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Transitory hypotony as a prognostic factor in combined procedures of phacoemulsification and deep sclerectomy

Przejściowa hypotonia jako czynnik prognostyczny po operacji sklerektomii głębokiej łączonej z fakoemulsyfikacją

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Summary: **Purpose:** To determinate the influence of hypotonia on the effectiveness of phacoemulsification and deep sclerectomy performed simultanously with the SK-gel implant in 15 months follow up.
Material and methods: The retrospective analysis comprised group I (IOP ≤ 6 mm Hg) – 50 eyes and group II (IOP > 6 mm Hg) – 75 eyes. Uncontrolled primary open-angle glaucoma and coexisting cataract were the indication. DBCVA, IOP, anterior segment and eye fundus were assessed as well as the number of antiglaucoma medications. The patients were examined on the first and the seventh day as well as at 1, 3, 6, 12 and 15 months. IOP ≤ 12.15 and 18 mm Hg was accepted as surgical success criterion. T - Student test was used in statistical analysis and variance was analysed. The survival analysis was worked out with Kaplan-Meier method.
Results: After 15 months the decrease of mean IOP was obtained in group I by 35.9% ($p < 0.05$) and in group II by 33.5% ($p < 0.05$). There were no statistical differences between the number of the applied antiglaucoma medications in the investigated groups. Finally, a qualified surgical success was obtained for the criterion ≤ 18 mmHg in 97.7% of cases in group I and in 87.9% in group II ($p = 0.013$). For the criterion ≤ 15 mm Hg – in group I 84.3% and in group II 66.4% ($p < 0.001$), whereas for the criterion ≤ 12 mm Hg respectively in group I 41.2% and in group II 39.3% ($p = 0.015$). DCBVA 15 months after the surgery was 0.84 ± 0.24 in group I and 0.71 ± 0.25 in group II. At the end of the follow up no significant differences of DBCVA were found between the investigated groups ($p > 0.05$).
Conclusions: Hypotonia is an important positive prognostic factor in the first 24 h after surgery in the case of phacoemulsification, performed at the same time with deep sclerectomy.

Słowa kluczowe: hypotonia, sklerektomia głęboka, SK-gel implant.
Key words: hypotonia, deep sclerectomy, SK-gel implant.

Introduction

The fibrosis in postoperative period is a limitation in penetrated procedures applied in current glaucoma surgery (1,2). This process can limit to a lesser extent the results of non-penetrating surgeries because subconjunctival route is one of four routes of aqueous humour outflow (3). However, it should be emphasized that the presence of a flat filtering bleb also in this case is a favourable prognostic symptom (4). In the initial postoperative period deep sclerectomy functions similarly to classic trabeculectomy through subconjunctival route and only then transcleral, suprachoroid and Schlemm's canal routes are activated (3). Thus, the filtering membrane TDM (trabeculo-Descemet's membrane), containing Descemet's membrane and Schlemm's canal devoid during surgery of the external wall, is the main barrier between the anterior chamber and subconjunctival space. Particularly that the scleral flap contrary to trabeculectomy is not a marked counterbalance for this outflow in the case of non-penetrating procedures due to decompressive space formed in the sclera.

Non-penetrating deep sclerectomy is technically a difficult surgical procedure and thus it does not find many supporters among glaucoma surgeons. The most difficult technically moment of the surgery is identification of Schlemm's canal and its deroofing as well as separation of the Descemet's membrane from the sclera (5). Cicatricial changes resulting either from the nature of the pathological process or from iatrogenic effect of previous procedures such as trabeculoplasty, goniopuncture or prolonged pharmacotherapy can be the cause of technical problems and in consequence of intraoperative complications (6). And in this aspect, to achieve good follow up results the above remarks should be taken into account in the qualification for surgery.

Hypotony in the initial postoperative period may be the reflection of the surgical technique particularly of the correctness of TDM dissection. Thus, it is justified to verify its effect on the outcome of non-penetrating surgeries combined with phacoemulsification which has become the aim of this study.

