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The effectiveness of phacodeepsclerectomy performed with implantation Sk-gel and T-flux – 12 months observations

Skuteczność sklerektomii głębokiej z implantacją Sk-gel i T-flux w 12-miesięcznej obserwacji

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Summary: Purpose: The purpose of this work was to present effectiveness and safety of phacodeepsclerectomy with SK-gel and T-flux implant in 12 months observation.

Materials and methods: Retrospective analysis included group I (SK-gel) – 40 eyes and group II (T-flux) – 23 eyes. At the control studies best corrected visual acuity (BCVA), intraocular pressure (IOP), anterior and posterior segment of the eye were examined. Control testing was done in the first day and 7-th day, and 1, 3, 6, 12 months after surgery. In the case of elevated IOP (>15 mmHg) goniopuncture was performed. IOP (>15 mmHg) with fibrosis signs of the filtration bleb was an indication to use antimetabolites. Complete and qualified success rate was defined as IOP≤18 mmHg. In statistical analysis one-way ANOVA and Kaplan-Meier survival analysis, were used.

Results: After 12 months mean IOP in the SK-gel group was 12.7 ± 0.6 mmHg and in T-flux group 14.6 ± 0.7 mmHg. It was a decrease in the mean IOP by 39.1% ($p<.001$) and 35.7% ($p<.001$). In both groups fewer medications were used than before surgery. Complete surgical and qualified success rate was reached in group I (81.7% and 91.9%) and in group II (72.7% and 83.8%). Nd:YAG goniopuncture performed in 10 eyes with implant SK-gel (25.0%) and 6 eyes with implant T-flux (26.1%) ($p>.05$). Subconjunctival injections with 5-FU were done in 5 eyes in the SK-gel group (12.5%) and in 3 eyes in the T-flux group (13.0%) ($p>.05$).

Conclusions: Phacodeepsclerectomy (PDS) with SK-gel and T-flux implant are both effective and safe surgical methods in the treatment of POAG in 12 months observation.

Słowa klucze: sklerotomia głęboka, implanty wchłanialne, implanty niewchłanialne.
Key words: phacodeepsclerectomy; absorbable implants; non-absorbable implants.

Introduction

Correctly functional filtration membrane comprised of Descemet's membrane and Schlemm's canal with outer wall removed during surgery, as well as decompression space maintained in the sclera and functional drainage of the aqueous fluid are determined about the effectiveness of deep sclerectomy (DS). Decompression space maintains negative pressure in relation to anterior chamber, which enables its decompression. On the other hand it serves as specific retention cistern on the way of aqueous fluid drainage pathway from the anterior chamber. Maintenance of decompression space in the sclera is one of the conditions of correctly functioning deep sclerectomy. Non-perforating techniques presented at first by Epstein and Krasnow at the end of fifties in the past century, improved later in the eighties by Russian school (Fiodorow, Kozlow) and North American school (Zimmerman), were for many years in the shadow of classical trabeculectomy as less effective. The progress of non-perforating glaucoma surgery was possible not only due to the progress in eye microsurgery, but also due to new biotechnology achievements. Nowadays to fix the created decompression space the use of different implants in the scleral bed is performed. The advantage of DS with the use of scleral implants over classical surgery is pretty obvious at this time (1-4). The first used implants were obtained from freeze-dried bovine collagen (Aquaflow). The most popular among the absorbable implants is SK-gel, which is a biosynthetic Sodium hialuronate. In UBM studies it is confirmed the reabsorption from the scleral bed after about 4 months from surgery in hialuronic implants and 6 to 9 months after collagen implants (5). Absorbable implants leave a large niche with a capacity of about 6-8 mm^3 as a result of reparation processes in the sclera. At present non-absorbable implants T-flux are used as well made of hydrophilic acryl. This type of implant is placed in scleral bed and fixed with one suture to its fundus. Fixing the implant enables insertion of its ends into Schlemm's canal, which is important in facilitation of drainage from decompression space in physiological way. From the other point the capacity of decompression space is diminished by the capacity of implant itself, and reparation processes in the sclera being the reaction to the foreign body may be the cause of unfavorable final effect of the surgery.

Materials and methods

Retrospective analysis included two groups of patients after phacoemulsification combined with DS performed in the Department of Ophthalmology, Military Health Service Institute in Warsaw from October 2003 to November 2004. Group I comprised of 36 patients (40 eyes, 21 females and 15 males) after sclerectomy with SK-gel implant into the scleral bed. 23 patients (23 eyes, 19 females and 4 males) qualified to group II, who received T-flux implant.

