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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

The effect of three different acrylic intraocular lenses and capsulorhexis diameter on the posterior capsule opacification development

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SUMMARY

Introduction/Objective Cataract represents a blur of the crystalline lens. The only possible way of cataract treatment is the surgical one. One of the most common postoperative complications is the development of posterior capsule opacification (PCO). The aim of this study was to exam the effect of three different acrylic intraocular lenses (IOLs) and the capsulorhexis diameter on PCO development.

Methods The study included 92 patients with a diagnosis of senile cataract divided into three groups according to the IOL type. Every group was further divided into two subgroups depending on capsulorhexis size. PCO was measured in the first, sixth, 12th, 18th, and 24th month after the phacoemulsification.

Results The lowest PCO 24 months after phacoemulsification was measured in patients with three-piece hydrophobic IOL (0.3 ± 0.08). Capsulorhexis diameter less than 5 mm had a statistically significant effect in patients with single-piece hydrophilic (0.416 ± 0.187) and single-piece hydrophobic IOL (0.411 ± 0.082) for two years follow-up.

Conclusion PCO causes a decrease of visual acuity and can be a reason for patients' dissatisfaction in postoperative period. The only possible way for the treatment of developed PCO is the usage of YAG laser capsulotomy, a procedure which can be associated with serious complications. Thereby, the finest way for PCO treatment is its prevention. The main role in that prevention has a choice of adequate surgical technique and IOL.

Keywords: posterior capsule opacification; intraocular lens; phacoemulsification

INTRODUCTION

Cataract represents a blur of the crystalline lens. It is followed by the decrease of the visual acuity as the main symptom of the disease. Other symptoms include lental myopia, monocular diplopia, glare, decreased contrast sensitivity [1]. According to research from 2010, it is believed that over 90 million people in the world have some kind of visual impairment, and about 40 million are blind. Cataract is not only the most common lens disease, but it is also the leading cause of blindness in the world [2]. It is known that senile cataracts begin to develop in every patient who is over 65 years old. It develops due to agglomeration of proteins, influx of water into the lens or disorders of lens fiber differentiation. For this reason, we clinically distinguish the three most common types of cataracts: nuclear, cortical, and subcapsular [3]. Even though many investigators attempted to discover a substance which would be able to stop and reverse the process of cataract forming, the surgery remains the only possible way for treatment of developed cataract [4, 5]. Cataract surgery is the most performed surgical procedure in medicine worldwide [6].

For the last few decades phacoemulsification has been established as the most effective method in cataract surgery [7]. Using ultrasound energy, phaco probe aspirates the cataract. The probe contains a piezoelectric crystal, which vibrates with ultrasonic frequencies [8]. Among the many advantages is the creation of a relatively closed system during cataract surgery with a deeper and stable anterior chamber, which is associated with a reduced risk of intraoperative and postoperative complications [9]. Even though this technique has improved all aspects of cataract surgery, complications still occur. One of the most common postoperative complication is posterior capsule opacification (PCO) (Figure 1) [10]. By reducing postoperative best corrected visual acuity PCO could be a reason for patient's dissatisfaction in postoperative period. Good control of preoperative inflammation and glycemia, capsulorhexis diameter, enhanced hydrodissection, bimanual aspiration, choice of an adequate intraocular lens (IOL), postoperative anti-inflammatory therapy are some of the possibilities to reduce PCO incidence [11].

The aim of this study was to examine the effect of three different acrylic IOLs and

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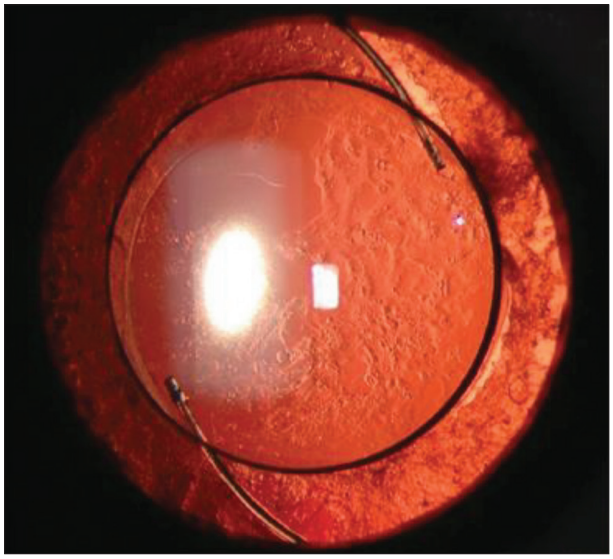

Figure 1. Posterior capsule opacification

capsulorhexis diameter on the PCO development in two years follow-up.