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Material and methods

125 eyes of 111 patients with medically uncontrolled primary open angle glaucoma were subjected to prospective analysis. All these patients were treated at the Military Health Service Institute in Warsaw. There were 59 women and 52 men, mean age 73.4 ± 7.5 years. Each patient underwent phacoemulsification and deep sclerectomy at the same time with SK-gel implant. Open angle glaucoma treated with at least two antiglaucoma drugs, without satisfying IOP control or progression of defects in visual field and coexisting cataract, were the indications for surgery.

In the first stage non-penetrating deep sclerectomy was performed according to the technique suggested by Shaarawy et al. (7). In the next stage phacoemulsification was performed with implantation of intraocular lens (IOL) MA60BM, SA60AT, SN60AT or SN60WF into the lens capsule.

The patients received an antibiotic with corticosteroid and nonsteroidal anti-inflammatory drugs into the conjunctival sac for 4 weeks after the procedure. Then, topical steroid drops were applied again for 4 weeks to preserve the effect of the surgery.

The investigated group was divided into two groups according to the occurrence of hypotony within the first postoperative day or its lack. The criterion of division was accepted at 6 mm Hg on the basis of hazard coefficient ≈ 1.0. Group I (IOP ≤ 6 mm Hg) included 50 eyes (40% of all cases), whereas group II (IOP > 6 mm Hg) included 75 eyes (60% of all cases). Demographic data of both groups are demonstrated in table I.

Demographic	Group I (n=50)	Group II (n=75)	p
Follow up (d)	540	540	1.000*
Age (y)			
Mean ± SD	71.0 ± 7.9	74.1 ± 7.1	.476†
Range	46-82	32-86	
Sex (n)			.106*
Female	27(46)	32(65)	
Male	19(46)	33(65)	
Eye (n)			.498*
Right	24(50)	36(75)	
Left	26(50)	39(75)	
P_0 (mmHg)			
Mean ± SE	19.5 ± 4.5	20.3 ± 5.9	.413¤
Range	12-32	11-36	

Tabl. I. Demographic data of the investigated groups.
Tabl. I. Dane demograficzne badanych grup.
* U Mann-Whitney's test
† t-Student's test
¤ one-way ANOVA
* one-way ANOVA

Before surgery, the patients underwent distance and near corrected visual acuity assessment (DBCVA, NBCVA), IOP was measured using applanation tonometry method, anterior segment was estimated in biomicroscope and fundus stereoscopy was performed. After surgery the examinations were conducted on the first and the 7, 30, 60, 90, 180, 360 and 450 day.

Surgery was considered a complete success when IOP was ≤ 12, 15, 18 mm Hg without glaucoma medication and a qualified success when IOP was ≤ 12, 15, 18 mm Hg without or with maximum 2 antiglaucoma medications.

Statistical analysis was performed using t-Student test and variance was analysed. The survival analysis was worked out with Kaplan-Meier method using log rank and regression was analysed with Cox proportional hazards model.

Results

IOP control

The mean IOP before surgery was in group one 19.5 ± 4. 5 mm Hg and it decreased at the first postoperative day by 72.3% to the value 5.4 ± 0.9 mm Hg ($p < 0.001$) (Tab. II, Fig. 1). After 15 months follow up mean IOP was 12.5 ± 2.5 mm Hg and it was lower by 35.9% ($p < 0.05$) in relation to IOP before the surgery. Mean IOP in group II was respectively before

IOP (mmHg)			
Time (d)	Group I	Group II	p*
1			.006
Mean ± SE	5.4 ± 0.9	12.6 ± 4.9	
Range	4 – 6	7 – 40	
7			
Mean ± SE	7.4 ± 3.7	11.6 ± 4.3	
Range	2 – 19	4 – 28	
30			.014
Mean ± SE	12.2 ± 4.4	12.7 ± 2.7	
Range	4 – 30	6 – 19	
180			
Mean ± SE	12.9 ± 2.5	13.4 ± 3.2	
Range	7 – 18	6 – 23	
360			
Mean ± SE	13.0 ± 2.1	13.8 ± 4.3	
Range	9 – 18	6 – 38	
450			
Mean ± SE	12.5 ± 2.5	13.5 ± 2.0	
Range	8 – 16	10 – 17	

Tabl. II. Mean values of intraocular pressure in particular postoperative stages.
Tabl. II. Średnie wartości ciśnienia wewnątrzgałkowego w poszczególnych okresach po zabiegu.

