# (79) Efficacy and safety of deep sclerectomy and phacoemulsification and deep sclerectomy in clinical material of Military Health Service Institute — yearly observations

Skuteczność i bezpieczeństwo głębokiej sklerektomii i fakoemulsyfikacji z głęboką sklerektomią w materiale klinicznym WIM – roczna obserwacja

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### Summary:

Purpose: Comparison of the effectiveness of nonpenetrated deep sclerectomy (DS) as the only procedure in relation to operation combined with phacoemulsification (FDS) in treatment of patients with open-angle glaucoma based on yearly observation. Material and methods: 67 eyes with open-angle glaucoma were retrospectively analyzed. Applying layer-systematic criteria 21 eyes after deep sclerectomy with scleral implant (SKGEL/Corneal or T-flux/I-Tech) were selected into group I (DS implant) and 23 eyes after phacoemulsification with simultaneously performed deep sclerectomy and scleral implants were selected into group II (FDS implant). In control studies best corected visual acuity (BCVA), intraocular pressure (IOP), anterior chamber and fundus, were examined. Postoperative complications and applied procedures were analyzed especially controlling hypotensive effect (goniopuncture, antimetabolites), as well as number of glaucoma medications used. Tests were performed in 1 and 7 days after surgery, and later after 1, 3, 6, 12 months. Statistically test U Mann-Whitney was used as well as pair sequence Wilcoxon test. Survival analysis was done with Kaplan-Meier method with the use of log rank test.

Results: After 360 days of observation mean values of IOP in group I was 14.3  $\pm$  3.6 mmHg, and in group II - 12.9  $\pm$  3.0 mmHg. It was a decrease of mean IOP by 29.6% (p=.000) and 41.4% (p=.000) in comparison to preoperative IOP in particular groups. In both groups fewer glaucoma medications were used after surgery and the results were statistically significant (p<.05). As a complete success rate was considered IOP of  $\leq$  18 mmHg without glaucoma medications, and qualified success rate was IOP of  $\leq$  18 mmHg without medications or with the most of two glaucoma medications. Complete and qualified success rate were achieved respectively in group I (72.6% and 88.4%) and in group II (74.3% and 86.9%) at the end of observation. In the entire observation there were no statistically significant differences between group I and 2 (p>.05). After 360 days of observation there was no statistically significant difference between mean BCVA in group I and II (p>.05).

Słowa kluczowe: Key words: **Conclusions:** DS with scleral implant performed as a single procedure or FDS is effective treatment in open-angle glaucoma. glęboka sklerektomia, glęboka sklerektomia z fakoemulsyfikacją, jaskra otwartego kąta. deep sclerectomy, phacoemulsification and deep scelerectomy, open angle-glaucoma.

### Introduction

Despite the fact that trabeculectomy is still the most frequently used operation in open-angle glaucoma, it is not difficult to notice the importance of nonperforated techniques in recent years. Development of these techniques was influenced by desire to limit complications after classical perforating surgeries, which resulted in opening of the anterior chamber (hypotonia, making shallow the anterior chamber, choroid detachment, development of cataract) and further progress was stimulated by promising surgical results. Not without the meaning for the later is further growing offer of intrascleral implants and correct intra and post surgical strategy, which includes antimetabolites and laser procedures. In essence DS comes to development of filtration membrane (trabeculo-Descemet's membrane), composed of Descemet's membrane and Schlemm's canal deprived of exterior wall during surgery. Filtration membrane filters aque-

ous to decompression space, which is formed by lamellar dissected sclera. Decompression space should have about 8 mm<sup>3</sup> in volume. At the present time in order to preserve this space different implants are used. Implant, which is present in decompression space for several months between dissected sclera prevents the fibrosis of filtration space, besides that its hydrophilic properties increase drainage of aqueous from Schlemm's canal and is responsible for greater reduction of IOP. The first used were absorbable implants made of collagen, later-from sodium hialuronide, and as the latest were introduced non absorbable acrylic implants (Aquaflow, SKGEL, T-flux). Reduction in IOP is mainly a result of the reduction of drainage resistance of aqueous in the distal part of Schlemm's canal; other mechanisms for hypotensive effect are: flow through sclera, microperforations of anterior chamber, opening of previously inactive foci in Schlemm's canal and finally uveoscleral drainage.

