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Prevention of Posterior Capsule Opacification With 3 Intraocular Lens Models: a Prospective, Randomized, Long-Term Clinical Trial

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Key words: *posterior capsule opacification; intraocular lens; hydrophobic acrylic; silicone.*

Summary. *The aim of this prospective randomized study was to evaluate the impact of different sharp-edged intraocular lenses (IOLs) (hydrophobic acrylic or silicone) on posterior and anterior lens capsule opacification (PCO and ACO) at 3-year postoperative follow-up.*

Material and Methods. A total of 96 eyes (89 patients) having a standard uncomplicated phacoemulsification procedure for age-related cataract were included in a prospective clinical study: 34 eyes with a 3-piece acrylic hydrophobic (AcrySof, MA30BA), 32 eyes with a 1-piece acrylic hydrophobic (AcrySof, SA30AL), and 30 eyes with a 3-piece silicone (CeeOn 911A) IOL. Visual acuity, capsulorrhexis/optic overlapping, ACO and PCO (using EPCO2000 system) were evaluated at 3-year follow-up. Capsulotomies performed by means of neodymium-yttrium-aluminum-garnet (Nd:YAG) laser were recorded.

Results. Three years after surgery, the grade of ACO of the capsulorrhexis rim area and the capsule/optic area was significantly greater in the silicone IOL group than in the acrylic IOL groups ($P<0.05$). During 3 postoperative years, there were no significant differences in the PCO values either in the entire IOL optic area or in the central 3-mm optic zone comparing the groups. Three years after surgery, 9% of eyes with a 3-piece acrylic IOL, 3.1% of eyes with a 1-piece acrylic IOL, and no case in the silicone IOL group had Nd:YAG capsulotomy ($P>0.05$).

Conclusion. The 3-year follow-up after cataract surgery showed no difference in PCO development (EPCO2000) between acrylic hydrophobic and silicone sharp-edged IOLs. However, the need for Nd:YAG laser capsulotomy was higher in the acrylic IOL groups than the silicone IOL group, though the difference was not significant. ACO was greatest in the eyes with 3-piece silicone IOLs.

Introduction

Posterior capsule opacification (PCO) or secondary cataract is a major long-term complication of successful cataract surgery starting from the beginning of extra capsule cataract extraction with intraocular lens (IOL) implantation (H. Ridley, 1949) (1). In recent years, cataract surgery technique and IOL design have undergone the significant changes. The development of modern foldable IOLs with square-edged optics has greatly reduced the incidence of PCO following cataract surgery. Despite major improvements, PCO is still the most frequent long-term complication of cataract surgery and is the most common cause of nonrefractive decreased postoperative vision (2, 3).

PCO is the result of proliferation, growth, migration, and transdifferentiation of residual lens epithelial cells (LECs) in the capsule bag after cataract surgery. The pathogenesis of PCO is multifactorial; thus, the rate of PCO development can vary (1). Neodymium-yttrium-aluminum-garnet (Nd: YAG) laser capsulotomy, the most common and effective treatment for clinically significant PCO, can lead to other significant complications (4); moreover, it is expensive and not available in large parts of the developing world. Because of that, investigators are constantly working to advance a safe and effective way to reduce and eventually eradicate PCO.

Many techniques have been advocated to prevent PCO including intraocular lens material and design (5–7), surgical techniques (8), and therapeutic agents (9).

It is still not known whether the sharp-edged IOL produces less PCO because of the optic geometry alone or whether the biomaterial, especially acrylic hydrophobic, contributes to the inhibition of PCO. There has been a general shift toward the use of acrylic IOL material. Despite this, the question of whether eyes with acrylic IOLs develop less PCO than eyes with other materials remains controversial, especially in a long-term postoperative period (10–13).

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The aim of the current study was to compare the impact of 3 foldable sharp-edged IOLs made from hydrophobic acrylic material (1-piece and 3-piece) or silicone material (3-piece) on posterior and anterior lens capsule opacification at 3-year postoperative follow-up.

Materials and Methods

This study was a prospective, randomized, nonblinded clinical trial. After approval of the regional ethics committees, patients were recruited in a continuous cohort. The principle inclusion criterion was the presence of senile cataract in an otherwise healthy eye in patients older than 50 years who underwent a cataract phacoemulsification procedure with the same technique including anterior capsule overlapping of the IOL optic for 360° performed by the same well-experienced surgeon.