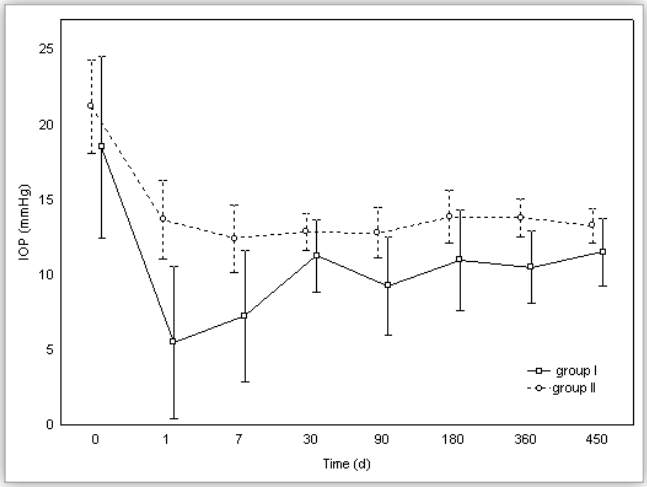

Fig. 1. Mean values of intraocular pressure in particular periods after surgery.
Ryc. 1. Średnie wartości ciśnienia wewnątrzgałkowego w poszczególnych okresach po zabiegu.

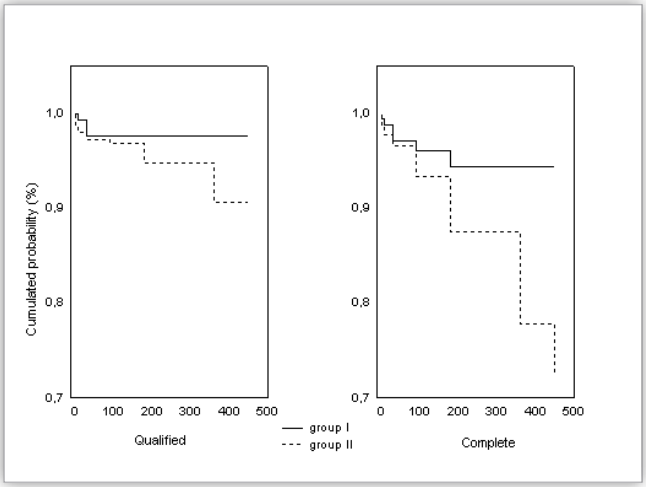

Fig. 2. Cumulated probability of postoperative success in the investigated groups (success criterion IOP ≤ 18 mm Hg).
Ryc. 2. Skumulowane prawdopodobieństwo sukcesu pooperacyjnego w badanych grupach (kryterium sukcesu IOP ≤ 18 mm Hg).

the procedure 20.3 ± 5.9 mm Hg and it decreased at the first postoperative day by 38.5% to the value 12.6 ± 4.9 mm Hg ($p < 0.001$) (Tab. II, Fig. 1). After 15 months follow up mean IOP was 13.5 ± 2.0 mm Hg and it was lower by 33.5% ($p < 0.05$) in relation to IOP before the surgery. In the whole follow up period mean IOP values in group I were significantly lower than in group II ($p < 0.05$).

Glaucoma medications

The number of the administered antiglaucoma medications decreased in group I from 2.28 ± 0.68 before surgery to 0.20 ± 0.64 after 15 months follow up ($p < 0.05$). Whereas in group II it decreased from 2.29 ± 0.74 before the procedure to 0.26 ± 0.78 at the end of the follow up ($p < 0.05$).

