УДК 617.7-007.681-089

A new stainless steel spiral Schlemm's canal expander in surgical treatment open-angle glaucoma

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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 the safety and effectiveness of Schlemm's canal (SC) dilation with stainless steel spiral Schlemm's canal expander (SCE) in decreasing intraocular pressure (IOP) in patients with open angle glaucoma (OAG).

MATERIAL AND METHODS: Eighteen consecutive patients (18 eyes) with OAG, who's IOP was insufficiently controlled by their current ocular hypotensive medications were operated upon. A 4-5 mm long SCE made from 0.05 mm thick medical grade stainless steel wire was implanted into the SC lumen ab externo. In 6 cases with coexisting pathology a combined two site procedure — phacoemulsification with implantation of an intraocular lens (IOL) and SCE implantation was performed. Primary outcome measure was IOP change, secondary — 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 mm Hg or less without medication was considered a complete success, with medication — partial success. Failure was considered if the patient needed subsequent filtering surgery. Results were significant with p‹0.05. Mean postoperative follow-up was 9.5±2.7 months.

RESULTS: Mean preoperative IOP was 25.8±6.2 mm Hg (95% CI 22.7-28.9), mean number of medications — 2.4±0.8 (95% CI 2.2-2.6). At each follow-up a decrease in mean IOP was observed, resulting in 11.9±3.0 mm Hg (95% CI 11.5-13.1) at 6 months (p=0.000000008) and 12.3±2.5 mm Hg (n=10; 95% CI 11.2-12.6) at 12 months (p=0.00000001). This represents a reduction in IOP from baseline of 51.7±19.0% (95% CI 47.2-56.2) at 6 months and 49.8±15.3% (95% CI 45.0-54.6) at 12 months. Mean number of medications use decreased to 0.6±1.1 (95% CI 0.3-0.9; p=0.0000002) and 0.9±1.3 (95% CI 0.5-1.3; p=0.004) at 6 and 12 months respectively. Complete and partial success were observed in 13 and 5 cases at 6 months and 6 and 4 cases at 12 months (n=10). Intraoperatively, microperforation of trabecular meshwork (TM) in areas other than exposed part of SC occurred in 3 out of 18 cases. Postoperatively, not a single case of inflammation at insertion site, of hypotony, or shallow chamber was observed. Gonioscopically the device was in SC in all, except 2 cases, where one end of the device was lying in anterior chamber without contact with intraocular structures. Some blood was observed in SC at the device site in 3 cases, which cleared spontaneously after 3-4 days. There was 1 case with raised IOP after operation, which required Nd-YAG laser trabeculopuncture and one glaucoma medication. There were no failure cases.

CONCLUSION: Six months and one year results of SCE insertion in surgical management of OAG show significant reduction in IOP from the baseline and in hypotensive medications use.

KEY WORDS: Schlemm's canal surgery, Schlemm's canal expander, glaucoma surgery, open angle glaucoma, minimally invasive glaucoma surgery.

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Новый спиральный экспандер шлеммова канала в хирургии открытоугольной глаукомы

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

Резюме

ЦЕЛЬ. Оценить эффективность и безопасность применения нового спирального экспандера шлеммова канала (ЭШК) для дилятации шлеммова канала (ШК) для снижения внутриглазного давления (ВГД) у пациентов с ОУГ.

МАТЕРИАЛЫ И МЕТОДЫ. Прооперированы 18 человек (18 глаз) с открытоугольной глаукомой (ОУГ), у которых ВГД не компенсировалось на максимальной гипотензивной терапии. Всем пациентам имплантировали ЭШК наружным доступом. ЭШК изготовлен из проволоки нержавеющей стали медицинского качества толщиной 0,05 мм, длиной 4-5 мм, кривизна соответствует кривизне ШК. В 6 случаях была произведена одномоментная комбинированная хирургия по поводу катаракты и глаукомы — факоэмульсификация с имплантацией интраокулярной линзы и имплантацией ЭШК в ШК. Критериями оценки являлись динамика ВГД, необходимость применения гипотензивных капель до и после операции и частота осложнений. Для статистического анализа использовали двухвыборочный t-тест. Результаты считались достоверными при $p<0,05$. Снижение ВГД более чем на 25% или ВГД, равное 18 мм рт.ст. и меньше без применения гипотензивной терапии, считалось полным успехом, с применением гипотензивной терапии — частичным. Необходимость в проведении последующей операции считалась неудачей. Средний период послеоперационного наблюдения составил 9,5±2,7 (стандартное отклонение) мес.

