obvious injury to the adjacent sclera. The Trabectome removed a large portion of the central TM, but leaflets of residual tissue remained and thermal injury was noted in all samples. The dual-blade device achieved a more complete removal of TM without injury to surrounding tissues. All devices resulted in statistically significant lowering of IOP during perfusion model studies. MVR blade treatment across 170.0±14.1 degrees of TM resulted in a decrease of IOP from 18.5±1.9 mm Hg to 12.8±2.2 mm Hg (P < .01). Trabectome treatment across 117.5±12.6 degrees resulted in a decrease of IOP from 18.8±1.7 mm Hg to 11.3±1.0 mm Hg (P < .01). Dual-blade device treatment across 157.5±26.3 degrees resulted in a decrease of IOP from 18.3±3.0 mm Hg to 11.0±2.2 mm Hg (P < .01).

All mentioned devices are inserted into AC through a small corneal incision and surgery is performed under gonioscopic control. But these 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 these surgeries more challenging. Sometimes it is difficult visualizing the AC angle through the gonioprism, especially if blood refluxes into TM.

Ab-externo Schlemm's canal surgery. Ab-externo trabeculotomy was first described by Redmond S. [53]. A redial incision was made to expose and enter SC from its outer aspect and a fine nylon thread was pushed through both sides into SC. Two identical vertical incisions were made at 2 and 10 o'clock and thread was drawn out. After fixing one end with a clamp the upper end of the nylon was then firmly pulled and the suture appeared, like a bowstring, in the AC, having burst through the antero-medial wall of the canal of Schlemm. Krasnov M.M. (1964, 1968) proposed a new procedure in management of open-angle glaucoma — externalization of the SC (sinusotomy) [54, 55]. Sinusotomy entails the opening of SC from outside, its principle being the opposite of goniotomy. It is designed to restore the normal outflow when this is obstructed somewhere between SC and the anterior ciliary veins. The technique included removal of external wall of the SC from 2 to 10 o'clock i.e. about one-fourth to one-third of its circumference. The results after 1 to 5 years demonstrated stable normalization of the IOP in about 83 per cent of cases, the tonographic coefficients after successful surgery on SC being closer to physiological (normal) limits than with conventional fistulizing operations.

Stegmann R. (1999) proposed to enhance outflow of aqueous humour through natural channels. He performed a deep sclerectomy and dilated the SC

lumen with cohesive viscoelastic — 1% hyaluronic acid — viscocanalostomy [20]. Viscocanalostomy have fewer risks for early postoperative complications than traditional filtering surgery, but this procedure is bleb dependent [20-22]. Canaloplasty was developed from viscocanalostomy. It is an ab externo non-penetrating procedure that includes deep sclerectomy, viscodilation of the SC 360 degree with the placement of an intracanalicular tension suture. The procedure is technically difficult and placement of suture in SC is likely to disturb intracanalicular structures [9, 26, 56-58]. The most difficult steps in canaloplasty surgery are dissection of Descemete's membrane, circumferential viscodilation of SC, placement of 10-0 suture, proper tensioning of SC and watertight suturing of flaps. Combining canaloplasty with phacoemulsification is a more challenging surgery.

We report 18 months functional results after implantation of a novel SCE in a series of 7 eyes suffering from cataract and glaucoma. Our results were compared with results of phacoemulsification with canaloplasty. As in canaloplasty procedure the approach to SC in our method is also ab externo. Segmental viscodilation of SC is a standard part of our technique to facilitate insertion of the device into SC. In comparison to canaloplasty in the proposed method no Descemete's window is created, SC is not deroofed, it is only exposed to insert the device through the ostia. Hence intraoperative complications are maximally minimized.

In our study at 6, 12 and 18 months after surgery IOP decreased from baseline to 10.8±3.6 mm Hg, 11.0±2.7 mm Hg and 11.3±3.0 mmHg accounting for reduction of IOP by more than 55%. This demonstrates that the device may be helpful in advanced cases where maximum reduction in IOP is required in order to preserve visual functions. Additional to the IOP lowering effect, a significant decrease in the number of ocular medications was observed as well. The difference was highly significant at each follow up visit ($p<0.01$). At 18 months the use of medications decreased from 2.4 to 0.9.