At the end of 15 months follow up the difference between both groups was statistically insignificant (Tab. III).

Surgical success rate

At the end of the follow up a complete success for the criterion ≤ 18 mm Hg was obtained in 94% of group I cases and in 72% of group II cases ($p < 0.013$), a qualified success in 98% of group I cases and in 88% of group II cases ($p = 0.011$) (Fig. 2).

Medication	Group I	Group II	p*
Preoperative			
Mean ± SD	2.28 ± 0.68	2.29 ± 0.74	.935
Range	1 – 4	1 – 4	
450 days after			
Mean ± SD	0.20 ± 0.64	0.26 ± 0.78	.612
Range	0 – 3	0 – 2	
p†	<.001	<.001	

Tabl. III. Antiglaucoma medication before and 450 days after surgery.
Tabl. III. Stosowane leki przeciwjaskrowe – przed zabiegiem i 450 dni po operacji.
* U Mann-Whitney's test
† pair sequence Wilcoxon's test

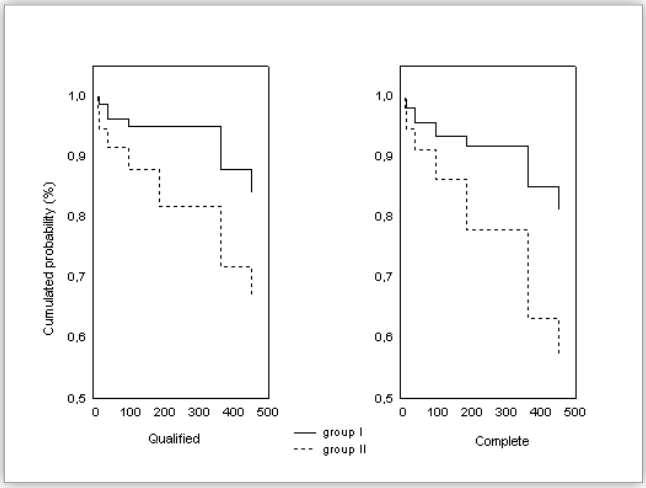

Fig. 3. Cumulated probability of postoperative success in the investigated groups (success criterion IOP ≤ 15 mm Hg).
Ryc. 3. Skumulowane prawdopodobieństwo sukcesu pooperacyjnego w badanych grupach (kryterium sukcesu IOP ≤ 15 mm Hg).

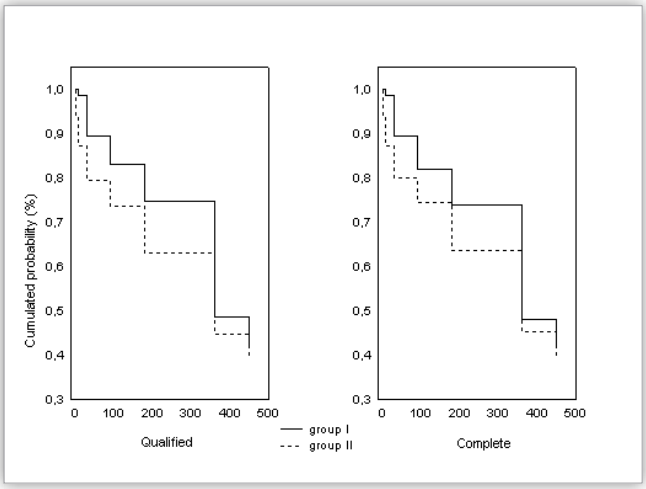

Fig. 4. Cumulated probability of postoperative success in the investigated groups (success criterion IOP ≤ 12 mm Hg).
Ryc. 4. Skumulowane prawdopodobieństwo sukcesu pooperacyjnego w badanych grupach (kryterium sukcesu IOP ≤ 12 mm Hg).