The indication for surgery was open-angle glaucoma, treated with at least two medications without satisfactory control of IOP or with the progression of changes in the visual field. Cataract was removed with phacoemulsyfication method.

Pre-operation testing included: BCVA, applanation tonometry, gonioscopy, pachymetry, examination of the anterior chamber in biomicroscope, fundoscopic exam, perimetry with threshold strategy with the use of computerized perimeter Centerfield/ Oculus.

Surgeries performed by one surgeon (MR), were done with retrobulbar anesthesia with 2% Xylocaine supported by NLA. After the cut off of bulbar sclera from the corneal limbus in the upper quadrant, square flap from superficial sclera was separated, measuring 5 x 5 mm with the base in the limbus. Later in the deep layer of sclera, square flap, measuring 3.5 x 3.5 mm, was separated reaching spurs of sclera. Phacoemulsification was performed through the clear corneal temporal incisions. IOL was placed in the capsule. Further deep flap of sclera was separated showing Schlemm's canal and Descemet's membrane comprising the filtration membrane, (trabecular-Descemet`s membrane). Deep flap of the sclera was cut off at the Schwalbe line and outer wall of the Schlemm's canal, was removed. After the placement of the implant into the scleral bed (acrylic implant was additionally sutured with Nylon 10-0, the superficial flap was closed with single stitches Nylon 10-0 and conjunctival opening was closed with single stitches Vicryl 8-0.

In control testing BCVA, IOP, anterior chamber and fundus were examined, postoperative course was analyzed with complications and procedures used to fix hypotensive effect (goniopuncture, antimetabolites), as well as number of used medications. Testing was done 1 and 7 days after surgery and later after 1, 3, 6 and 12 months. In the case of increased IOP (>15 mmHg) caused by the failure of the filtration membrane (lack or poorly developed filtration bleb), goniopuncture was performed with laser Nd:YAG. Elevated IOP (>15 mmHg) with signs of inflammation or fibrosis of the filtration bleb was the indication to use antimetabolites. 5-flurouracyl (5-FU) was used as 5 mg subconjunctival injection, 180 degrees from the surgical wound in the area of inferior conjunctival crease. Injections were given daily for five consecutive days and as needed were repeated after a week. Antimetabolites were discontinued earlier when good regulation of IOP was achieved or complications appeared. During the first four weeks after operation all the patients received antibiotic with steroids with non-steroidal anti-inflammatory agent into the conjunctival sac.

Complete surgical success rate was defined as IOP≤18 mmHg without anti-glaucoma medications and qualified success rate as IOP≤18 mmHg without and with medications.
Statistical analysis was done with the U Mann-Whitney's test, t-Student's test, pair sequence Wilcoxon's test and variance was analyzed (one-way ANOVA) and chi square test. Survival analysis was assessed with Kaplan-Meier method with the use of log rank test.

Results

Studied groups were homogenous according to age, sex and original IOP (p>.05) (Tab. I). The mean time of observation was 360 days in both groups.

Demographic	SK-gel (n=40)	T-flux (n=23)	p
Follow-up (d)	360	360	1.000*
Age (y)			
Mean ± SD	72.9 ± 5.5	73.2 ± 6.2	.822†
Range	60-84	57-85	
Sex, n (%)			.118*
Female	21(36)	19(23)	
Male	15(36)	4(23)	
Eye, n (%)			.561*
Right	15(40)	15(23)	
Left	25(40)	8(23)	
Preoperative IOP (mmHg)			
Mean ± SD	21.1 ± 1.3	22.7 ± 1.5	1.000¤
Range	11-45	14-38	

Tab. I. Demographical data of studied groups.
Tab. I. Dane demograficzne badanych grup.
* U Mann-Whitney's test
† t-Studen's test
¤ one-way ANOVA

IOP control

The mean IOP in the SK-gel group was 21.1 ± 1.3 (SE) mmHg and was decreased in day 1-st after surgery by 49.8% and was 10.6 ± 1.0 (SE) mmHg (p<.001). In the group T-flux