Intra-operatively, except one case, where micro-perforation of TM was suspected based on increased fluid flow through SC after insertion of the device, we did not observe any major peri- or postoperative complications of this technique, whereas reported complications of canaloplasty include inability to cannulate SC, Descemete's membrane detachment and improper microcatheter passage [26, 56, 58]. In rare settings, the microcatheter could exit SC and violate surrounding structures. It is not always possible to canalize the SC 3600. Shingleton B. et al (2008) published a prospective uncontrolled study to examine the results of canaloplasty combined with phacoemulsification and reported that complete canalization of SC with the probe was successful in 81% of the procedures and tension sutures could be placed in 74% [60]. Intraoperative trans-TM suture extrusion has also been reported [56, 60]. In our series the device was inserted into SC completely in all cases and it remained there in all, but 1 case.

As per published reports postoperative hyphema or microhyphema following canaloplasty occurs with an incidence of 3.2 to 21% [57, 60]. In our study we did not observe any case with hyphema. Increase in IOP after canaloplasty procedure in immediate postoperative period has been reported from 1.6 to 18.2% of eyes, which was thought by some authors to be secondary to retained viscoelastic in the AC [26, 56, 57, 60]. In our series there was not a single case with high IOP spike in immediate postoperative period.

Persistent elevation in IOP requiring laser goniopuncture after canaloplasty was necessary in 8.3-18.8% in some studies; however, in other reports no eyes required laser goniopuncture [26, 56, 60]. In our case series laser trabeculopuncture was not required in any of the cases. Other postoperative complications of canaloplasty reported in the literature include suture 'cheese-wiring' through the TM (up to 9.1%), wound hemorrhage (up to 2.5%) and hypotony (up to 0.6%) [26, 56, 58]. In our series we did not encounter any of the mentioned complications. Bleb formation after canaloplasty has been reported upto 12% of patients [56]. In the presented case series, some degree of bleb formation was observed in 5 cases the next day after surgery, the number reduced to 2 cases at 1 week and 1 case at 1 month. No bleb was noticed thereafter. The reason of bleb formation could have been the technical fault while suturing the flaps water tightly. Another explanation of formation of bleb after our technique may be that during dissection of conjunctival and scleral flaps the channels taking out aqueous fluid from AC are severed and fluid directly drains under conjunctiva, resulting in formation of filtration blebs.

As in our previous study, certain advantages of this device were noticed during this study as well [33]. First of all, it was easy to implant it in the SC lumen. The key to successful implantation of SCE lies in well dilation of SC opening and its lumen with cohesive viscoelastic and microprobes of varying diameters. Bimanual technique of implantation, use of fenestrated Hoskin's forceps help in least traumatic implantation of the device. Another advantage is that the implantation technique does not require mastering of other unfamiliar to surgeon techniques and maneuvers. Surgery can be performed by using usual settings of the operating microscope. Surgeon familiar to non-penetrating technique of glaucoma surgery can easily perform this procedure. Intraoperative complications with this technique are few. Once inserted into SC, the device stretched TM and dilates SC and keeps it dilated. The increased fluid outflow by insertion of SCE may be hypothized as follows: at the insertion site aqueous humor is filtered through stretched TM into dilated SC and further flows through either the lumen of device or SC lumen into collector channels and into the episcleral venous system. Other advantage of this technique may be reduced trauma to SC, as only a sector of the canal is manipulated; other portion is left untouched saving it's all inner structures (Johnstone's transparent tubules), whose function is not yet fully studied and understood in fluid outflow mechanism [57].

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.

Conclusion

Eighteen months results of SCE implantation in surgical management of OAG in cataract patients show significant reduction in IOP from the baseline and in hypotensive medication(s) use.