РЕЗУЛЬТАТЫ. До операции среднее ВГД составляло 25,8±6,2 мм рт.ст. (95% доверительный интервал (ДИ) 22,7-28,9), среднее число используемых гипотензивных лекарств — 2,4±0,8 (95% ДИ 2,2-2,6). Спустя 6 и 12 мес. после операции среднее ВГД снизилось до 11,9±3,0 мм рт.ст. (95% ДИ 11,5-13,1; p=0,000000008) и 12,3±2,5 мм рт.ст. (n=10; 95% ДИ 11,2-12,6; p=0,00000001). Через 6 мес. снижение ВГД от исходного составляло 51,7±10,0% (95% ДИ 47,2-56,2), через 12 мес. — 49,8±15,3% (95% ДИ 45,0-54,6). Среднее количество лекарств сократилось до 0,6±1,1 (95% ДИ 0,3-0,9; p=0,0000002) и 0,9±1,3 (95% ДИ 0,5-1,3; p=0,004) через 6 и 12 мес. Полный и частичный успех был достигнут в 13 и 5 случаях через 6 мес. и в 6 и 4 случаях через 12 мес. соответственно. Во время операции микроперфорация трабекулы внутри ШК произошла в 3 из 18 случаев. В послеоперационном периоде воспалительная реакция, геморрагические осложнения, гипотония и мелкая передняя камера не наблюдались. Гониоскопически все ЭШК находились в ШК, кроме 2 случаев, где один конец устройства находился в углу передней камеры без контакта с интраокулярными структурами. В 3 из 18 случаев отмечалась регургитация крови в ШК, которая самостоятельно резорбировалась спустя 3-4 дня. Повышенное ВГД имело место в 1 случае, что потребовало проведения ИАГ-лазерной трабекулопунктуры и назначения одного вида капель.

ЗАКЛЮЧЕНИЕ. Имплантация ЭШК в ШК в хирургическом лечении ОУГ достоверно снижает ВГД, что в свою очередь приводит к сокращению используемых гипотензивных лекарств в отдаленные сроки.

КЛЮЧЕВЫЕ СЛОВА: хирургия шлеммова канала, экспандер шлеммова канала, хирургия глаукомы, открытоугольная глаукома, миниинвазивная хирургия глаукомы.

The objective of glaucoma management is to preserve visual function by decreasing IOP. Currently there are no ideal methods available that ensure patient compliance and have a favorable safety profile. The therapeutic potential of external filtration penetrating procedures like trabeculectomy, implantation of shunts is limited because of complications during surgery and in early postoperative period [1-5]. Cataract surgery alone leads to a modest IOP reduction and has been suggested for patients with early or moderate disease [6, 7]. Non-penetrating filtration procedures like deep sclerectomy and viscocanalostomy have fewer risks for early postoperative complications than traditional filtering surgery, but they are bleb dependent and their utility is often limited by their inability to reduce IOP in the low teens, especially for the long term, and by their technical difficulty [8-12]. 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 [13-17]. A novel stainless steel spiral SCE to increase fluid outflow by reducing resistance at the TM area and by dilating SC has been proposed (the device has been patented in Russian Federation as a useful device, patent number 130840 dated 10.08.2013).

Aim. To evaluate the safety and effectiveness of SC dilation using SCE in decreasing IOP in OAG cases.

Material and Methods

In this prospective, non-comparative, uncontrolled, non-randomized, interventional case series study the clinical evaluation of the safety and efficacy of SCE in decreasing IOP in 18 consecutive patients having OAG (18 eyes) whose IOP was insufficiently controlled by their current ocular hypotensive medication(s) 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.

Inclusion criteria: Patients with OAG with high IOP on maximum hypotensive medications. Previous cataract or glaucoma surgery was not considered as an indication for exclusion of the case from the study.

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 6 months. Cases having macro perforation of TM in exposed SC area during surgery were also excluded from the study, whereas cases having micro perforation of TM in areas other than exposed SC were included.