After the patients provided informed consent, they were randomly assigned to receive a 3-piece AcrySof MA3OBA hydrophobic acrylic IOL or 1-piece AcrySof SA3OAL hydrophobic acrylic IOL or 3-piece CeeOn 911A silicone IOL. A total of 107 patients (123 eyes) were enrolled into the study. Eighteen patients (27 eyes, 21.9%) were not able to participate in the last examination (3 years following surgery). Seven patients were known to have died, and 6 patients were too ill or frail to attend. It was not possible to contact 2 patients. Three patients refused to participate in the study. At the final 3-year examination, 96 eyes of the 89 patients were evaluated. Thirty-four eyes were implanted with a MA3OBA IOL (group 1), 32 eyes with a SA3OAL IOL (group 2), and 30 eyes were implanted with a CeeOn 911A IOL (group 3). All implanted IOLs are foldable with a square-edged biconvex optic. MA-3OBA and SA3OAL are acrylic hydrophobic IOLs with a 5.5-mm optics and overall diameter of 12.5 mm. The MA3OBA has poly (methyl methacrylate) (PMMA) haptics angled at 5°. The SA3OAL is a 1-piece lens with no haptic angulation. The CeeOn 911A is a silicone IOL with a 6.0-mm optics and overall diameter of 12.0 mm and has polyvinylidene fluoride haptics angled at 6°.

All patients were operated on under topical and intravenous anesthesia. Clear corneal phacoemulsification procedure was performed using the "divide and conquer" technique, and one of the three foldable IOLs was implanted in the bag using the same viscoelastic material. At the end of the procedure, the viscoelastic material was removed from the anterior chamber of the eye and from behind the IOL optic with a manual irrigation/aspiration tip. Intracameral injections of cefuroxime (2 mg), subconjunctival injections of dexamethasone (2 mg), and application of 0.3% tobramycin into the conjunctival sac were performed. Any surgical complications led to patient exclusion from the study.

At the 3-year follow-up visit, the best-corrected distance visual acuity (BCDVA) was recorded. During examination (under maximum pupil dilation), the lens capsules were evaluated using a slit lamp. In order to evaluate anterior capsule opacification (ACO), the anterior capsule leaf on the IOL optics was divided into 2 parts: capsulorrhexis rim area and capsule/optic area. Capsule opacification was graded as follows: 0, clear capsule; 1, mild opacification; 2, moderate opacification; 3, severe opacification with dense whitening of the anterior capsule, hindering the view of underlying intraocular structures. After examining the posterior lens capsule using a slit lamp, standardized retroillumination images of the posterior lens capsule were taken using a TOPCON SL8Z digital slit-lamp. Images were then analyzed using the EPCO2000 (evaluation of posterior capsule opacification) program (14). PCO was evaluated for the entire IOL optic and in the central 3-mm optic zone. The boundaries of the posterior capsule and each opaque area of the posterior capsule were drawn on the stored images using a computer mouse, so that the fraction of the opaque area could be calculated with the EPCO software. The density of the opacification was clinically graded from 0 (none) to 4 (severe). Individual PCO values (PCO index) for each image were calculated by multiplying the density of opacification by the fraction of the capsule area involved behind the entire IOL optics and central 3-mm optic zone. The anterior capsule overlapping area on the IOL optics (percentage of the optic area) was calculated using the same system. The Nd:YAG laser capsulotomy rate was recorded. The eyes treated with Nd:YAG laser capsulotomy were excluded from EPCO2000 and visual acuity evaluation.

Statistical Analysis. SPSS18.0 software (Chicago, USA) was used for the statistical analysis. All variables were expressed as means and standard deviations (SD) or frequencies. Overall group comparisons were performed using the Kruskal-Wallis test. The differences in the results between two independent samples were analyzed using the Mann-Whitney *U* or Student *t* tests. The statistical significance of differences in frequencies was assessed using the chi-square test. The relation between investigated variables was estimated using the Spearman correlation coefficients. A two-sided *P* value less than 0.05 was considered statistically significant.

Results

The mean age of patients at the time of cataract surgery was 67.6 years (SD, 7.7) in the 3-piece acrylic IOL group, 67.3 years (SD, 7.6) in the 1-piece acrylic group, and 66.9 years (SD, 7.9) in the 3-piece silicone group. There was no difference in age, gender distribution, and follow-up time from surgery to examination among the groups.

Table. Clinical Parameters in the IOL Groups at the 3-Year Follow-Up

Parameter	3-piece AcrySof n=31	1-piece AcrySof n=31	Silicone CeeOn n=30	*P*
BCDVA	0.994 (0.025)	0.984 (0.058)	0.993 (0.036)	0.793
ACO grade				
rr area	1.580 (0.886)	1.613 (0.919)	2.333 (0.758)	0.001
c/o area	1.355 (0.551)	1.258 (0.728)	1.800 (0.805)	0.017
PCO (EPCO) value				
Total area	0.171 (0.208)	0.145 (0.159)	0.158 (0.194)	0.995
Central area	0.077 (0.138)	0.081 (0.150)	0.046 (0.151)	0.460

Values are mean (standard deviation). BCDVA, best-corrected distant visual acuity; ACO, anterior capsule opacification; rr area, rhexis area; c/o area, capsule/optic area; PCO, posterior capsule opacification; EPCO, evaluation of posterior capsule opacification system.