In post surgical management, for the purpose of functional improvement of the filtration membrane and confirming proper functioning of filtration bleb it is common to use goniopuncture with Nd:YAG laser and antimetabolites.

The purpose of this paper was to compare the effectiveness of DS as a single procedure in relation to FDS in treatment of patients with open-angle glaucoma based on yearly observation.

## **Materials and methods**

Retrospective analysis was used in 67 eyes in 60 patients with open-angle glaucoma, 40 females and 20 males, operated in the Departament of Ophthalmology, Military Health Service Institute in Warsaw from October 2004 until November 2005. In the group of 67eyes there were eyes after DS with scleral implant (SKGEL/Corneal or T-flux/I-Tech), 21 eyes-group I (DS implant). The remaining 47 eyes were eyes after FDS and scleral implants. Because groups were diverse as to the number, from the FDS group 23 eyes were chosen using layer-systematical criteria-group II (FDS implant).

It was open-angle glaucoma as an indication for surgery, which was treated with at least two glaucoma medications without satisfactory control of IOP or progression of changes in the visual field, and in 23 eyes co morbid cataract.

Pre surgical examination included: distance and near BCVA, applanation tonometry, gonioscopy, pachymetry, evaluation of the anterior chamber with biomicroscope, fundoscopic examination in stereoscopic image, statical perimetry with threshold strategy using computerized perimeter Centerfield/Oculus. In 21 eyes DS was performed in one of upper quadrants, and in 23 eyes with concurrent cataract simultaneous phacoemulsification was performed.

Operations were performed by one surgeon (M.R.), in retro bulbar analgesia with 2% Xylocaine augmented by NLA. After cut off of ocular conjunctiva from corneal limbus in upper quadrant, scleral flap was dissected superficially measuring 5.0 x 5.0 mm at the base in limbus. Later a flap measuring 3.5 x 3.5 mm was dissected in the deep sclera reaching sclera spur. In eyes with concurrent cataract in subsequent step phacoemulsification performed from temporal clear cornea incision, combined with coiling lens implant in the posterior chamber into capsular bed. Later deep scleral flap was dissected showing Schlemm's canal and Descemet's membrane included in filtration membrane, (trabeculo-Descemet's membrane). Deep scleral flap was cut off at the Schwalbe line and outer wall of Schlemm's canal was removed. After positioning of the implant in the scleral bed (acrylic implant was sutured with Nvlon 10-0), the superficial flap was closed with single sutures with Nylon 10-0 and conjunctiva was sutured with single Vicryl 8-0 sutures.

In control examination BCVA, IOP, anterior chamber and fundus were examined, post surgical course was analyzed, including complications, applied procedures fixing hypotensive effect (goniopuncture, antimetabolites) and amount of used medications for glaucoma. Examinations were done in 1 and 7 days after surgery, and 1, 3, 6, and 12 months. In case of elevated IOP (>15 mmHg), which was due to filtration membrane failure (lack of or poorly developed filtration bleb), goniopuncture with Nd:YAG laser was used. Elevated IOP (>15 mmHg) with signs of inflammation or fibrosis of the filtering bleb were indication to begin

treatment with antimetabolites. 5-fluorouracyl (5-FU) was used in dose of 5.0 mg, which was given subconjunctivally, 180 degrees from surgical wound, in the area of conjunctival crease. Injections were given daily for 5 subsequent days, and if necessary it was repeated after one week. Antimetabolites were discontinued earlier when IOP was well regulated or side effects occurred. Four weeks after surgery all patients received in the conjunctival sack antibiotic with corticosteroid and NSAID.

Complete success rate was defined as IOP  $\leq$  18 mmHg without glaucoma medication and qualified success rate as IOP  $\leq$  18 mmHg without and with glaucoma medications.

In statistical analysis test U Mann-Whitney was employed as well as pair sequence Wilcoxon test, Ch-square Yates test and Fisher test. Survival analysis was done with Kaplan-Meier method with usage of log rank test.

### Results

Studied groups were homogenous for age, sex, observation time and preoperative IOP (p>.05) (Table I). The mean observation time was 360 days in both groups (Table I).