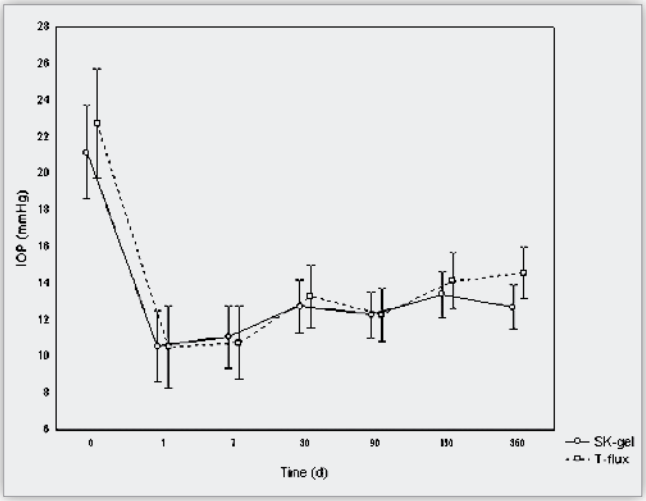

Fig. 1. Mean values of IOP in particular periods after surgery in observed groups.
Ryc. 1. Średnie wartości ciśnienia wewnątrzgałkowego w poszczególnych okresach obserwacji.

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the mean IOP in day 1 after surgery was decreased by 53.7% from original 22.7 ± 1.5 (SE) mmHg to 10.5 ± 1.1 (SE) mmHg ($p<.001$). After 360 days of observation the mean values of IOP in SK-gel group was 12.7 ± 0.6 (SE) mmHg and in T-flux group 14.6 ± 0.7 (SE) mmHg. It was decrease in the mean IOP by 39.1% ($p<.001$) and 35.7% ($p<.001$) respectively in relation to pre-surgical values in particular groups (Fig. 1).

Medications

In both groups after surgery fewer medications were used than before surgery and the results were statistically significant ($p<.05$) (Tab. II). In SK-gel group at the end of observation, 33 eyes (82.5%) did not require medications. In T-flux group 69.6% (16 eyes) did not require medications at the same time after operation. There was no statistical difference between numbers of used medications in both studied groups at the end of observation (Tab. II).

Medication (n)	SK-gel	T-flux	p*
Preoperative			
Mean ± SD	2.4 ± 0.8	2.3 ± 0.8	.502
Range	1 – 4	1 – 4	
360 days after			
Mean ± SD	0.26 ± 0.7	0.4 ± 0.7	.364
Range	0 – 3	0 – 2	
p†	.000	.000	

Tab. II. Glaucoma medications used before surgery and 360 days after surgery.
Tab. II. Liczba stosowanych leków przeciwjaskrowych w badanych grupach przed operacją i 360 dni po operacji.
* U Mann-Whitney's test.
† pair sequence Wilcoxon's test.

Surgical success

Complete success rate was achieved when IOP was ≤18 mmHg 360 days after surgery without medications and qualified success rate was with IOP≤18 mmHg without medications or with maximum two medications. Cumulated success probability based on the above criteria for the particular periods of observation is shown in Tab. III. Graphs of Kaplan-Meier survival analysis for qualified and complete surgical success rate criteria are shown in figure 2. In the entire observation period there were no statistically significant differences between SK-gel group and T-flux group ($p>.05$) (Tab. III, Fig. 2).

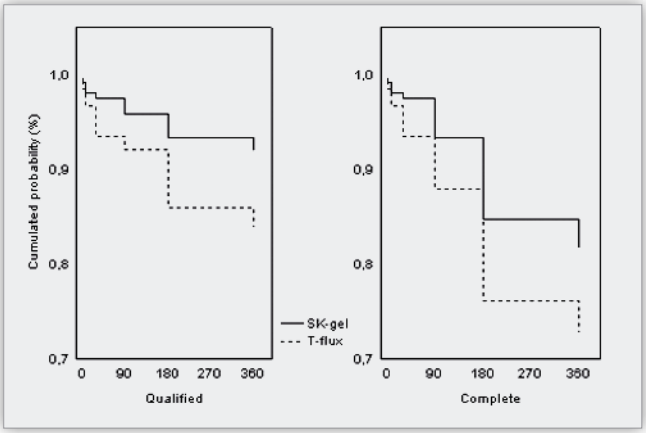

Fig. 2. Cumulated probability of complete and qualified surgical success rate in studied groups.
Ryc. 2. Skumulowane prawdopodobieństwo pełnego i satysfakcjonującego sukcesu w badanych grupach.