METHODS

The study was designed as a prospective, randomized study. It was conducted at the Clinic of ophthalmology, University Clinical Centre Kragujevac, Serbia. It included 92 patients with a diagnosis of senile cataract who were scheduled for cataract surgery. With the approval of the institutional Committee on Ethics (number 01/17/1829) and according to the tenets of the Declaration of Helsinki, the patients gave their written consent at the beginning of the study.

The main inclusion criteria were the presence of senile cataract. Patients under the age of 65 or those with other cataract types were excluded from the study. Patients with previous history of intraocular injuries or surgeries, as well as those who treated uveitis, glaucoma, retinal diseases or had zonular weakness were not able to participate in the study. Patients who were on chronic anti-inflammatory therapy were also excluded. The existence of pseudoexfoliation or pigment dispersive syndrome was also an exclusion criterion.

Before and after the surgery patients passed a complete ophthalmological examination including visual acuity measurement, Goldmann tonometry, slit lamp examination, ophthalmoscopy, ocular biometry and B scan ultrasonography. Before phacoemulsification, the patients were randomized into three groups according to the IOL which would be implanted:

First group (n = 31) – single-piece hydrophilic acrylic IOL (Eyecryl plus 600, Biotech Healthcare, Luzern, Switzerland);

Second group (n = 31) – single-piece hydrophobic acrylic IOL (AcrySof SA60AT, Alcon-Couvreur NV, Puurs, Belgium);

Third group (n = 30) – three-piece hydrophobic acrylic IOL (AcrySof MA60AC, Alcon-Couvreur NV).

All the surgeries were performed by an experienced surgeon under topical anesthesia. Phaco machine used in all surgeries was "Stellaris" (Bausch & Lomb, Laval, Quebec, Canada). Adequate preoperative mydriasis was achieved using topical application of phenylephrine and tropicamide (2.5% Phenylephrine®, 0.5% Tropicamide®, Zaječar Pharmacy, Zaječar, Serbia). Paracentesis at 2 and 10 o'clock were made and anterior chamber was fulfilled with 1% sodium hyaluronate viscoelastic (Bio-Hyalur, Biotech Healthcare). Central corneal incision and continuous curvilinear capsulorhexis were performed. Using a sterile ruler, under the microscope, capsulorhexis diameter was measured and recorded. A hydrodissection and nucleus rotation followed. When the nucleus was completely free, it was fragmented using "divide and conquer" technique. The remaining cortex was aspirated using bimanual aspiration and the capsular bag was fulfilled with cohesive viscoelastic. IOL was implanted in capsular bag. Viscoelastic was aspirated and an intracameral solution of cefuroxime with 1 mg / 0.1 ml balances salt solution (BSS) was injected. Corneal incisions were hydrated using a BSS. Postoperatively patients were administrated topical dexamethasone-tobramycin (Tobradex®, Alcon-Couvreur NV) six times a day for three weeks and nepafenac (Nevanac®, Alcon-Couvreur NV) four times a day for two weeks in the operated eye.

During patients' visits in postoperative periods a high-resolution image in retroillumination and maximal mydriasis were made at the biomicroscope. A PCO were measured using "Evaluation of Posterior Capsule Opacification 2000," a standard software program for PCO analysis [12]. PCO was measured five times in postoperative period: one, six, 12, 18, and 24 months after the cataract surgery. According to the capsulorhexis size every group was further divided into two subgroups: above and less of 5 mm. PCO was compared according to the IOL type and capsulorhexis diameter during two years of follow-up period.

IBM SPSS Statistics Version 22.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. For comparing PCO values among the groups and during the study period paired t-test and ANOVA were used ($p < 0.05$ and $p < 0.001$ were considered statistically significant).