Demographic	DS implant FDS implant		p*
Follow-up (d)	360	360	1.000
Age (y)			
Mean ± SD	73.9 ± 3.8	72.2 ± 5.4	.963
Range	65-81	60-83	
Sex, n (%)			.341
Female	12(57)	17(74)	
Male	9(43)	6(26)	
Eye, n (%)			.814
Right	10(48)	10(44)	
Left	11(52)	13(56)	
Preoperative IOP (mmHg)			
Mean ± SD	20.3 ± 5.9	22.0 ± 7.6	.511
Range	11 – 45	12 – 33	

Tab. I. Demographical data of studied groups.

Tab. I. Dane demograficzne badanych grup.

# Intraocular pressure control

Mean IOP in group I before surgery was 20.3  $\pm$  5.9 mmHg and was decreased in day one after operation by 57.6% and was 8.6  $\pm$  4.3 mmHg (p=.000). In group II mean IOP in day 1 after surgery decreased by 45.0% from the original 22.0  $\pm$  7.6 mmHg to 12.1  $\pm$  5.2 mmHg (p=.000). After 360 days of observation mean values of IOP in group I were 14.3  $\pm$  3.6 mmHg. and in group II 12.9  $\pm$  3.0 mmHg. It was decrease in mean IOP by 29.6% (p=.000) and 41.4% (p=.000) respectively in particular groups as compared to preoperative IOP (Figure 1). Values

<sup>\*</sup> U Manna-Whitney test

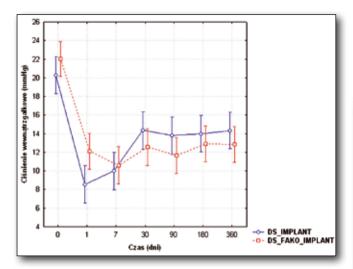


Fig. 1. Mean values of IOP in particular periods after surgery in observed groups.

**Ryc. 1.** Średnie wartości ciśnienia wewnątrzgałkowego w poszczególnych okresach po zabiegu w obserwowanych grupach.

IOP (mmHg)				
Postop (d)	DS implant	p*		
	1			
Mean ± SD	8.6 ± 4.3	12.1 ± 5.2	.022	
Range	4 – 16	4 – 19		
	7			
Mean ± SD	10.0 ± 4.1	10.6 ± 4.7	.669	
Range	4 – 16	3 – 21		
	30			
Mean ± SD	14.4 ± 4.2	1.2 12.6 ± 3.7		
Range	6 – 25	5 – 25		
	90			
Mean ± SD	13.8 ± 4.2	11.6 ± 3.5	.079	
Range	7 – 21	5 – 22		
	180			
Mean ± SD	14.0 ± 4.3	12.9 ± 3.2	.355	
Range	5 – 26	8 – 23		
360				
Mean ± SD	14.3 ± 3.6	12.9 ± 3.0	.159	
Range	10 – 24	6 – 18		

**Tab. II.** Mean values of IOP in particular periods after surgery.

Tab. II. Średnie wartości ciśnienia wewnątrzgałkowego w poszczególnych okresach po zabiegu.

of IOP in studied groups are shown in Table II. Statistically significant differences between group I and 2 were noted in day 1 after surgery (p < .05) (Table II).

### **Medications**

In both groups after surgery fewer medications were used than before operation, and results were statistically significant (p<.05) (Table III). In group I 360 days after operation 13 pa-

Medication (n)	DS implant	FDS implant	p*			
	Preoperative					
Mean ± SD	2.47 ± 0.7	2.24 ± 0.7	.215			
Range	1 – 3	1 – 4				
360 days after						
Mean ± SD	0.71 ± 1.06	0.23 ± 0.61	.164			
Range	0 – 3	0 – 2				
pt	.000	.000				

**Tab. III.** Glaucoma medications used before surgery and 360 days after surgery.

**Tab. III.** Leki przeciwjaskrowe podane przed zabiegiem i 360 dni po nim.

tients (61.9%) did not require glaucoma medications. In group II as many as 82.6% (19 patients) did not require glaucoma medications in the same time after surgery. There were no statistically significant differences between a number of used glaucoma medications in both studied groups at the end of observation (Table III).