BCVA

The mean visual acuity in SK-gel group was changed from 0.52 ± 0.29 before surgery to 0.47 ± 0.30 in the first day after surgery, 0.73 ± 0.28 after a month and maintaining this value

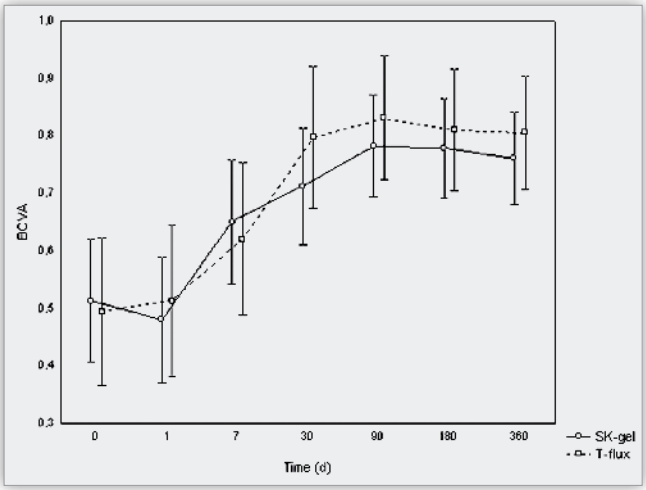

Fig. 3. BCVA in studied groups.
Ryc. 3. Najlepsza skorygowana ostrość wzroku do dali w badanych grupach.

Postop (d)	Success rate (%)					
	SK-gel*		T-flux*		p†	
	Complete	Qualified	Complete	Qualified	Complete	Qualified
30	97.1	97.1	93.2	93.2	.959	.959
90	97.1	97.1	93.2	93.2	.910	.943
180	92.2	95.1	86.8	91.6	.804	.902
360	81.7	91.9	72.7	83.8	.591	.869

Tab. III. Cumulative probability of complete and qualified success rate.
Tab. III. Skumulowane prawdopodobieństwo pełnego i satysfakcjonującego sukcesu w badanych grupach.
* Kaplan – Meier's survival analisis.
† log rank test.

in the subsequent tests ($p<.05$). The mean visual acuity in T-flux group changed from 0.49 $\pm$ 0.24 before surgery to 0.80 $\pm$ 0.19 at the end of observation ($p<.05$). For all the tests there was no statistically significant difference between mean visual acuity in groups I and II ($p>.05$) (Fig. 3).

Goniopuncture, antimetabolites

Goniopuncture with Nd:YAG laser was performed in 16 eyes, including 10 eyes with SK-gel implant (25.0%) and in 6 eyes with T-flux implant (26.1%) ($p>.05$). Subconjunctival injections with 5-FU was done in 5 eyes in SK-gel group (12.5%) and 3 eyes in T-flux group (13.0%) ($p>.05$). The mean time to begin the treatment with antimetabolites was 11.2 days (range 2-16 days) from surgery in SK-gel group and 17.0 days (range 13-20 days) in T-flux group; the mean dosages of 5-FU was 17.0 mg and 13.3 mg respectively and mean number of injections was 3.4 (range 1-6) vs. 2.7 (range 2-4).

Complications

Early complications included: transient hypotonia (<6 mmHg) in 10 eyes in SK-gel group (25.0%) and 4 eyes in T-flux group (17.4%) ($p>.05$), increased IOP (>20 mmHg) in 3 eyes in group I (7.5%) and 4 eyes in group II (17.4%) ($p>.05$), inflammatory exudates in 2 eyes in group I (5.0%) and 1 eye in group II (4.3%), bleeding into the anterior chamber in 2 eyes in SK-gel group and 1 eye in T-flux group (5.0% vs. 4.3%) ($p>.05$), shalowing of the anterior chamber in 2 eyes in group I (5.0%), choroid detachment in 1 eye of both groups (2.5% vs. 4.3%) and vitreous hemorrhage in 1 eye in group I (2.5%). Late complications included: fibrosis of the filtration bleb in 8 eyes in group I (20.0%) and 5 eyes in group II (21.7%) ($p>.05$), macular edema in 1 eye of both groups (2.5% vs. 4.3%) ($p>.05$) and the peripheral iris incanceration in 1 eye in T-flux group (4.3%) that underwent goniopuncture with Nd:YAG laser. Complications with antimetabolites pertained to 7 eyes in both groups and were transient corneal epitheliopathy – in 3 eyes of both groups (7.5% vs. 13%) and induction of irregular astigmatism– in 1 eye in T-flux group (4.3%).