References

1. Friedman D.S., Jampel H.D., Lubomski L.H., Kempen J.H., Quigley H., Congdon N., Levkovitch-Verbin H., Robinson K.A., Bass E.B. Surgical strategies for coexisting glaucoma and cataract: an evidence-based update. *Ophthalmology* 2002; 109(10): 1902-1913. doi.org/10.1016/S0161-6420(02)01267-8
2. Vass C., Menapace R. Surgical strategies in patients with combined cataract and glaucoma. *Curr Opin Ophthalmol* 2004; 15(1):61-66. doi.org/10.1097/00055735-200402000-00012
3. Verges C., Cazal J., Lavin C. Surgical strategies in patients with cataract and glaucoma. *Curr Opin Ophthalmol* 2005; 16(1): 44-52. doi.org/10.1097/00055735-200502000-00008
4. Matsumura M., Mizogouchi, T., Kuroda S., Terauchi H., Nagata M. Intraocular pressure decrease after phacoemulsification-aspiration and intraocular lens implantation in primary open-angle glaucoma eyes. *Nippon Ganka Gakkai Zaashi* 1996; 100:885-889.
5. Kim D.D., Doyle J.W., Smith M.F. Intraocular pressure reduction following phacoemulsification cataract extraction with posterior chamber lens implantation in glaucoma patients. *Ophthalmic Surg Lasers* 1999; 30:37-40.
6. Mathalone N., Hyams M., Neiman S., Buckman G., Hod Y., Geyer O. Long-term intraocular pressure control after clear cornea phacoemulsification in glaucoma patients. *J Cataract Refract Surg* 2005; 31:479-483. doi.org/10.1016/j.jcrs.2004.06.046.
7. Shingleton B.J., Pasternack J.J., Hung J.W., O'Donoghue M.W. Three and five year changes in intraocular pressures after clear corneal phacoemulsification inopen angle glaucoma patients, glaucoma suspects, and normal patients. *J Glaucoma* 2006; 15(6):494-498. doi.org/10.1097/01.ijg.0000212294.31411.92
8. Poley B.J., Lindstrom R.L., Samuelson T.W. Long-term effects of phacoemulsification with intraocular lens implantation in normotensive and ocular hypertensive eyes. *J Cataract Refract Surg* 2008; 34:735-742. doi.org/10.1016/j.jcrs.2007.12.045
9. Shingleton B.J., Laul A., Nagao K., Wolff B., O'Donoghue M., Eagan E., Flattem N., Desai-Bartoli S. Effect of phacoemulsification on intraocular pressure in eyes with pseudoexfoliation: single-surgeon series. *J Cataract Refract Surg* 2008;34(11):1834-1841. doi.org/10.1016/j.jcrs.2008.07.025
10. Shrivastava A., Singh K. The effect of cataract extraction on intraocular pressure. *Curr Opin Ophthalmol* 2010; 21(2):118-122. doi.org/10.1097/icu.0b013e3283360ac3
11. Mansberger S.L., Gordon M.O., Jampel H., Bhorade A., Brandt J.D., Wilson B., Kass M.A. Reduction in intraocular pressure after cataract extraction: the Ocular Hypertension Treatment Study. *Ophthalmology* 2012; 119:1826-1831. doi.org/10.1016/j.ophtha.2012.02.050
12. Choi D.Y., Suramethakul P., Lindstrom R.L., Singh K. Glaucoma surgery with or without cataract surgery, revolution or evolution. *J Cataract Refract Surg* 2012; 38:1121-1122. doi.org/10.1016/j.jcrs.2012.05.005
13. Augustinus C.J., Zeyen T. The effect of phacoemulsification and combined phaco/glaucoma procedures on the intraocular pressure in open angle glaucoma. A review of literature. *Bull Soc Belge ophthalmol* 2012; 320:51-66.
14. Casson R.J., Salmon J.F. Combined surgery in the treatment of patients with cataract and primary open-angle glaucoma. *J Cataract Refract Surg* 2001; 27:1854-1863. doi.org/10.1016/s0886-3350(01)01127-0
15. Rosdahl J.A., Chen T.C. Combined cataract and glaucoma surgeries: traditional and new combinations. *Int Ophthalmol Clin* 2010; 50:95-106. doi.org/10.1097/iio.0b013e3181c5563a
16. Poulsen E.J., Allingham R.R. Characteristics and risk factors of infections after glaucoma filtering surgery. *J Glaucoma* 2000; 9:438-443. doi.org/10.1097/00061198-200012000-00004