RESULTS

The research included 92 patients who were divided according to the implanted IOL type into three groups. In all patients, cataract surgery was performed in only one eye, so the number of included eyes was equal to the number of patients (n = 92). In total, 48 were males (52.2%) and 44 females (47.8%). No statistically significant difference was recorded among sexes in the study, as well as in every group ($p > 0.05$).

Mean patients' age in the study was 73.5 ± 5.95 years (median 72, range 65–87 years). No statistically significant difference was recorded in patients' age depending on the type of implanted IOL ($p > 0.05$) (Table 1).

Table 1. Mean patients' age depending on the intraocular lens type

Intraocular lens (IOL)	n	Mean	Sd	Range
Single-piece hydrophilic IOL	31	72.94	6.12	65–86
Single-piece hydrophobic IOL	31	73.42	5.39	65–85
Three-piece hydrophobic IOL	30	74.03	6.44	65–87
Significance		p > 0.05		

Table 2. Posterior capsule opacification one month after phacoemulsification

Intraocular lens (IOL)	Mean	> 5 mm	< 5 mm
Single-piece hydrophilic IOL	0.004 ± 0.002	0.005 ± 0.001	0.002 ± 0.007
Single-piece hydrophobic IOL	0.003 ± 0.005	0.002 ± 0.005	0.002 ± 0.005
Three-piece hydrophobic IOL	0.003 ± 0.008	0.001 ± 0.005	0.005 ± 0.012
Significance	> 0.05	> 0.05	

Table 3. Posterior capsule opacification six months after phacoemulsification

Intraocular lens (IOL)	Mean	> 5 mm	< 5 mm
Single-piece hydrophilic IOL	0.041 ± 0.002	0.042 ± 0.001	0.034 ± 0.021
Single-piece hydrophobic IOL	0.031 ± 0.019	0.035 ± 0.017	0.027 ± 0.02
Three-piece hydrophobic IOL	0.03 ± 0.014	0.032 ± 0.013	0.027 ± 0.016
Significance	> 0.05	> 0.05	

Table 4. Posterior capsule opacification 12 months after phacoemulsification

Intraocular lens	Mean	> 5 mm	< 5 mm
Single-piece hydrophilic IOL	0.133 ± 0.027	0.147 ± 0.02	0.132 ± 0.03
Single-piece hydrophobic IOL	0.097 ± 0.02	0.1 ± 0.02	0.092 ± 0.02
Three-piece hydrophobic IOL	0.055 ± 0.009	0.061 ± 0.006	0.055 ± 0.012
Significance	< 0.001**	> 0.05	

**Highly statistically significant

Table 5. Posterior capsule opacification 18 months after phacoemulsification

Intraocular lens (IOL)	Mean	> 5 mm	< 5 mm
Single-piece hydrophilic IOL	0.316 ± 0.07	0.335 ± 0.057	0.311 ± 0.076
Single-piece hydrophobic IOL	0.305 ± 0.05	0.305 ± 0.047	0.292 ± 0.05
Three-piece hydrophobic IOL	0.154 ± 0.03	0.159 ± 0.022	0.148 ± 0.028
Significance	< 0.001**	< 0.05*	

*Statistically significant;
**highly statistically significant

Table 6. Posterior capsule opacification 24 months after phacoemulsification

Intraocular lens (IOL)	Mean	> 5 mm	< 5 mm
Single-piece hydrophilic IOL	0.445 ± 0.2	0.481 ± 0.219	0.416 ± 0.187
Single-piece hydrophobic IOL	0.446 ± 0.16	0.482 ± 0.21	0.411 ± 0.082
Three-piece hydrophobic IOL	0.3 ± 0.08	0.304 ± 0.07	0.293 ± 0.09
Significance	< 0.05*	< 0.05*	

*Statistically significant

In single-piece hydrophilic IOL and single-piece hydrophobic IOL groups 14 patients had capsulorhexis diameter above 5 mm and 17 patients capsulorhexis diameter less than 5 mm. In three-piece hydrophobic IOL group 16 patients had capsulorhexis diameter above 5 mm and 14 patients capsulorhexis diameter less than 5 mm.

One and six months after phacoemulsification, the highest mean PCO was measured in single-piece hydrophilic IOL group, but no statistical significance was noticed among the groups during these measurements ($p > 0.05$). Also, an analysis of the subgroups within each group did not determine the influence of the capsulorhexis diameter PCO development (Tables 2 and 3).

