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The effect of intraocular lens material and postoperative therapy on the posterior capsule opacification development after the senile cataract surgery

Ефекат материјала интраокуларног сочива и постоперативне терапије на развој замућења задње капсуле сочива након операције сенилне катаракте

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The effect of intraocular lens material and postoperative therapy on the posterior capsule opacification development after the senile cataract surgery

Ефекат материјала интраокуларног сочива и постоперативне терапије на развој замућења задње капсуле сочива након операције сенилне катаракте

SUMMARY

Introduction/Objective The most frequent postoperative complication of a successfully performed phacoemulsification cataract surgery is the development of posterior capsule opacification (PCO). It is caused by the proliferation and migration of the remaining residual epithelial cells.

The objective of this study was to investigate the influence of two different intraocular lens and two different anti-inflammatory drugs on the development of posterior capsule opacification in one-year follow-up period.

Methods Investigation included 120 patients, (120 eyes), equally divided into four groups. The first two groups included patients who used postoperatively non steroid anti-inflammatory drug (NSAID), while the rest groups had corticosteroid therapy. The first and third group got hydrophilic intraocular lenses (IOLs), the second and fourth group had hydrophobic IOLs. Software program EPCO 2000 was used for the analysis of PCO. Statistical analysis was done by using IBM SPSS. Student's *t*-test, Wilcoxon test and ANOVA were used for data analysis and $p < 0.05$ value was accepted as statistically significant.

Results After the first three postoperative months patients from NSAID groups had mean PCO score 0.25 ± 0.03, which was statistically significant higher ($p = 0.042$) comparing to corticosteroid groups. At the end of the investigation, the best result in PCO preventing was seen in the group of patients with hydrophobic IOLs and corticosteroid therapy, with the mean PCO score of 0.47 ± 0.08.

Conclusion This study has revealed that IOLs made of acrylic hydrophobic material seemed to be the right choice when choosing intraocular lens to prevent PCO development. On the other side, NSAID and corticosteroid therapy have showed similar results in preventing postoperative, intraocular inflammation. This fact can be very useful in situations when corticosteroids must be used with great caution.

Keywords: posterior capsule opacification; intraocular lens; nonsteroidal anti-inflammatory drugs; corticosteroids

САЖЕТАК

Увод/Циљ Најчешћа постоперативна компликација успешно изведене операције катаракте факоемулзификацијом је развој замућења задње капсуле сочива. То је проузроковано пролиферацијом и миграцијом преосталих резидуалних епителних ћелија.

Циљ ове студије је испитивање утицаја два различита интраокуларна сочива и два различита анти-инфламаторна лека на развој замућења задње капсуле сочива током једногодишњег периода праћења.

Методе Истраживање је обухватило 120 пацијената (120 очију), подједнако подељених у четири групе. Прве две групе укључивале су пацијенте који су користили постоперативно нестероидни антиинфламаторни лек (*NSAIL*), док су остале групе добиле кортикостероидну терапију. Прва и трећа група добиле су хидрофилна интраокуларна сочива (ИОС), а друга и четврта хидрофобна ИОС. За анализу замућења задње капсуле сочива коришћен је софтверски програм *EPKO 2000*. За статистичку обраду коришћен је програм *IBM SPSS*. Студенов Т тест, Вилкоксонов тест и *ANOVA* коришћени су за анализу података, а $p < 0,05$ вредност је прихваћена као статистички значајна.

Резултати Након три постоперативна месеца пацијенти из група *NSAIL*-а имали су средњу вредност замућења задње капсуле сочива 0.25 ± 0.03, што је било статистички значајно више ($p = 0,042$) у поређењу са кортикостероидним групама. На крају студије, најбољи резултати у спречавању настанка замућења задње капсуле сочива забележени су у групи пацијената са хидрофобним ИОС и кортикостероидном терапијом, са средњом вредношћу 0,47 ± 0,08.

Закључак Ова студија је показала да су интраокуларна сочива израђена од акрилатног хидрофобног материјала била прави избор приликом одабира интраокуларног сочива у спречавању развоја замућења задње капсуле сочива. Са друге стране, *NSAIL* и терапија кортикостероидима су показале сличне резултате у превенцији постоперативне, интраокуларне инфламације. Ова чињеница може бити веома корисна у ситуацијама када се кортикостероиди морају употребљавати са великим опрезом.