Discussion

Sudden decompression of the eyeball associated with classical trabeculectomy is prone for significant risk of complications as: hypotonia, anterior chamber shallowing or decrease in visual acuity. This fact was not left without the influence on laying grounds in the past few decades of traditional approach to glaucoma therapy, which treats the surgery as a last resort in the sequence of therapeutic options in glaucoma. The change of the philosophy in the therapy of glaucoma and earlier application of surgical modalities-among the others as an alternative for compound pharmacological treatment would be possible with the rise of the safety profile level of the surgical technique, and simultaneously maintaining its high effectiveness. Conditions for safe and effective surgery are met by DS with its modifications, tied with the usage of different scleral implants and pharmacological strategy of tissue regeneration.

Implant, which is fulfilling decompression space between the separated scleral tissues, is fixing decompression space and preventing the fibrosis of the filtration space, is increasing drainage of the aqueous fluid from Schlemm's canal and contributes to greater reduction of IOP. The implant is also helpful in development of the filtration bleb, very infrequently observed in non-perforating surgery without the use of implants (60% vs. 5%), is facilitating supra-choroid drainage and is stimulating production of new scleral vessels, draining the aqueous fluid (6,7). Nowadays the absorbable implants are used, made of collagen or sodium hialuronate, non-absorbable acrylic implants or monofilament chromic sutures, as the last ones bioimplants were introduced from the amniotic sac membrane or autologous sclera. The reason to use non-absorbable implants is to maintain constant decompression space under superficial scleral flap and extension of the effectiveness of nonperforating surgery. This is confirmed by 30-months observation by Dahan (8), who did not notice any statistically significant differences in reduction of IOP between the eyes with T-flux implant and the eyes without the implant in the first 18 months after surgery, but during the course of further observation (from 23rd month), stable profile of reduction of IOP was noted only in eyes with implant (62% vs. 32%). The positive effect of implants on the level of reduction of IOP in the light of up to date studies seems to be unquestionable (6,8,9), but very few studies pertains to comparative analysis (10,11).

The purpose of this work was to show effectiveness and safety of deep phacosclerectomy with absorbable implant made of sodium hialuronate (SK-gel/ Corneal) or non-absorbable acrylic implant (T-flux/ IOLTech), in the material of the Department of Ophthalmology, Military Health Service Institute in Warsaw based on 12-months observation.

In 1-st day after surgery the mean IOP was decreased by 49.8% in the SK-gel group and 53.7% in T-flux group, there was no statistically significant difference between groups. Greater reduction of IOP (by 84%) in the first day after surgery in eyes with T-flux implant noted Dahan (8), who thought that this positive sign is a proof of increased permeability of the trabecular texture preparation. In our own material early transient hypotonia (<6 mmHg) was observed in 25% of eyes with SK-gel implant and 17.4% eyes with T-flux implant. According to Shaarawy (12), hypotonia below 6 mmHg in the first day after surgery has a positive prognostic value of the far-reaching surgical success. In this work, after 12 months of observation reduction of the mean IOP was 39.1% in SK-gel group and 35.7% in T-flux group in comparison to pre-surgery values. Complete surgical success rate was achieved by 81.7% of eyes in SK-gel group and in 72.7% of eyes in T-flux group and qualified success rate in 91.9% and 83.8% of eyes respectively. The tendency that was observed in our own studies of smaller reduction of IOP in eyes with T-flux implant does not confirm the main advantages of the non-absorbable implant and cited before work by Dahan (8) and maybe it has a connection with gradual shrinking of the decompression space as a fibrotic reaction to the foreign body that is an implant. Histopathological tests on rabbits showed that a condition of effective sclerectomy is maintenance of a large and regular intrascleral lake with the lack of tissue destruction, fibrosis and inflammation (13). It was noted that in eyes with the collagen implant the walls of the lake are selectively covered with spindle cells (this process begins two months after the operation and ends after nine months), without

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simultaneous infiltration by mononuclear cells (7). The induction of inflammatory processes and fibrosis in the decompression space is observed in eyes with an implanted chromic suture (13); theoretically these processes cannot be excluded in the case of an acrylic implant, which requires additional intraoperative manipulations that traumatize the tissues such as suturing of the implant or fixing its branches in Schlemm's canal.