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At the same time for the criterion ≤ 15 mm Hg a complete success was obtained in 81% of group I cases and in 57% of group II cases (p = 0.001), whereas a qualified success in 84% of group I cases and in 66% of group II cases (p = 0.001) (Fig. 3). For the criterion ≤ 12 mm Hg a complete success was obtained in 41% of group I cases and in 39% of group II patients (p < 0.015) and a qualified success in 42% of group I cases and in 38% of group II cases (p = 0.013) (Fig. 4).

Best corrected visual acuity (BCVA)

BCVA in group I changed from 0.56 ± 0.28 before surgery to 0.84 ± 0.24 after 15 months follow up, whereas in group II it changed from 0.44 ± 0.27 to 0.71 ± 0.25. At first day post surgery BCVA in group I was 0.45 ± 0.23 and in group II 0.47 ± 0.26. Both, at first day 1 post surgery and at the end of the follow up no significant differences were observed in visual acuity between the investigated groups (p> 0.05) (Tab. IV, Fig. 5).

BCVA (wg Snellena)			
Czas (dni)	**grupa I**	**grupa II**	**p***
0			
Mean ± SD	0.56 ± 0.28	0.44 ± 0.27	.245
Range	0.1 – 1.0	0.1 – 1.0	
1			
Mean ± SD	0.45 ± 0.23	0.47 ± 0.26	
Range	0.1 – 1.0	0.1 – 1.0	
7			
Mean ± SD	0.60 ± 0.23	0.55 ± 0.29	
Range	0.2 – 1.0	0.1 – 1.0	
30			
Mean ± SD	0.69 ± 0.23	0.61 ± 0.27	
Range	0.1 – 1.0	0.1 – 1.0	
180			
Mean ± SD	0.83 ± 0.27	0.71 ± 0.26	
Range	0.1 – 1.0	0.1 – 1.0	
360			.729 .249
Mean ± SD	0.84 ± 0.23	0.71 ± 0.25	
Range	0.1 – 1.0	0.1 – 1.0	
450			
Mean ± SD	0.84 ± 0.24	0.71 ± 0.23	
Range	0.3 – 1.0	0.1 – 1.0	

Tabl. IV. Mean distance best corrected visual acuity in the investigated groups in particular periods of follow up.

Tabl. IV. Średnia najlepsza skorygowana ostrość wzroku do dali w badanych grupach w poszczególnych okresach obserwacji.

* Jednoczynnikowa analiza wariancji (ANOVA) – porównania zaplanowane

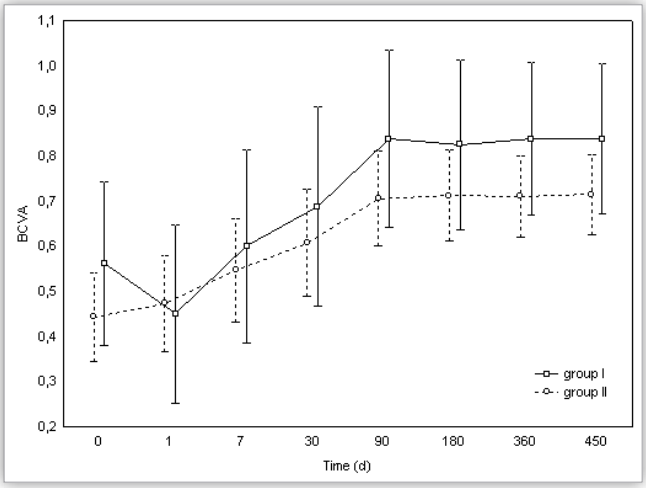

Fig. 5. Mean distance best corrected visual acuity in the investigated groups.

Ryc. 5. Średnia najlepsza skorygowana ostrość wzroku do dali w badanych grupach.