Figure 1. The SCE mounted on 0.2 mm thick microprobe having curvature as of SC. The distal end of the microprobe had certain angulations to facilitate device insertion into SC

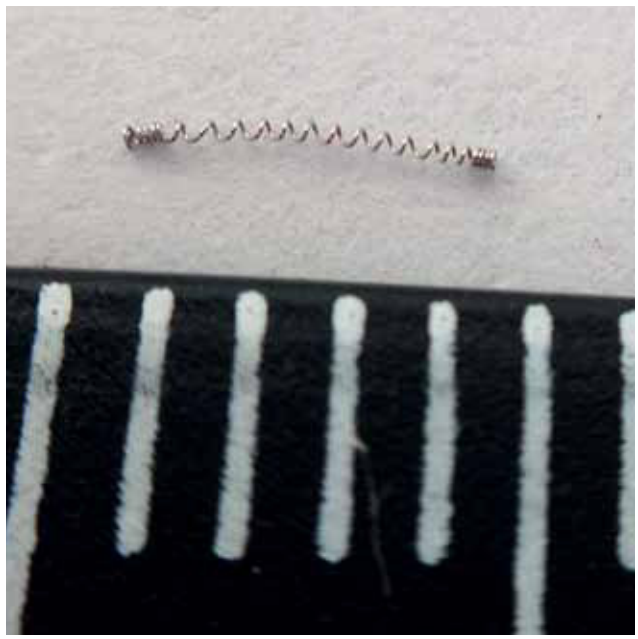

Figure 2. Actual size of SCE. The end loops of the device are closely placed for easy insertion into SC

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: SCE is made from 0.05 mm 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 lumen 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 1 mm *(figures 1, 2)*.

Surgical technique: after creating a 8 mm fornix based conjunctival flap, 1/2 thickness superficial (5×5 mm) and deep (3×3 mm) scleral flap upto ciliary

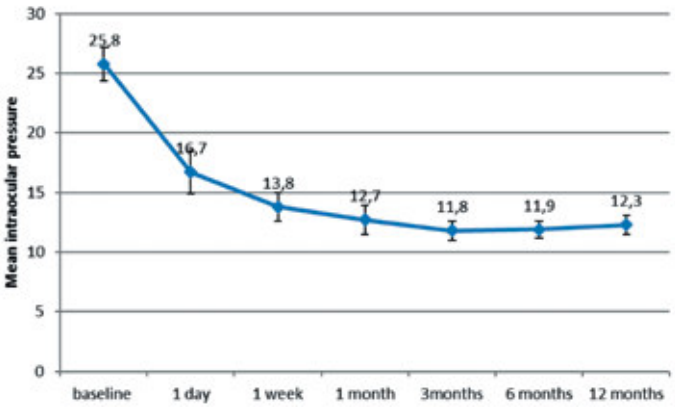

Figure 3. Mean IOP at each visit

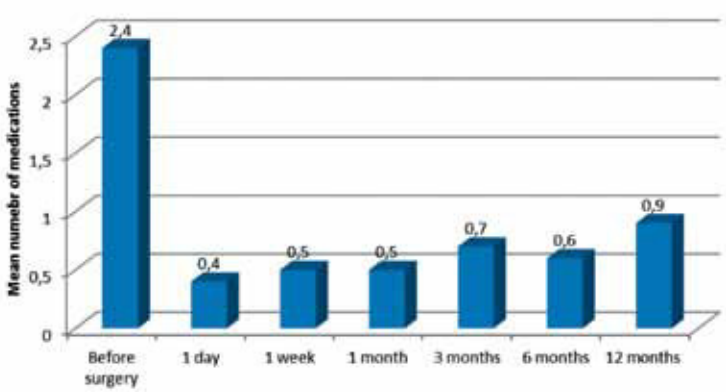

Figure 4. Mean number of hypotensive medications used at each follow up visit

body were dissected. The SC was exposed without creating a window in Descemete's membrane. Further 5-6 mm of SC was dilated with cohesive viscoelastic device (1.4% hyaluronic acid) and microprobes of varying diameters from 0.2 to 0.3 mm. The SCE mounted on 0.2 mm thick microprobe was inserted into dilated SC and held there with second instrument (modified Hoskin corneal forceps — working part with groove 0.2 mm) followed by careful removal of microprobe. The conjunctival, superficial and deep scleral flaps were sutured back water tightly.