### Surgical success

Complete success rate was IOP of  $\leq$  18 mmHg 360 days after surgery without glaucoma medications, and qualified success rate was IOP  $\leq$  18 mmHg without medications or with two medications at the most. Cumulative probability of success based on above criteria for particular periods in observation are shown in Table IV. The Kaplan-Meier curves of survival analysis

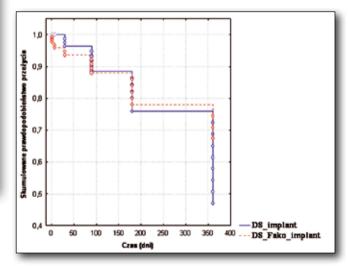


Fig. 2. Cumulated probability of complete surgical success rate in studied groups.

**Ryc. 2.** Skumulowane prawdopodobieństwo pełnego sukcesu pooperacyjnego w badanych grupach.

<sup>\*</sup> U Manna-Whitney test

<sup>\*</sup> U Manna-Whitney test

<sup>†</sup> pair sequence Wilcoxon test

Success rate (%)								
	DS im	DS implant* FDS implant*		DS implant* FDS implant* p†		FDS implant*		t
Postop (d)	Complete	Qualified	Complete	Qualified	Complete	Qualified		
30	96.8	97.8	93.1	94.0	.948	.961		
90	96.8	97.8	93.1	94.0	.878	.937		
180	87.9	94.2	86.5	92.3	.751	.891		
360	72.6	88.4	74.3	86.9	.495	.844		

Tab. IV. Cumulative probability of complete and qualified success rate.

Tab. IV. Skumulowane prawdopodobieństwo pełnego i satysfakcjonującego sukcesu pooperacyjnego.

<sup>†</sup> Log rank test

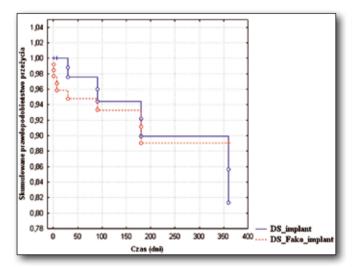


Fig. 3. Cumulated probability of qualified surgical success rate in studied groups.

Ryc. 3. Skumulowane prawdopodobieństwo satysfakcjonującego sukcesu pooperacyjnego w badanych grupach.

for full and satisfactory criteria are shown in Figure 2 and 3. In the entire observation period there were no statistically significant differences between group I and II (p>.05) (Table IV, Figure 2 and 3).

### **Best corrected visual acuity**

Mean BCVA in group I one day after surgery was decreased from 0.77  $\pm$  0.27 to 0.62  $\pm$  0.27, and a month later returned to preoperative values 0.81  $\pm$  0.22 and remained unchanged until the end of observation 0.79  $\pm$  0.21 (p>.05) (Table V). After 12 months from surgery visual acuity did not change in 13 patients (62.0%), improved by 1-2 Snellen lines in 3 patients (14.0%) and deteriorated by 1-2 Snellen lines in 5 patients (24.0%) due to cataract (2 patients-10.0%) and age-related macular degeneration (3 patients – 14.0%). Mean BCVA in group II was changed from 0.40  $\pm$  0.19 before surgery to 0.43  $\pm$  0.26 one day after surgery, to 0.75  $\pm$  0.27 after one month and remained the same for the duration of observation (p < .05) (Table V). At the end of observation visual acuity improved in 21 (91.0%) patients, and in 2 (9.0%) patients was unchanged; due to age-related macular degeneration. After 360 days there was no statistically significant dif-

BCVA (Snellena chart)				
, ,				
Postop (d)	DS implant	FDS implant	p*	
	0			
Mean ± SD	0.77 ± 0.27	0.40 ± 0.19	.000	
Range	0.1 – 1.0	0.05 – 0.8		
	1			
Mean ± SD	0.62 ± 0.27	0.43 ± 0.26	.037	
Range	0.1 – 1.0	0.05 - 0.9		
	30			
Mean ± SD	0.81 ± 0.22	0.75 ± 0.27	.681	
Range	0.15 – 1.0	0.1 – 1.0		
	90			
Mean ± SD	0.79 ± 0.24	0.80 ± 0.25	.649	
Range	0.1 – 1.0	0.1 – 1.0		
	180			
Mean ± SD	0.80 ± 0.22	0.79 ± 0.23	1.000	
Range	0.2 – 1.0	0.1 – 1.0		
360				
Mean ± SD	0.79 ± 0.21	0.79 ± 0.22	.795	
Range	0.3 – 1.0	0.1 – 1.0		
p†	.776	.000		