Intergroup analysis twelve months after phacoemulsification revealed the existence of high statistically significant difference among all groups ($p < 0.001$). The highest PCO was measured in single-piece hydrophilic IOL group, then single-piece hydrophobic IOL group and then three-piece hydrophobic IOL group. No significant difference was revealed according to the capsulorhexis size in all groups ($p > 0.05$) (Table 4).

PCO in patients with three-piece hydrophobic IOL group 18 months after the cataract surgery was 0.154 ± 0.03, which was significantly lower compared to single- IOLs groups ($p < 0.001$). PCO between patients with single-piece hydrophilic IOL and single-piece hydrophobic IOL was not significant ($p < 0.05$). Patients from single-piece hydrophilic IOL group and single-piece hydrophobic IOL group with capsulorhexis diameter less than 5 mm had significantly lower PCO compared with patients from the same groups but with capsulorhexis diameter above 5 mm ($p < 0.05$). No influence of capsulorhexis size was recorded in three-piece hydrophobic IOL group. (Table 5). The same trend of significance continued two years after phacoemulsification (Table 6).

DISCUSSION

Phacoemulsification reduced the incidence of PCO compared to the previously used extracapsular cataract extraction and intracapsular cataract extraction [13, 14]. Using phacoemulsification probe, as well as irrigation and aspiration it is possible to remove far more lens epithelial cells (LEC) during cataract surgery. But even this technique is not able to remove all LEC. In the postoperative period they undergo proliferation, migration and differentiation which is clinically manifested as PCO. It is known that postoperative inflammation has a key role in PCO development [15]. The incidence of PCO varies depending on ocular comorbidities, patients' age, used surgical technique, type of implanted IOL, length of the postoperative period. Many studies suggest incidence varies by 7–40% in patients with senile cataract, while in pediatric cataract PCO rate reaches 100%, due to high mitogenic potential of the remaining LECs [16, 17, 18]. The only possible treatment of developed PCO is YAG laser capsulotomy. This procedure could cause some serious side effects: iatrogenic IOL perforation ("pitting"), hyphema, corneal edema, intraocular pressure rise, retinal break, cystoid macular edema, chronic endophthalmitis. Therefore, research is unanimous that the best treatment of PCO is its prevention [19, 20].

Material and design of IOL have a huge effect in reducing PCO. Currently, the most used are IOLs made of acrylic material. Acrylic IOLs are associated with lower PCO compared to previously used silicone or hydrogel IOLs due to their great biocompatibility [21]. They are characterized by excellent optical performance, as well as the absence of an inflammatory response. Depending on the water content, acrylate IOLs can be hydrophobic containing less than 1% water, and hydrophilic containing

18–35% water. Considering design, acrylate IOLs can be single piece, made entirely of the same material, and three-piece with a haptics made of polymethyl methacrylate [22]. Researchers still do not agree which acrylate IOL is associated with the lowest PCO rate. The results are different depending on the IOL manufacturer, surgical technique, and duration of the follow-up. Analyzing all three groups in our study the first formation of PCO was recorded already one month after phacoemulsification. That indicates the process of proliferation, migration and differentiation of residual LECs began immediately after the cataract surgery. Until the end of the study, continuous progression of PCO was recorded in all groups. Six months after phacoemulsification the highest PCO was measured in single-piece hydrophilic IOL group, but without significance compared to other groups. At the 12th postoperative month, we observed a highly statistically significant difference among all groups. Again, the highest PCO was seen in single-piece hydrophilic IOL group (0.133 ± 0.027), then in the single-piece hydrophobic IOL group (0.097 ± 0.02) and finally in the three-piece hydrophobic IOL group (0.055 ± 0.009). That indicates material and design of the IOL had an influence in PCO. These results are similar with many previous studies [23, 24].

Ursell et al. [25] explained the possible reason for the lower PCO rate of hydrophobic acrylate IOLs. These IOLs have an adhesive surface on their back side, which binds tightly IOL to fibronectin and laminin contained in posterior lens capsule. In that way, a better barrier to the migration of residual LECs is created. Leydolt et al. [22] suggested that the higher PCO rate in hydrophilic IOLs may be in manner of its production. It is produced in a dehydrated form, only to be rehydrated afterwards. As a result of this process, the sharpness of the edges of the IOL may decrease, which facilitates the migration of LECs [22].