Кључне речи: замућење задње капсуле сочива; интраокуларна сочива; нестероидни анти-инфламаторни лекови; кортикостероиди

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INTRODUCTION

Cataract represents blur of the eye lens, which affects everyone over the age of 65. This process is physiological and occurs due to the morphological and biochemical processes of

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the eye lens that appear with aging. Cataract developed in this manner is known as a senile cataract [1]. The only possible cataract treatment is a surgical one, and that procedure is entitled phacoemulsification [1, 2]. Cataract surgery is one of the most commonly performed surgical procedures worldwide [3]. Although it represents a routine, this surgery is neither without risk, nor without complications. Those complications could be temporary and mild, such as corneal edema or temporary postoperative intraocular pressure rise, but also very serious like posterior capsule rupture, suprachoroidal hemorrhage, and postoperative endophthalmitis [3]. The most frequent postoperative complication of a successfully performed cataract surgery is the development of PCO, also known as the secondary cataract [4] (Figure1). It could provoke decreased best corrected visual acuity, contrast sensitivity reduction, glare occurrence or monocular diplopia [4].

Posterior capsule opacification is caused by proliferation and migration of the remaining residual epithelial cells. These cells are divided into "A" cells which are situated under at the anterior lens capsule, and "E" cells situated near lens equator [1]. Phacoemulsification breaks down the blood-aqueous barrier and releases inflammatory cytokines. This local inflammatory reaction, activates "E" cells that proliferate, migrate, and lead to the posterior capsule opacification [1, 2]. Many methods are used to reduce inflammation and cells migration. They are performed during the phacoemulsification, such as emphasized hydrodisection, in-the-bag IOL implantation, capsulorhexis size, or postoperative by picking adequate IOLs and anti-inflammatory therapy [5–8].

The aim of this study is to investigate the influence of two different intraocular lenses and two different anti-inflammatory drugs on the development PCO in a one-year follow-up period.

METHODS

This study was a prospective, randomized study, conducted at the Clinic of Ophthalmology, Clinical Centre Kragujevac, Serbia from 1st Jun 2017 until the 1st Jun 2018. It included 120 patients (120 eyes), who were recruited for the cataract surgery. After the successfully performed phacoemulsification, patients were divided into four groups according to the implanted IOL and postoperative anti-inflammatory therapy.

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The main inclusion criterion was the existence of the senile cataract. Patients with all other cataract types, such as traumatic, iatrogenic, complicated or presenile cataract, were not allowed to participate in the study. The patients with previous history of intraocular surgery, trauma, inflammatory diseases of anterior eye segment, zonular weakness, glaucoma, were not able to participate. Those patients who were on a chronic topical, intraocular or systemic anti-inflammatory therapy were also excluded. The study involved only participants who underwent uncomplicated phacoemulsification.

With the approval of institutional Ethics Committee and according to the tenets of the Declaration of Helsinki, all patients gave their written consent at the beginning of the investigation.

A complete ocular examination was performed before the surgery as well as at every postoperative visit for every patient. That included: visual acuity, intraocular pressure measurement, slit lamp evaluation, retinal examination and ocular ultrasonography. Five days before the surgery, topically 0.3% solution of ofloxacin was administrated, 5 times per day.

The patients were randomized by picking two unmarked, opaque envelopes. The first envelope determined which IOL would be implanted. We used two acrylic, single-piece, square-edged IOLs: hydrophilic – Eyecryl plus 600 (Biotech visioncare, Luzern, Switzerland) and hydrophobic – SA60AT (Alcon-Couvreur NV, Puurs, Belgium). The second envelope was about postoperative therapy: NSAID – nepafenac ophthalmic suspension 0.1% or dexamethasone phosphate 0.1%.

When all preoperative protocols were satisfied, the phacoemulsification was performed by two experienced surgeons. Phaco machine for all surgeries was Stellaris (Bausch & Lomb). Adequate mydriasis was achieved using topical phenylephrine hydrochloride ophthalmic solution 2.5%. Tetracaine eye drops was the only anesthetic drug used during the surgery. Paracentesis and clear corneal incisions were made. Viscoelastic sodium hyaluronate ophthalmic solution 1.4% fulfilled the anterior chamber and continuous curvilinear capsulorhexis, hydrodisection and nucleus rotation followed. Then the nucleus was cracked and aspirated using the “stop and chop” technique. Irrigation and aspiration were performed to aspirate the remaining lens cortex. Capsular bag was fulfilled with viscoelastic and intraocular lens was implanted with adequate injector. When the viscoelastic was removed, intracameral solution of cefuroxime with 1mg/0.1 ml balanced salt solution was injected.

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Corneal incisions hydrated by balanced salt solution using a blunt injection needle. Postoperatively patients instilled topically 0.3% solution of ofloxacin 5 times daily, for 1 postoperative week, and one of two possible anti-inflammatory drugs, 4 times a day, during the first postoperative month.

After the randomization and phacoemulsification, 120 patients were equally divided into four groups (n = 30). The first two groups included patients who used postoperatively non steroid anti-inflammatory drug with the difference that patients in the first group got hydrophilic intraocular lens, and the patients in the second group got hydrophobic intraocular lens. The other two groups were the corticosteroid groups. Hydrophilic IOLs were implanted in group three, while the patients from the fourth group got hydrophobic IOLs (Table 1).