17. DeBry P.W., Perkins T.W., Heatley G., Kaufman P., Brumback L.C. Incidence of late onset bleb-related complications following trabeculectomy with mitomycin. *Arch Ophthalmol* 2002; 120:297-300. doi.org/10.1001/archopht.120.3.297
18. Федоров С.Н., Козлов В.И., Тимошкина Н.Т. и др. Непроникающая глубокая склерэктомия при открытоугольной глаукоме. *Офтальмохирургия* 1989; 3-4:52-55. [Fyodorov S.N., Kozlov V.I., Timoshkina N.T. et al. Non penetrating deep sclerectomy in open angle glaucoma. *Ophthalmosurgery* 1989; 3-4:52-55. (In Russ.)].
19. Николашин С.И., Мачехин В.А. Непроникающая глубокая склерэктомия с дренированием шлеммова канала в лечении первичной открытоугольной глаукомы. *Офтальмохирургия* 2002; 1:17-20. [Nikolashin S.I., Machekhin V.A. Non-penetrating deep sclerectomy with drainage of Schlemm's canal in treatment of primary open angle glaucoma. *Ophthalmosurgery* 2002; 1:17-20. (In Russ.)].
20. Stegmann R., Pienaar A., Miller D. Viscocanalostomy for open-angle glaucoma in black African patients. *J Cataract Refract Surg* 1999; 25:316-322. doi.org/10.1016/s0886-3350(99)80078-9
21. Carassa R.G., Bettin P., Fiori M., Brancato R. Viscocanalostomy versus trabeculectomy in white adults affected by open-angle glaucoma. A 2-year randomized, controlled trial. *Ophthalmology* 2003; 110:882-887. doi.org/10.1016/s0161-6420(03)00081-2
22. Kobayashi H., Kobayashi K., Okinami S. A comparison of the intraocular pressure-lowering effect and safety of viscocanalostomy and trabeculectomy with mitomycin C in bilateral open-angle glaucoma. *Graefes Arch Clin Exp Ophthalmol* 2003; 241:359-366. doi.org/10.1007/s00417-003-0652-6
23. Ferrari E., Bandello F., Roman-Pognuz D., Menchini F. Combined clear corneal phacoemulsification and ab interno trabeculectomy: three-year case series. *J Cataract Refract Surg* 2005;31(9): 1783-1788. doi.org/10.1016/j.jcrs.2004.10.050
24. Lüke C., Dietlein T.S., Lüke M., Konen W., Krieglstein G.K. Phacotrabeculotomy combined with deep sclerectomy, a new technique in combined cataract and glaucoma surgery: complication profile. *Acta Ophthalmol Scand* 2007; 85(2):143-148. doi.org/10.1111/j.1600-0420.2006.00785.x
25. 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.org/10.1016/j.jcrs.2008.03.032
26. Lewis R.A., von Wolff K., Tetz M., Koerber N., Kearney J.R., Shingleton B.J., Samuelson T.W. Canaloplasty: circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults: two-year interim clinical study results. *J Cataract Refract Surg* 2009; 35(5):814-824. doi.org/10.1016/j.jcrs.2009.01.010
27. Craven E.R., Katz L.J., Wells J.M., Giamporcaro J.E. iStent Study Group. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: two-year follow-up. *J Cataract Refract Surg* 2012; 38(8):1339-1345. doi.org/10.1016/j.jcrs.2012.03.025
28. Tetz M., Koerber N., Shingleton B.J., von Wolff K., Bull H., Samuelson T.W., Lewis R.A. Phacoemulsification and intraocular lens implantation before, during, or after canaloplasty in eyes with open-angle glaucoma. *J Glaucoma* 2015; 24(3):187-194. doi.org/10.1097/ijg.0b013e318285ff13
29. Введенский А.С., Юсеф С.Н., Шарнина Т.В., Воробьева М.В. Гипотензивная эффективность комбинированного патогенетически ориентированного хирургического лечения катаракты и первичной открытоугольной глаукомы. *Вестник офтальмол* 2013; 129(6):19-23. [Vvedenskiĭ A.S., Iusef S.N., Sharnina T.V., Vorob'eva M.V. Hypotensive efficacy of combined pathogenically oriented surgical treatment of cataract and primary open-angle glaucoma. *Vestn Oftalmol* 2013; 129(6):19-23 (In Russ.)].