In our study, mean PCO in patients with implanted single-piece hydrophilic IOL and single-piece hydrophobic IOL 18 and 24 months after phacoemulsification was almost identical, while PCO in three-piece hydrophobic IOL group remained significantly lower. It can be concluded that in our study IOL material had no influence, while IOL design has shown to be a major factor in PCO reduction. The explanation of these results can be in different haptic-optic junctions in single-piece IOL and three-piece IOL. Haptics of single-piece IOL are made of the same material as optic and represent an extension of the optic. They are characterized by a notably wider root, which creates discontinuity in the capsular wrap around the IOL. That facilitates a migration of residual LECs [26]. The lower PCO incidence in three-piece IOL contributes to the presence of angulation between the optic and haptic, which is associated with a better positioning of the IOL inside the capsular bag. The angulation pushes the IOL towards the posterior lens capsule, significantly narrowing the space for LECs to migrate [27].

Capsulorhexis size could also have an influence on PCO development [28]. It is believed that when a capsulorhexis diameter is little less than IOL optic diameter the rest of anterior capsule and posterior capsule are ideally twisted around IOL creating an IOL – capsular bag complex. In some way, its content is protected from circulating pro-inflammatory mediators, as well as the complex narrows the space for LECs' migration [29]. In our study, significance was recorded in patients with single-piece hydrophilic IOL and single-piece hydrophobic IOL 18 and 24 months after phacoemulsification. Our results are in accordance with the results of Langwińska-Wośko et al. [30] who examined the influence of capsulorhexis size on the PCO occurrence on a sample of 297 eyes. Based on our results, according to the increase of significance during of the research, we can conclude that the influence of capsulorhexis diameter would achieve an even more intense impact in following years in PCO reduction.

CONCLUSION

We believe this research will be of great use in clinical practice knowing that PCO remains the most common postoperative complication of uneventful phacoemulsification. Knowing the possible complications of YAG laser capsulotomy, prevention of PCO development becomes even more important. Our study showed that PCO rate was very low in all groups, but if it is possible our results suggest the usage of three-piece IOL. If surgeon decides to implant single-piece IOL, we advocate him to make an extra effort and performs capsulorhexis less than 5 mm, so the reduced PCO rate is expected to be achieved in the years ahead.

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Ефекат три различита акрилна интраокуларна сочива и дијаметра капсулорексе на настанак опацификације задње капсуле сочива

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САЖЕТАК

Увод/Циљ Катаракта представља замућење кристалног сочива. Једини могући начин лечења катаракте је хируршки. Једна од најчешћих постоперативних компликација је развој опацификације задње капсуле.

Циљ ове студије је био да се испита ефекат три различита акрилна интраокуларна сочива и дијаметра капсулорексе на развој опацификације задње капсуле.

Методе Истраживањем су обухваћена 92 пацијента са дијагнозом сенилне катаракте подељена у три групе према типу интраокуларног сочива. Свака група је даље подељена у две подгрупе у зависности од дијаметра капсулорексе. Опацификација задње капсуле је мерена првог, шестог, 12, 18. и 24. месеца након факоемулзификације.

Резултати Најнижа опацификација задње капсуле сочива 24 месеца након факоемулзификације измерена је код пацијената са троделним хидрофобним интраокуларним сочивом (0,3 ± 0,08). Дијаметар капсулорексе мањи од 5 *mm* имао је статистички значајан ефекат код пацијената са једноделним хидрофилним интраокуларним сочивом (0,416 ± 0,187) и једноделним хидрофобним интраокуларним сочивом (0,411 ± 0,082) током две године праћења.

Закључак Опацификација задње капсуле изазива смањење видне оштрине и може представљати разлог незадовољства пацијената у постоперативном периоду. Једини могући начин лечења развијене опацификације задње капсуле је *YAG* ласерска капсулотомија, процедура која може бити праћена озбиљним компликацијама. Самим тим, најбољи третман опацификације задње капсуле је њена превенција. Главну улогу у тој превенцији има избор адекватне хируршке технике и интраокуларног сочива.

Кључне речи: опацификација задње капсуле; интраокуларно сочиво; факоемулзификација