After the release from the Clinic, follow-up examinations were performed on one, three, six and twelve months after the cataract surgery. At these visits, during the slit lamp examination in a full mydriasis and retroillumination, digital high-resolution images were taken for each patient. All images were analyzed by using EPCO 2000, a standard software program for analysis of posterior capsule opacification [6]. The boundaries of each opaque area noticed at the posterior capsule were marked using a computer mouse. According to the density of these areas, opacification was scaled from 0 to 4 grade. Posterior capsule without any opacification was considered as 0 grade. Other grades included: minimal (1st grade), mild (2nd grade), moderate (3rd grade) and severe (4th grade) posterior capsule opacification. The PCO score for each area was calculating by multiplying the opacification density grade with the fraction of the capsule area. Sum of all these individual PCO scores defined total PCO score for the analyzed image.

Statistical analysis was done by using SPSS. The significance at different time intervals during the study was tested by the Student's t-test, or by the Wilcoxon equivalence test in case where the distribution was not normal. Examination of the incidence of opacification in dependence on the type of intraocular lens, was done by using the χ^2 test and ANOVA ($p < 0.05$ value was accepted as statistically significant).

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RESULTS

Examined patients had mean age 76.4 ± 6.8 years (range 66–88 years) without statistical significance among the groups. Sixty-four females and 56 males were equally divided into four groups. During the study, 4 patients from corticosteroid groups had temporary intraocular pressure rise which was efficiently treated with antiglaucomatous eye drops. Two patients developed postoperative macular edema (both from the corticosteroid groups) and one patient died, so they were excluded from the investigation.

At the first control, one month after the phacoemulsification, the mean PCO score among the groups was: I = 0.12 ± 0.03, II = 0.08 ± 0.02, III = 0.06 ± 0.01, IV = 0.05 ± 0.01 (Table 2). Groups II–IV had first grade opacification, while some patients from the first group developed second grade opacification. Statistically significant difference was noticed among first and all other groups, as well as between NSAID and corticosteroid groups (p=0.032).

At the next visit, once more participants from NSAID groups had worse mean PCO score (I = 0.26 ± 0.04; II = 0.23 ± 0.03) compared to those with topical corticosteroid (III = 0.21 ± 0.03; IV = 0.18 ± 0.05), with calculated statistical significance (p=0.042). Comparing all four groups separately, statistically significant difference was detected only between I and IV group (p = 0.03).

After six posteroperative months, the mean PCO score in the fourth group was statistacally different from other groups (I = 0.44 ± 0.10; II = 0.37 ± 0.05; III = 0.42 ± 0.08; IV = 0.32 ± 0.04). Analyzing participants who have got hydrophilic IOLs, the difference between these groups was not significant, p = 0.069.

Twelve months after the cataract surgery, the fourth group had the lowest mean PCO score, 0.47 ± 0.08. The mean PCO score in other groups was: I = 0.64 ± 0,12, II = 0.49 ± 0.06 and III = 0.57 ± 0.09. No statistically significant difference was found between II and IV group (p = 0.061). Statistical significance was seen among the first and all other groups, as well as between hydrophobic vs hydrophilic groups (p < 0.001).

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DISCUSSION

According to many studies, PCO still remains the most common complication of successfully performed cataract surgery [6,9,10]. The only known treatment of formed PCO is Nd:YAG capsulotomy. This procedure is not without risk. Some of the possible complications are IOL damage, retinal detachment, macular edema, intraocular pressure rise [11]. So, all investigators agree that the best treatment of PCO is to prevent it [10, 11].

Corticosteroids are well known to have anti-inflammatory action, but they can cause severe ocular side effects: intraocular pressure rise, cataract development, disturbance of corneal wound healing [12]. For this reason, not small number of phaco surgeons are interested in some alternatives. NSAIDs for ocular use are mostly administrated in the management of ocular inflammation with non-infectious origin. In postoperative period, they reduce anti-inflammatory reaction, and consequently the development of PCO [13]. Corticosteroids block the release of arachidonic acid by the suppression of the enzyme phospholipase A2. That action stops the production of inflammatory mediators, such as leukotrienes and prostaglandins [14]. NSAIDs act through the inhibition of the enzyme cyclooxygenase, which causes the suspension of prostaglandin production. Thereby, NSAIDs are mostly in usage as antipyretic, anti-inflammatory and analgesic drugs [15].

Intraocular lens material and design have an important impact on preventing PCO. Acrylic material is associated with reduced PCO rate by causing a lower postoperative inflammation than the materials previously used [9]. In addition, lenses with sharp edge design have better outcomes by the inhibition of lens epithelial cells' (LECs) migration [16].