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 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 as determined by Maklakov's applanation tonometry. The measured IOP was converted to P0 using special conversion table for the purpose [18]. 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 >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 rates were evaluated at each further follow-up visit after 1 week 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

Eighteen eyes (18 patients) were included in the study. There were 9 female and 9 male patients with an average age of 72.3±-7.5 yrs. Mean postoperative follow-up was 9.5±-2.7 months. The demographic characteristics of the study population is presented in the *table 1*.

There were 8 right eyes and 10 left eyes. Six eyes with coexistent pathology underwent combined two site procedure (phacoemuclification with implantation of a foldable IOL followed by SCE implantation), and the remaining 12 eyes had SCE implantation only. There were 5 eyes with end stage OAG in whom glaucoma surgery with implantation of SCE was performed as an organ saving operation. In all cases anterior chamber angle was open.

Mean IOP at each follow-up visit. Mean preoperative IOP was 25.8±6.2 mm Hg (range: 19–34.9; 95% CI 22.7-28.9). At each follow-up a decrease in mean IOP was observed, resulting in 11.9±3.0 mm Hg (range: 7.1–18.1; 95% CI 11.5-13.1) after 6 months ($p=0.000000008$) and 12.3±2.5 mm Hg (n=10; range: 7.1–15.3; 95% CI 11.2-12.6) after 12 months ($p=0.00000001$) *(figure 3)*. This represents a reduction in IOP from baseline of 45.2±20.6 (95% CI 40.4-50.0) at one week, 49±21.4 (95% CI 43.9-53.9) at one month, 52.4±18.1 (95% CI 48.1-56.7) at 3 months, 51.7±19.0 (95% CI 47.2-56.2) at 6 months and 49.8±15.3% (95% CI 45.0-54.6) at 12 months.

Complete and partial success were observed in 12 and 6 cases at one week, one month and 3 months each and 13 and 5 cases at 6 months and 6 and 4 cases (n=10) at 12 months, respectively.

Mean number of preoperative medications. Mean number of preoperative medications was 2.4±0.8 (range: 1–4; 95% CI 2.2-2.6). After surgery mean number of

Table 1

The demographic characteristics of the study population

Case №	Gender	Age (yrs.)	Eye	BCVA before surgery (logMar)	Type and glaucoma stage	Coexisting pathology	Previous ocular surgery
1	F	77	OD	1	OAG 2a	Cataract	-
2	F	74	OD	1.6	OAG 4b	MD	Phaco+IOL
3	F	72	OD	1.6	OAG 2b	Cataract	-
4	F	75	OS	0.18	OAG 2a	MD	-
5	F	75	OD	NV	Refractory glaucoma	MD	Phaco+IOL+Trabeculectomy
6	M	65	OS	NV	Secondary glaucoma	Old case of CRVO	-
7	M	64	OS	0.2	OAG 3b	-	-
8	M	68	OS	NV	OAG 4c	-	-
9	F	82	OD	3	OAG 3a	Cataract	-
10	M	61	OS	0.54	OAG 2b	MD	-
11	M	60	OS	NV	OAG 4b	Cataract	-
12	M	64	OS	0.2	OAG 3c	Cataract	-
13	M	82	OD	NV	OAG 4c	Cataract	-
14	F	75	OS	3	Refractory glaucoma	-	Nd-YAG laser iridotomy
15	M	77	OD	0.3	OAG 2b	-	
16	F	84	OS	2	OAG 4c	MD	
17	F	79	OS	1	OAG 3c	MD	Phaco+IOL
18	M	67	OD	1	OAG 2b	-	

Note: M — male, F — female, OD — right eye, OS — left eye, BCVA — best corrected visual acuity, logMar — logarithm of the minimum angle of resolution; NV — no vision, blind eye, OAG — open angle glaucoma, MD — macular degeneration, Nd-YAG — neodymium-doped yttrium aluminum garnet, Phaco — phacoemulsification, IOL — intraocular lens.

glaucoma medications reduced at each follow up visit and was 0.6±1.1 (range: 0-3; 95% CI 0.3-0.9) and 0.9±1.3 (range: 0-3; 95% CI 0.5-1.3) at 6 and 12 months respectively ($p<0.004$ at each stage) *(figure 4)*.