Discussion

The safety of non-perforating operations results from the fact, that during the procedure the opening of the eye anterior chamber is not necessary. Owing to that, in the postoperative period no anatomical changes are observed between the anterior and posterior segment of the eye. Hypotony, being the complication of perforated operations, becomes simultaneously the limitation of their effects in long-term follow up due to fibrosis (1, 2). Both, in the case of perforating and non-perforating operations hypotony results from excessive outflow of aqueous humour from anterior chamber in postoperative period. However, in sclerectomy TDM provides outflow resistance and prevents from excessive filtration and the resulting hypotony is usually short-lasting and without changes of anatomical relations (1,8,9) (Fig. 1). Sclerectomy is in fact microtrabeculectomy, because during the Schelmm's canal deroofing there comes to perforation of its opposite wall through septa connecting these walls (10). On the other hand, the outflow of aqueous humour also takes place through Descemet's membrane, devoid of connective tissue. These two elements decide on the technique of surgical procedure and postoperative hypotony can be their derivative.

In our observations, mean IOP decreased at first day after surgery by 72.3% in group I and by 38.5% in group II, and after 15 months follow up the reduction of mean IOP was respectively 35.9% and 33.5%. In the group of patients with hypotony, lower IOP values were obtained throughout the whole follow up period and they differentiated significantly the investigated groups (p= 0.014). Shaarawy et al. (11) in similar study, in the group of patients with IOP 5.1 mm Hg at first day after surgery, noted reduction of mean IOP by 55.5% after 30 months and by 55.4% after 48 months of follow up. However, it should be observed that mean initial IOP in this group was 26.8 mm Hg, but at the end of the follow up period it was 12.2 mm Hg and it was similar to the value obtained in our study (tab. II). The authors emphasize in other studies that obtaining low IOP at first day of the surgery enables to obtain stable IOP in many years follow up (7,12). Nevertheless, there is a question whether IOP obtained in the group with hypotony is a sufficient indicator proving correct functioning of TDM? Similarly as in the case of trabeculectomy filtering bleb fibrosis also in sclerectomy is a limitation in the surgery

functioning, and the established balance between aqueous humour filtration through TDM and resistance of scleral flap and the remaining routes of outflow decide of the effective IOP control. Thus, in this aspect we analysed the success of the surgery according to the criteria of IOP ≤ 12, 15, 18 mm Hg. In the case of the group with hypotony a complete success was obtained respectively in 41, 81 and 94% of patients and the differences between the investigated groups were statistically significant at all levels ($p < 0.05$). Significant differences were also observed between the investigated groups in the case of qualified success ($p < 0.05$) in group I it was 42, 84 and 98% respectively for the criteria accepted for this study. Karlen et al. (13) in 38 months follow up noted a complete success in 44.6% of patients with hypotony and a qualified success in 97.7% . However, Shaarawy et al. (7) a complete success found in 61.9% of patients, a qualified success in 94.8% of patients after 60 months of follow up and they confirmed their results in 8 years follow up (14). In the mentioned studies a complete surgical success was defined as IOP < 21 mm Hg without antiglaucoma medications, a qualified surgical success as IOP < 21 mm Hg with or without medications (7,12,13,14). Thus, it seems that normally functioning TDM and at the same time not too aggressive process of bleb obliteration enable to control IOP after surgery at the level of 12 mm Hg which in our study concerned only 41% of patients. In the remaining cases when IOP was regulated at a higher level without medication we can assume that the cause of this condition may be TDM dysfunction. Introduction of medication results from progressing fibrosis of subconjuncitval route of outflow, particularly that we did not find differences between the number of applied medications after surgery in both the investigated groups ($p > 0.05$). However, these conclusions require confirmation in histological examinations of sclera and Schlemm's canal which we have not performed. The fact that the surgical technique decides on the effectiveness of non-perforating surgeries has been emphasized by numerous authors (11,15,16,17,18). Rossier et al. and Vandaux et al. think that appropriately deep excision of sclera guarantees IOP stabilisation (17,18), while Jonescu-Cuypers et al. (15) emphasize the surgeon's experience and Mermound points to the anatomy of iridocorneal angle (16). In our study hypotony was obtained in the first postoperative day in 40% of patients, while in the study of Shaarawy et al. (11) in as many as 61% of patients from the investigated group. In the first postoperative week in group I we observed decrease of BCVA resulting from hypotony, which finally did not have any effect on the result after 15 months. Similar tendency was observed in our previous study and it was also confirmed by other authors (7). Hypotony after phacodeepsclerectomy occurring directly after the procedure seems to be a prognostic factor which proves proper functioning of TDM. However, this conclusion requires confirmation in histological examinations of TDM in the aspect of its functioning after surgical procedure. Undoubtedly, the occurrence of hypotony affects the results of survival and IOP control in 15 months follow up.