After the appropriate surgical technique, our results indicated that the satisfactory PCO prophylaxis could be provided by implantation of acrylic hydrophobic IOLs. These results are in accordance with the earlier studies [9, 10, 11, 17]. Intraocular lenses made of hydrophobic material can adhere to collagen membrane and fibronectin. That creates less space between IOL and posterior lens capsule, making difficult for LECs to migrate and to develop PCO [18]. Some investigators advocate that the difference between these two materials is associated with less sharp edge of the hydrophilic lenses [9]. During the manufacture of hydrophilic IOLs, they are primarily produced dehydrated, and then rehydrated which can lead to the loss of sharpness [19].

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The results we collected highly indicated a strong anti-inflammatory potential of administrated corticosteroids in the first three postoperative months. This fact is similar to some earlier investigations [14, 15]. In the last six months of the study, it seemed to be, that IOL material had the main influence on preventing the PCO development.

Anti-inflammatory drugs have a huge effect in controlling the inflammation in early postoperative period. Lens epithelial cells cannot be completely removed during phacoemulsification even using advanced surgical techniques. After a few months, as a consequence of chronic inflammation, LECs start to proliferate and migrate towards the lens posterior capsule. In that period IOLs block the further migration of the LECs. So, the finest results in preventing the PCO development can be reached by the synergistic act of anti-inflammatory therapy and aqueous intraocular lens implantation.

CONCLUSION

Posterior capsule opacification still represents the most frequent postoperative complication of the uncomplicated cataract surgery. This condition causes decreased visual acuity and patients' dissatisfaction. In accordance with the results presented in this study, we believe that the adequate prevention of PCO forming is provided by the implantation of acrylic hydrophobic IOLs in capsular bag. Similar scores in PCO development one year after the phacoemulsification in hydrophobic IOL groups with NSAID or corticosteroid, provide the new possibilities in the prevention of postoperative inflammation. These results can be particularly useful in situations when corticosteroids must be used with great caution, such as glaucoma patients, the presence of active infection, or conditions with delayed corneal healing.

Conflict of interest: None declared.

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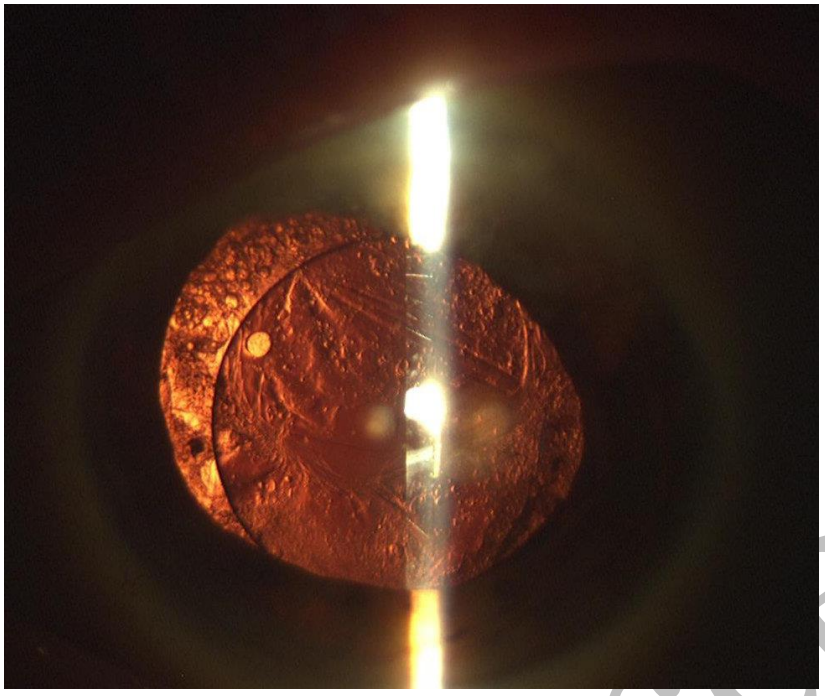

Figure 1. Posterior capsule opacification

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Table 1. Distribution of the groups

Group I	Eyecryl plus 600	nepafenac ophthalmic suspension 0.1%
Group II	SA60AT	nepafenac ophthalmic suspension 0.1%
Group III	Eyecryl plus 600	dexamethasone phosphate 0.1%
Group IV	SA60AT	dexamethasone phosphate 0.1%

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Table 2. The mean posterior capsule opacification score during one year of follow-up period

Group	1 month	3 months	6 months	12 months
I	0.16 ± 0.03	0.26 ± 0.04	0.48 ± 0.10	0.64 ± 0.12
II	0.08 ± 0.02	0.23 ± 0.03	0.37 ± 0.05	0.49 ± 0.06
III	0.06 ± 0.01	0.21 ± 0.03	0.42 ± 0.08	0.57 ± 0.09
IV	0.05 ± 0.01	0.18 ± 0.05	0.32 ± 0.04	0.47 ± 0.08

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