**Tab. V.** BCVA in studied groups in particular periods of observation. **Tab. V.** Najlepsza skorygowana ostrość wzroku do dali w poszczeg

**Tab. V.** Najlepsza skorygowana ostrość wzroku do dali w poszczególnych okresach obserwacji w badanych grupach.

ferences between mean BCVA between group I and II (p>.05) (Table V, Figure 4)

# Goniopuncture, antimetabolites

Goniopuncture Nd:YAG was performed in 6 eyes in group I (28.6%) and in 5 eyes in group II (21.7%) (p>.05) (Table VI).

<sup>\*</sup> Kaplan - Meier survival analisis

<sup>\*</sup> U Manna-Whitney test

<sup>†</sup> pair sequence Wilcoxon test

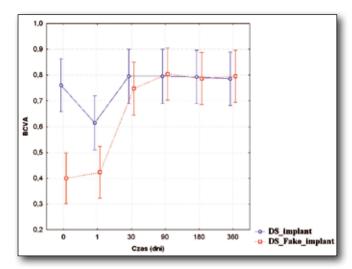


Fig. 4. BCDVA in studied groups.

Ryc. 4. Najlepsza skorygowana ostrość wzroku do dali w badanych grupach.

Goniopuncture, antimetabolites			
DS implant FDS implant			
Goniopuncture, n (%)	6 (28.6)	5 (21.7)	.865*
5-FU, n (%)	5 (23.8)	2 (8.9)	.170†

**Tab. VI.** Goniopuncture and therapy with 5-FU. **Tab. VI.** Goniopunktura i leczenie z użyciem 5-FU.

Subconjunctival injections with 5-FU was performed in 5 eyes in group I (23.8%), and in 2 eyes in group II (8.9%) (p>.05) (Table VI). Mean dose of antimetabolites was 13.0 mg in group I, and 15.0 mg in group II, and mean number of injections was 2.4 and 3.0 respectively.

### **Cocmplications**

Early post-surgical complications included: transient hypotonia (<6 mmHg) in 5 eyes (23.8%) in group I and in 6 eyes (26.0%) in group II, elevated IOP (>20 mmHg) in 2 eyes (9.5%) in group I and in 3 eyes (13.0%) in group II. Shallow the anterior chamber was observed in both groups in 2 eyes (9.5%) in group I and in 1 eye (4.3%) in group II. Choroid detachment (3 eyes-13.0%), and hemorrhage into vitreous body (1 eye – 4.3%) was noted in early postoperative period only in group II. Late postoperative complications included: fibrosis of the filtration bleb was noted in 6 eyes (28.6%) in group I and in 4 eyes (17.3%) in group II. After introduction of 5-FU transient epitheliopathy was observed in 4 eyes (19.0%) in group I and in 2 eyes (8.7%) in group II. Progression of cataract was noted in 2 eyes (9.5%) in group I (Table VII).

# **Discussion**

Traditional approach in treatment of glaucoma, assuming gradual steps from pharmacological therapy, through laser therapy to surgical treatment, after maximizing available means and

Eyes, n (%)					
	DS implant FDS implant		р		
	Early complica	ations			
Hypotony	5 (23.8)	6 (26.0)	. 862*		
IOP > 20 mmHg	2 (9.5)	3 (13.0)	.545†		
Hyphema	1 (4.8)	2 (8.7)	.535†		
Schallow anterior chamber	2 (9.5)	1 (4.3)	.465†		
Choroid detechment	0 (0) 3 (13.0)		.134†		
Vitreus hemorrhage	0 (0)	(0) 1 (4.3)			
	Late complications				
Bleb fibrosis	6 (28.6)	4 (17.3)	.300†		
Cystoid macular edema	2 (9.5)	0 (0)	.222†		
Cataract	2 (9.5)	0 (0)	.222†		
Epitheliopathy	4 (19.0)	2 (8.7)	.288†		

**Tab. VII.** Postoperative complications. **Tab. VII.** Powikłania pooperacyjne.

methods in particular form of therapy, underwent verification in recent years. Published results from multicenter prospective trials (e.g. The Advanced Glaucoma Intervention Study, AGIS) have influenced the verification with associated prostaglandin analogues, and return of pharmacological "philosophy" toward safety and quality of life for the patient.