Mean BCVA before surgery in 13 cases was 1.14±1.03 logMar (range: 0.18–3.0). BCVA improved in all cases having combined surgery. Mean logMar at 1 week, 1, 3, 6 and 12 months was 1.37±1.31, 0.70±0.51, 0.88±0.87, 0.95±1.05 and 1.05±1.02 respectively.

Complications: intraoperatively, microperforation of TM in areas other than exposed part of SC occurred in 3 cases. In these cases excess filtration of aqueous humor after SCE insertion was noticed and in 1 case there was flattening of anterior chamber. Next day the anterior chamber in all these cases was stable, of equal depth as compared to other eye.

Postoperatively, specific complications related to device were rare. After 12 months of follow up we have not come across a single case having inflammation at insertion site *(figure 5a-b)*. Though water tight suturing of scleral flaps was attempted in all cases, there were cases with some blebs on follow-up visits. The number of such cases reduced with time and was nil at 12 months follow-up. At 1 week after surgery bleb was prevalent in 13 eyes, at 1 month — in 5, at 3 months — in 1 eye, at 6 months — in 2 eyes and at 12 months there was not a single case with bleb (0/10 eyes). Gonioscopically device was in SC in all, except 2 cases at one week. In these cases one end of the device was lying in anterior chamber. These were the cases where micro-perforation was suspected during device insertion. The ends in the anterior chamber angle were not in contact with any of the intraocular structures

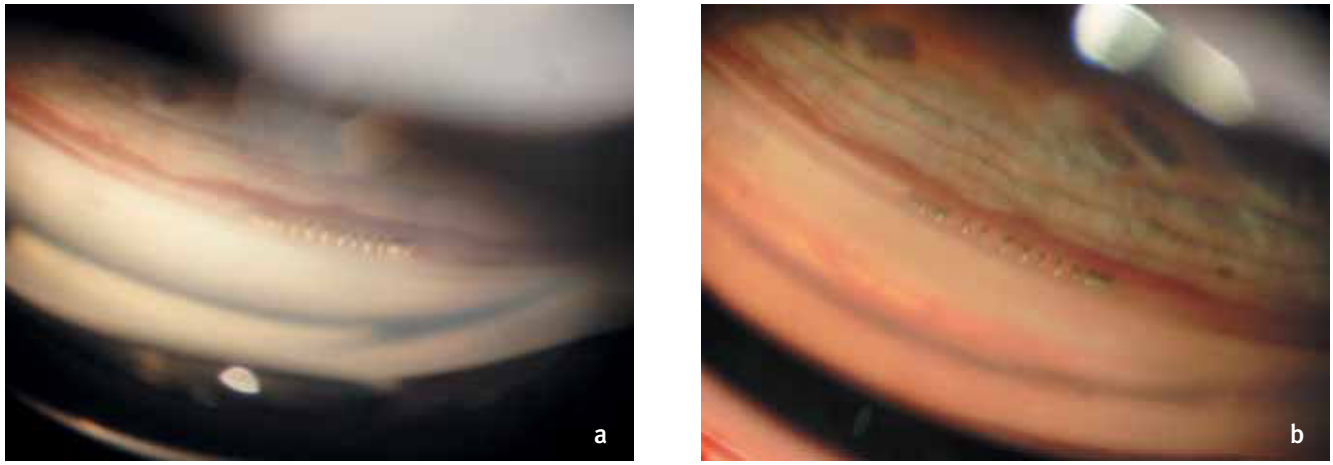

Figure 5. a — case N12. The SCE in SC, follow up 6 months; **b** — same case. Follow up 1 year after surgery. The angle is open, there is no sign of inflammation at the insertion site

Figure 6. A case with microperforation of SC during device insertion. Gonioscopic view after 6 months follow up. One end of SCE is lying freely in the anterior chamber angle, without any contact with any of intraocular tissue. Other end is well embedded in the SC. There is no sign of inflammation at the site

(figure 6). Some blood was observed in SC at the device site in 3 cases, which cleared spontaneously after 3-4 days. 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 anterior chamber 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 9 months follow up there has not been any change in device condition. IOP is under control on 2 glaucoma medications. There was 1 case with raised IOP after operation, which could not be controlled with maximum glaucoma medication. The case had glaucoma procedure previously (trabeculectomy). After one week Nd-YAG laser trabeculopuncture was done and IOP was controlled with one medication. No subsequent surgery was required in any of the cases.