30. MIGS: advances in glaucoma surgery/ edited by Kahook M.Y.; associate editors: Sarwat S., Leonard K. Seibold. USA. SLACK Incorporated 2014. 122 p.
31. 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.)].
32. Иванов Д.И. Трабекулотом ирригационный. Патент РФ на полезную модель № 109662. Опубликовано 27.10. 2911. Бюлл. 30. [Ivanov D.I. Irrigating trabeculotome. Patent of Russian Federation № 109662. Published on 27.10.2011. Bull. 30 (In Russ)].
33. 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]
34. Кумар Винод, Фролов М.А., Маковецкая И.Е., Божок Е.В. Способ окрашивания передней капсулы при узком зрачке. *Офтальмология* 2012; 9(4):39-42. [Kumar V., Frolov M.A., Makovetskaya I.E. Bozhok E.V. Method of capsule dyeing in small pupil. *Oftal'mologija* 2012; 9(4):39-42. (In Russ.)]
35. Краснов М.М. Микрохирургия глауком. М: 1980. 235-236. [Krasnov M.M. Mikrokhirurgiya glaukom [Microsurgery of glaucoma]. Moscow, 1980:235-236].
36. McCartney D.L., Memmen J.E., Stark W.J. Quigley H.A., Maumenee A.E., Gottsch J.D., Bernitsky D.A., Wong S.K. The efficacy and safety of combined trabeculectomy, cataract extraction, and intraocular lens implantation. *Ophthalmology* 1988; 95(6):754-763. doi.org/10.1016/s0161-6420(88)33112-x
37. Nakano Y., Araie M., Shirato S. Effect of postoperative subconjunctival 5-fluorouracil injections on the surgical outcome of trabeculectomy in the Japanese. *Graefes Arch Clin Exp Ophthalmol* 1989; 227(6):569-574. doi.org/10.1007/bf02169454
38. Mac I., Soltau J.B. Glaucoma-filtering bleb infections. *Curr Opin Ophthalmol* 2003; 14(2):91-94. Glaucoma-filtering bleb infections. doi.org/10.1097/00055735-200304000-00007
39. Zahid S., Musch D.C., Niziol L.M., Lichter P.R. Collaborative initial glaucoma treatment study group. risk of endophthalmitis and other long-term complications of trabeculectomy in the collaborative initial glaucoma treatment study (CIGTS). *Am J Ophthalmol* 2013; 155(4):674-680. doi.org/10.1016/j.ajo.2012.10.017
40. Rai P., Kotecha A., Kaltsos K., Ruddle J.B., Murdoch I.E., Bunce C., Barton K. Changing trends in the incidence of bleb-related infection in trabeculectomy. *Br J Ophthalmol* 2012; 96(7):971-975. doi.org/10.1136/bjophthalmol-2011-300926
41. Grant W.M. Experimental aqueous perfusion in enucleated human eyes. *Arch Ophthalmol* 1963;69:738-801. doi.org/10.1001/jama.1963.03700240109068
42. Johnson D.H., Johnson M. How does nonpenetrating glaucoma surgery work? Aqueous outflow pathway morphology. *Invest Ophthalmol Vis Sci* 1999; 40:1676-1680. doi.org/10.1097/00061198-200102000-00011
43. Vandewalle E., Zeyen T., Stalmans I. The iStent trabecular microbypass stent: a case series. *Bull Soc Belge Ophtalmol* 2009; (311):23-29.
44. Belovay G.W., Naqi A., Chan B.J. et al. Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. *J Cataract Refract Surg* 2012; 38(11):1911-1917. doi.org/10.1016/j.jcrs.2012.07.017
45. Tetz M. A novel intracanalicular implant for IOP reduction in patients with POAG: surgical and initial coutcomes from the HYDRUS I study. ESCRS 2011. Free paper. Vienna. http://escrs.org/abstracts/details.asp?confid=6&sessid=186&type=free&paperid=8922. Accessed on 25.12.2014.