References:

1. Dahan E, Drusedau MU: *Nonpenetratin filtration surgery for glaucoma: control by surgery only.* J Cataract Refract Surg 2000, 26, 695-701.
2. Kahook M, Schumann JS, Noecker RJ: *Needle bleb revision of encapsulated filtering bleb with bevacizumab*. Ophthalmic Surg Lasers Imaging 2006, 37, 148-150.
3. Mechanisms of filtration in non-penetrating filtering surgeries. Mermound A, Ravinet E: *Non-penetrating glaucoma surgery*, 1st ed. London: Martin Dunitz, 2001, 57-65.
4. Marchini G, Marraffa M, Brunelli C et al.: *Ultrasound biomicroscopy and intraocular-pressure-lowering mechanisms of deep sclerectomy with reticulated hyaluronic acid implant.* J Cataract Refract Surg 2001, 27, 507-517.
5. Price FW, Zeh WG: *Viscoelastic material as an adjunct to dissections and treat microperforations during nonpenetrating filtering surgery*. J Cataract Refract Surg 2001, 27, 639-641.
6. Drolsum L: *Conversion from trabekulektomy to deep sclerectomy.* Prospective study of the first 44 cases. J Cataract Refract Surg 2003, 29, 1378-1384.
7. Shaarawy T, Karlen M, Schnyder C et al.: *Five-year results of deep sclerectomy with collagen implant.* J Cataract Refract Surg 2001, 27, 1770-1778.
8. Rękas M, Wierzbowska J, Lewczuk K et al.: *Comparison of phacodeepsclerectomy performer with implantation SK-gel and T-flux – 12 months observation.* (in press)
9. Rękas M, Wierzbowska J, Lewczuk K et al.: *Efficacy and safety of deep sclerectomy and phacoemulsification and deep sclerectomy in clinical material of Military Health Service Institute – yearly observations*. Klin Oczna 2006, 108, 385-391.
10. Sit AJ, Coloma FM, Ethier CR et al.: *Factors affecting the pores of the inner wall endothelium of Schlemm's canal*. Invest Ophthalmol Vis Sci 1997, 38, 1517-1525.
11. Shaarawy T, Flammer J, Smits G et al.: *Low first postoperative day intraocular pressure as a positive prognostic indicator in deep sclerectomy.* Br J Ophthalmol 2004, 88, 658-661.
12. Shaarawy T, Nguyen C, Schnyder C et al.: *Comparative study between deep sclerectomy with and without collagen implant: long term follow up.* Br J Ophthalmol 2004, 88, 95-98.
13. Karlen ME, Sanchez E, Schnyder CC et al.: *Deep sclerectomy with collagen implant:medium term results.* Br J Ophtalmol 1999, 83, 6-11.
14. Shaarawy T, Mansuori K, Schnyder C et al.: *Long-term results of deep sclerectomy with collagen implant.* J Cataract Refract Surg 2004, 30, 1225-1231.
15. Janescu-Cuypers C, Jacobi P, Konen W et al.: *Primary viscocanalostomy versus trabeculectomy in white patients with open-angle glaucoma: a randomized clinical trial.* Ophthalmology 2001, 108, 254-258.
16. Mermound A: *Sinusotomy and deep sclerectomy.* Eye 2000, 14, 531-535.
17. Rossier A, Uffer S, Mermound A: *Aqueous dynamics in experimental ab externo trabeculectomy.* Ophthalmic Res 2000, 32, 165-171.
18. Vandaux J: *Aqueous dynamics after deep sclerectomy: in vitro study.* Ophthalmic Practice 1999, 16, 204-209.

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