The alternative for combined pharmacotherapy is nowadays frequently non penetrated surgery, providing decrease in IOP and preservation of visual acuity. Non penetrated techniques, presented for the first time by Epstein and Krasnow at the end of 50's in the last century, later improved in the 80's by Russian School (Fiodorow, Kozlow) and North American (Zimmerman), through several years they remained in the shadow of classical trabeculectomy, as less effective. Rediscovered again 10 years ago, considering high safety profile, they thrive nowadays, which is determined by biotechnological advances, enabled use of high class surgical microscopes and lasers, variety of scleral implants as well as pharmacological strategy of tissue regeneration.

The purpose of this work was to show effectiveness and safety of phacoemulsification and sclerectomy and deep sclerectomy in the material of Departament of Ophthalmology, Military Health Service Institute in Warsaw based on 12 months observation.

In day 1 after surgery, in 21 eyes operated by the DS method, mean IOP was lower by 57.6% than before surgery, and in 23 eyes operated with FDS method- by 45.0%, only for this comparison it was statistically significant difference. Early, tran-

<sup>\*</sup> Ch-square Yates test

<sup>†</sup> Ch-square Fisher test

<sup>\*</sup> Ch-square Yates test

<sup>†</sup> Ch-square Fisher test

sient hypotonia (<6 mmHg) was observed in 28.6% and 17.3% respectively; similar results were noted by D'Eliseo (32.2 vs. 20.0%) (1). Other authors had lower percentage (1.0-8.0%) (2-5). According to Shaarawy (6), hypotonia below 6 mmHg in the first postoperative day has positive prognostic value for the future operative success.

In our own studies, starting from day 7 post surgery in all comparisons statistically significant profile of IOP reduction in relation to pre operation were observed. In day 7 after surgery reduction of mean IOP achieved 50.7% in group I and 51.8% in group II, after a month - 29.1% and 42.7% respectively, after 3 months 32.0% and 47.3%, after 6 months - 31.0% and 41.4% and after 12 months - 29.6% and 41.3%. Despite the fact that from day 7 post operation there were no statistical differences noted between groups, in all comparisons lower IOP values were noted in the FDS group. Similar results after a year observation obtained D'Eliseo (13.1 mmHg vs. 15.2 mmHg) (1). Complete success rate, defined as IOP <20 mmHg without glaucoma medications, was achieved in 90.0% of eyes after FDS and 61.9% of eyes after DS alone. Differences stem from easier aqueous drainage in the pseudophakic eye, due to pulling of the ciliary rim and processes by contracting lens capsule and also by deepening in central and peripheral part of the anterior chamber and lower risk of impaction of peripheral iris in the filtration membrane window and development of so-called internal filtration block (1).

In our own studies complete success rate was achieved in 72.6% of eyes in group I and 74.3% of eyes in group II, and qualified success rate in 88.4% and 86.9% respectively. Studies done by other authors confirm high efficacy of DS in over a year observation. Demailly (4) in 219 eyes, complete success rate (IOP<21 mmHg without meds) noted in 89.0% of eyes after 6 months and 76.0% after 16 months, and qualified success rate (with meds) in 97.0% and 79.0% respectively. Similar results were obtained by Karlen (7). In longer, 36-months observation complete success rate (criteria as above) was achieved in 97.0% of eyes after 6 months, 71.0 % after 24 months and 45.0% after 36 months, and qualified success rate in 99.0%. 98.0% and 98.0% of eyes respectively. Shaarawy (8) in 60months observation of 60 eyes complete success rate noted in 62.0% of cases and qualified success rate in 95.0%. In the above mentioned studies other criteria are noted than authors of this work (IOP<21 mmHg vs. 18 mmHg in this work), which determines higher percentage of efficacy.