46. 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.
47. Tetz M., Pfeiffer N., Ramirez M., Scharioth G., Vass C., Samuelson T. 12 month results from a prospective, multicenter study of a nickel-titanium Schlemm's canal microstent for IOP reduction after cataract surgery in open angle glaucoma. Paper presented at: 30th Congress of European Society of cataract and refractive surgery. September 2012, Milan, Italy. http://escrs.org/abstracts/details.asp?confid=9&sessid=350&type=free&paperid=13857. Accessed on 25.12.2014.
48. Klamann M.K., Gonnermann J., Maier A.K., Ruokonen P.C., Torun N., Joussen A.M., Bertelmann E. Combined clear cornea phacoemulsification in the treatment of pseudoexfoliative glaucoma associated with cataract: significance of trabecular aspiration and ab interno trabeculectomy. *Graefes Arch Clin Exp Ophthalmol* 2013; 251(9):2195-2199. doi.org/10.1007/s00417-013-2408-2
49. Minckler D.S., Baerveldt G., Ramirez A.M., Francis B.A. Clinical Results with the trabectome for treatment of open-angle glaucoma. *Ophthalmology* 2005; 112(6):962-967. doi.org/10.1016/j.ophtha.2004.12.043
50. Nakasato H., Uemoto R., Isozaki M., Meguro A., Kawagoe T., Mizuki N. Trabeculotomy ab interno with internal limiting membrane forceps for open-angle glaucoma. *Graefes Arch Clin Exp Ophthalmol* 2014; 252(6):977-982. doi.org/10.1007/s00417-014-2616-4
51. Girkin C.A., Rhodes L., McGwin G., Marchase N., Cogen M.S. Goniotomy versus circumferential trabeculotomy with an illuminated microcatheter in congenital glaucoma. *J AAPOS* 2012; 16(5):424-427. doi.org/10.1016/j.jaapos.2012.05.013
52. Seibold L.K., Soohoo J.R., Ammar D.A., Kahook M.Y. Preclinical investigation of ab interno trabeculectomy using a novel dual-blade device. *Am J Ophthalmol* 2013; 155(3):524-529. doi.org/10.1016/j.ajo.2012.09.023
53. Redmond S. A new technique for opening the canal of Schlemm. Preliminary report. *Brit J Ophthal* 1960; 44:370-373. doi.org/10.1136/bjo.44.6.370
54. Краснов М.М. Синусотомия при глаукоме. *Вестн офтальмол* 1964; 2:37-42. [Krasnov M.M. Sinusotomyforglaucoma. *Vestnik ofatlmol* 1964; 2:37-42. (In Russ.)].
55. Krasnov M.M. Externalization of Schlemm's canal (sinusotomy) in glaucoma. *Brit J Ophthal* 1968; 52:157-161. doi.org/10.1136/bjo.52.2.157
56. Lewis R.A., von Wolff K., Tetz M., Koerber N., Kearney J.R., Shingleton B.J., Samuelson T.W. Canaloplasty: Three-year results of circumferential viscodilation and tensioning of Schlemm's canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg* 2011; 37(4):682-690. doi.org/10.1016/j.jcrs.2010.10.055
57. Ayyala R.S., Chaudhry A.L., Okogbaa C.B., Zurakowski D. Comparison of surgical outcomes between canaloplasty and trabeculectomy at 12 months' follow-up. *Ophthalmology* 2011; 118(12):2427-2433. doi.org/10.1016/j.ophtha.2011.05.021
58. 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.org/10.1136/bjo.2009.163170
59. Johnstone M., Curtis K., Passin D., Huang J., Slabaughet M. 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. http://journals.lww.com/glaucomajournal/Documents/AGS_Posters_2011.pdf.Accessed on 25.12.2014.
60. 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; 34:433-440. doi.org/10.1016/j.jcrs.2007.11.029

Поступила 15.01.2015