Discussion. External filtration procedures in surgical management of OAG though result in excellent long-term IOP control; they are frequently accompanied by numerous short- and long term complications. These include flat or shallow anterior chamber, wound leak, hypotony, suprachoroidal hemorrhage, choroidal effusions, accelerated cataract progression, fibrosis or encapsulation of the bleb leading to failure of the surgery, leaky cystic blebs with hypotony, decreased vision from hypotony maculopathy, and endophthalmitis [19, 20].

Lately much interest is seen in trabecular bypass surgery [21-24]. 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 [25, 26]. Theoretically, a moderate dilation of SC and the collector canal in conjunction with a trabecular bypass would reduce the IOP level significantly. The iStent, trabectome and Hydrus implant are some of the procedures, which enhance trabecular outflow. All mentioned three devices can be inserted through a small corneal incision under gonioscopic control — ab interno approach [23].

In a prospective case series of (ten eyes, eight patients), E. Vandewalle et al. [21] studied results of iStent implanation in reduction of IOP. Authors reported mean IOP drop from 19.6 mm Hg preoperatively to 15.8 mm Hg 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 did not report any vision-threatening complications and concluded that trabecular bypass results in significant mid-term reduction of IOP as well as the number of medications.

G.W. Belovay et al. [22] 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. As per the results of the study the overall mean 1-year postoperative IOP was 14.3 mm Hg, which was significantly lower than preoperative IOP overall and in each group ($p<0.001$). The target IOP was achieved in a significantly higher proportion of eyes at 1 year versus preoperatively (77% versus 43%; $p<0.001$). 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. Some of the reported complications of this device are 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. Learning curve of this procedure is steep.

Hydrus (Ivantis Inc., Irvine, CA, USA) is a SC scaffold made from nitinol intended to be placed through the TM into SC. The device had 3 posterior windows, which face the TM, and the structure of the device opens and dilates the TM and SC. The open posterior side 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. M. Tetz reported in 2011 the three months results of prospective uncontrolled study of 98 glaucoma patients receiving a Hydrus implant. Author reported mean preoperative IOP drop from 21.4±4.8 to 15.4±4.4 with an IOP decrease of 6 mm Hg (28%). The complications seen were blood reflux (15%) and iritis (4%). Advantages of this technique include short duration of device implantation, a low-risk safety profile and protection of the conjunctiva which enables later trabeculectomy if required [24].

The trabectome (Neomedix Inc., Tustin, CA) is a device designed to excise and cauterize the inner wall of the trabeculum ab interno. The purpose is to lower the IOP by enhancing trabecular outflow without external filtration. This procedure also can be easily combined with phacoemulsification. Combined procedure can give an IOP decrease of around 5 mm Hg. The main complication in the use of Trabectome is transient hyphema, which may vary from 79 to 100%. Other reported complications are early IOP spikes, failed procedure and blood reflux, though the later complication is considered as physiological [23].

The above mentioned 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.

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, including postoperative hypotony and choroidal effusions. But canaloplasty 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 SC, placement of 10-0 suture, proper tensioning of SC and watertight suturing of flaps. Combining canaloplasty with phacoemulsification is a more challenging surgery [13-17, 28-31].

We report six months and one year functional results after implantation of a novel SCE in a series of eighteen eyes suffering from OAG. We compared our results with results of canaloplasty. As in canaloplasty the approach to SC in our method is also ab externo. Segmental viscodilation of SC is a standard part of the 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.