Employed surgical therapy allowed discontinuation of glaucoma medications in 61.9% of eyes in group I and 82.6% in group II. Similar results were obtained by D'Eliseo (61.9 vs. 90.5%) (1). In our own study mean number of glaucoma medications was decreased from 2.47 (group I) and 2.24 (group II) before surgery to 0.71 and 0.23 respectively after 12 months from operation. Other authors in several year observations confirm stable hypotensive effect of DS. Karlen (7) in a group of 100 eyes achieved reduction of mean number of glaucoma medications from 2.2  $\pm$  0.7 before surgery to 0.2  $\pm$  0.4 3 years from surgery, and Dahan (9) in the material of 48 eyes after 30 months observation noted decrease of the number of glaucoma medications from 2.3  $\pm$  1.0 to 0.3  $\pm$  0.6 in eyes without implants and complete discontinuation of medications in eyes where DS with implant was performed.

Shaarawy (8) in group of 60 eyes reports almost 5-fold decrease in mean number of glaucoma medications (2.3 vs. 0.49) after five years from operation.

In case of filtration membrane failure and IOP > 15 mmHg goniopuncture was done with laser Nd:YAG. This therapy was used in 28.6% of eyes in group I and 21.7% of eyes in group II, and it was performed in the first month after surgery. Similar or higher percentage of applying this procedure (23.0-47.0%) was noted by other authors (7, 8, 9, 10). Breaking of the filtration membrane caused a change from non penetrated surgical method to penetrated.

In our own material fibrosis and encapsulation of the filtration bleb was observed in 23.8% of eyes in group I and 8.9% of eyes in group II, and percentage was lower than cited by other authors (24.0-34.0%) (7, 8). The treatment of choice in those cases were subconjunctival injections of 5-FU (single dose 5.0 mg); mean number of injections was 2.4 and 3.0 respectively. Although recommended by Fluorouracil Filtering Surgery Study Group (FFSSG) (12), cumulated dose of 5-FU is 35-105 mg (7-21 injections), generally lower dosages (22-35 mg) are used (12, 13). Complications observed in our study after injections of antimetabolites were transient and frequency was lower than reported by other authors (13).

In group II, early hypotonia was associated with minimal (mean 1.5 Snellen line) and short-lived decrease in visual acuity in the first week after surgery, and in group I improvement in visual function was observed. Besides the first week after surgery visual acuity in the group of 21 eyes, which underwent DS, did not change. Non penetrated character of the operation influenced protection against inflammatory reaction in early post operative period in the anterior chamber and long lasting hypotonia, and in late stage-development of the cataract. Observed progression of lens clouding in 9.5% of eyes was not higher than natural lens opacification in a year time in the comparable age group population (7) and was lower than in the eyes after trabeculectomy (14).

In our studies DS and FDS were proven to be safe. Presence of blood in the anterior chamber, noted in the first day post surgery in 1 patient (4.8%) in group I and 2 patients (8.7%) in group II, was probably the effect of backwards drainage from sclera through trabeculum or microperforation of the filtration membrane; frequency of this complication by other authors is around 3.0-7.0% (6, 7). Hemorrhage into vitreous body observed in the first day after surgery in one patient was the consequence of central retinal vein thrombosis. Other complications (shallow anterior chamber, choroid detachment, cystoid macular edema were encountered sporadically (in 2.0-3.0%) and were reversible.

In this work we did not obtain statistically lower values of IOP in group of eyes treated with FDS in comparison with the group of eyes treated with DS alone-some tendency was noted. Observed tendency toward greater reduction of IOP in eyes operated simultaneously for glaucoma and cataract, is confirmed by observations of other authors (6, 15, 16), who prefer in eyes with co morbid cataract combined procedure as a method of choice. FDS is necessary to consider especially in patients with a goal of low IOP and high risk of scar formation in the area of filtration bleb. Combined procedure lowers the risk associated with two subsequent surgical procedures and double anesthe-

sia and influences quick recovery of visual acuity. To fully assess presented surgical technique it seems necessary to continue studies on greater clinical material.

### **Conclusions**

- DS and FDS are effective and safe surgical methods in the treatment of open-angle glaucoma.
- Subconjunctival injections with 5-FU through inhibition of inflammatory reaction in the area of filtration bleb and goniopuncture with YAG laser improving filtration through filtration membrane are effective methods in fixing the filtration pathway.
- DS used as a single method does not influence decrease in the quality of life through lowering of visual acuity, but performed simultaneously with phacoemulsification contributes to significant improvement of visual acuity.

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