Up to now the comparison of the effectiveness of DS with the use of sodium hialuronate implant (SK-gel/ Corneal) or acrylic implant (T-flux/ IOLTech), was the topic of very few publications. Detry-Morel (10) in the material of 20 eyes, complete surgical success rate (defined as achievement of individual level of goal pressure without medications and without goniopuncture Nd:YAG), noted in 80% of eyes in SK-gel group and in 60% of eyes in T-flux group, and qualified success rate (with medications and goniopuncture Nd:YAG) in 100% and 80% of eyes respectively. The mean IOP after 7 months of observation was lower by 46.5% than the value before surgery and no statistical difference was observed between groups. Drosum (11), comparing non-absorbable acrylic implant (T-flux/ IOLTech) with absorbable collagen implant (Aquaflow/ Staar Surgical) did not find any statistical differences between the groups after 6 months observation (14.8 vs. 16.4 mmHg). Studies by other authors confirm as well high effectiveness of DS with usage of the above-mentioned implants. Ravinet (14), in longer, 24 months observation noted on average 53% reduction of IOP in eyes with acrylic implant T-flux and surgical success defined as IOP< 15 mmHg without medications was achieved in 81.8% of eyes. Ates (15) using the same implant complete surgical success rate (IOP<21 mmHg without medications) noted in 86.9% of eyes after one month from surgery and in 56.5% after 12 months. Drosum (11) noted higher percentage of the effectiveness of DS with the use of T-flux in eyes with pseudoexfoliating glaucoma than primary open-angle glaucoma (IOP<19 mmHg without medications in 61% of eyes vs. 38%) after 18 months observation. In studies with the use of sodium hialuronate implants (SK-gel) the mean IOP was lower by 41-47% after 12 months (16,17) as well as after 30 months from surgery (10).

In the case of filtration membrane failure and IOP above 15 mmHg goniopuncture with Nd:YAG laser was done. In our own material there was no statistical difference between groups. Goniopuncture Nd:YAG was used in 10 eyes in SK-gel group (25%) and in 6 eyes in T-flux group (26.1%) and it was performed in the first month after operation. Other authors report similar or higher percentage of the use of this procedure: 13.0-63.6% for eyes with acrylic implant (8,14,15) and 16.6% for sodium hialuronate implant (10).

In our own studies, fibrosis and encapsulation of the filtration bleb was observed in similar prevalence in both groups-in 20.0% of eyes with SK-gel implant and 21.7% of eyes with T-flux implant and percentage was lower than reported by other authors (28.5%) (10). The treatment of choice in these cases were subconjunctival injections with 5-FU, the mean dosage 17.5 mg in SK-gel group and 13.3 mg in T-flux group and was lower than recommended by Fluorouracil Filtering Surgery Study Group (18) minimal dose (35 mg). Observed side effects after antimetabolites injections were transient in character and there was no difference between groups.

Applied surgical therapy enabled discontinuation of medications in 82.5% of patients in SK-gel group and 69.6% of patients in T-flux group. The mean number of medications was decreased from 2.4 before surgery to 0.26 after 12 months from the operation in the group of eyes with absorbable implant and from 2.3 to 0.4 in the group of eyes with non-absorbable implant. There was no statistical difference between groups. Drosum (11) did not observe any differences as well for acrylic implant T-flux and collagen implant Aquaflow (0.6 vs. 0.7). The stable hypotensive effect of DS was confirmed as well by Dahan, who noted complete discontinuation of medications at the end of two-year observation (3.4 vs. 0.0) and for SK-gel implant, Ravinet (14) (2.5 vs. 0.4).

In our own studies deep phacosclerectomy with the use of implants SK-gel or T-flux were shown to be equally safe. The presence of blood in the anterior chamber, noted in 5.0% of patients with SK-gel implant and 4.3% of patients with T-flux implant, was probably a consequence of its reverse flow from the scleral bed through trabeculation or micro perforations of the filtration membrane. Vitreus hemorrhage observed in the first day after surgery in one patient, was a consequence of central retinal vein thrombosis. Other complications (anterior chamber shallowing, choroid detachment, inflammatory exudates, macular edema) did not differ between groups, were encountered rarely (2-3%) and had a reversible character.

Deep phacosclerectomy with absorbable implant SK-gel or non-absorbable implant T-flux is effective and safe method of surgical therapy of open-angle glaucoma.

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