Fujita et al. [32] reported results of small case series of Japanese patients receiving canaloplasty or phacocanaloplasty. In this study 11 eyes of 9 Japanese patients with OAG underwent canaloplasty (three eyes) or phacocanaloplasty (eight eyes). The mean preoperative IOP was 23.4±5.5 mm Hg on 2.8±0.6 medications. At 1, 3, 6 and 12 months the mean IOP was 13.7±2.8, 12.8±3.5, 14.0±4.4, and 15.0±4.1 mm Hg, respectively. The mean postoperative medications significantly decreased to 1.2±0.8 ($p<0.01$). A qualified success rate was achieved in 81.8, 54.5 and 54.5%, respectively. In our study at 6 months and 12 months after surgery IOP decreased from baseline to 11.9±3.0 and 12.3±2.5 mm Hg accounting for reduction of IOP by more than 50%. 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 ($p<0.004$). At 12 months the use of medications decreased from 2.4 to 0.9. Complete success was achieved in more than 60% of cases at 6 and 12 months.

Intraopoeratively, except two cases, where microperforation 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 Schlemm's canal, Descemete's membrane detachment and improper microcatheter passage [13-15, 17, 31, 32]. In rare settings, the microcatheter could exit SC and violate surrounding structures. It is not always

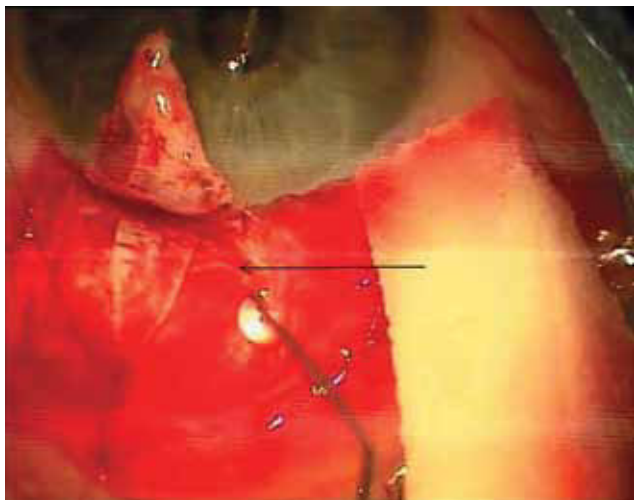

Figure 7. The arrow showed severed channel during dissection of flaps. After device insertion, a free flow of fluid in the mid of blood from the vessel ostia was observed, which could have resulted in bleb formation

possible to canalize the SC 3600. Shingleton B. et al 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% [13]. Intraoperative trans-TM suture extrusion has also been reported [13, 15]. In our series the device was inserted into SC completely in all cases and it remained there in all, but 1 cases.

As per published reports postoperative hyphema or microhyphema following canaloplasty occurs with an incidence of 3.2 to 21% [13, 16]. In our study we did not observed any case with hyphema, but gonioscopically there were 3 cases having blood in SC at the device site, which dissolved spontaneously. 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 anterior chamber [11-16]. Persistent elevation in IOP requiring laser goniopuncture was necessary in 8.3–18.8% in some studies; however, in other reports no eyes required laser goniopuncture [11-15]. In our study there was 1 case with high IOP in immediate postoperative period, which could not be controlled by glaucoma medications. This case had previous glaucoma (trabeculectomy) surgery, and due to scarring of tissue at 12 o'clock position there were certain difficulties in SC dissection, its viscodilation and during insertion of the device. Nd-YAG laser trabeculopuncture considerably reduced IOP and it was well controlled on 1 medication. 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%) [13-15, 17, 31, 32]. In our series we did not encounter any of the mentioned complications. Bleb formation after canaloplasty has been reported upto 12% of patients [15]. In the presented study, some degree of bleb formation was observed in 2 out of 18 cases at 6 months and nil at 12 months (n=10). 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 anterior chamber are severed and fluid directly drains under conjunctiva, resulting in formation of filtration blebs *(figure 7)*.

Certain advantages of this device were noticed during this study. It was easy to implant it in the SC lumen. 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 nonpenetrating technique of glaucoma surgery can easily perform this procedure. Intraoperative complications with this technique are few. After dilation of SC the device can be easily inserted into it. 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 [30].

Shortcomings of this study are small sample size, short follow up period and 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 technique.

Conclusion: Six months and 1 year results of SCE insertion in surgical management of OAG show significant reduction in IOP from the baseline and in hypotensive medication(s) use.

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Поступила 21.05.2014