For visual acuity, there was no significant difference in the preoperative BCDVA and postoperative BCDVA at 3 years comparing patients with 3-piece acrylic, 1-piece acrylic, and 3-piece silicone IOLs (Table).

The grades of ACO density of the capsulorrhexis rim area and the capsule/optic area were significantly greater in the 3-piece silicone IOL group than in the acrylic hydrophobic IOL groups (P=0.001 and P=0.017, respectively) (Table).

The 3-year postoperative follow-up revealed that there were no significant differences between the mean PCO values in the entire IOL optic area as well as in the central 3-mm optic zone (P=0.995 and P=0.460, respectively) comparing 3-piece acrylic, 1-piece acrylic, and 3-piece silicone IOLs (Table).

An Nd:YAG laser capsulotomy was performed in 9.0% of patients (3 eyes) in the 3-piece acrylic IOL group and in 3.1% of patients (1 eye) in the 1-piece acrylic IOL group. There was no case of PCO with a decrease of 2 or more lines of visual acuity that required Nd:YAG laser capsulotomy in the 3-piece silicone IOL group. The difference in the Nd:YAG capsulotomy rate was not significant comparing the groups.

This study included only those eyes where the anterior capsule overlapped the edges of the IOL optic by 360°. The mean overlap of the capsulorrhexis on the intraocular lens optic was 28.02% (SD, 14.37) in the 3-piece acrylic IOL group, 27.46% (SD, 8.40) in the 1-piece acrylic IOL group, and 32.41% (SD, 9.92) in the 3-piece silicone IOL group 3 years postoperatively (P=0.171). There was no correlation between PCO values and overlapping in all three IOL groups.

Discussion

In this prospective clinical study, PCO performance of two models of a hydrophobic acrylic IOL (3-piece and 1-piece) and silicone IOL (3-piece) at the long-term (3-year) follow-up was compared. All IOLs had a square-edged biconvex optic. Our results showed no significant difference in the PCO values in the entire IOL optic area and in the central 3-mm optic zone 3 years postoperatively among 3-piece and 1-piece acrylic hydrophobic IOLs and 3-piece silicone IOL.

The sharp optic edge was first postulated in the early 1980s by Hoffer (15). Nishi et al. in their experimental studies demonstrated that the PCO-reducing effect is mainly related to a sharp-edge optic IOL design and the formation of a capsular bend (5, 6). The effect of the sharp optic edge as a major inhibitory factor on the PCO development has been described and confirmed by the findings in many studies (2, 5–7). The recent meta-analysis of the 66 prospective, randomized, and controlled trials showed significantly less PCO in sharp-edge then in round-edge IOLs of the same optic material (3). The results of our current study – very low PCO value without any difference among acrylic hydrophobic and silicone IOLs 3 years after surgery – first confirm the effect of sharp-edge optics design on PCO prevention.

Many studies have been performed to evaluate the performance of acrylic hydrophobic and silicon IOLs in PCO prevention. Most of the earlier studies comparing sharp-edge acrylic and sharp-edge or round-edge silicone IOLs did not show any differences between these both evaluated different material IOLs in PCO prevention (16–18). Some studies with a shorter follow-up showed that the acrylic IOL was better than the silicone IOL in preventing PCO (19); the other studies reported silicone IOLs to be superior to acrylic ones with very low PCO scores and Nd:YAG capsulotomy rate in both IOL groups during the first 2 years after surgery (20). The results of the recent long-term retrospective (2–10-year) studies suggest a tendency toward a reduction in the PCO protective effect of sharp-edged acrylic hydrophobic IOLs compared with silicone IOLs even round-edged (10–12, 21). In a retrospective study by Vock et al., 18% of eyes with a silicone IOL and even 42% with an acrylic hydrophobic IOL

had Nd:YAG capsulotomy l0 years after surgery (P=0.007) (12). This unexpected finding may be explained by the delayed redivision of the once-fused capsule leaves caused by the emerging Soemmering's ring forming in the periphery of the capsular bag (late barrier failure), which can be held up only by firm collagenous sealing of the capsule leaves along the optic rim. Silicone material might maintain a more permanent barrier effect, which may be explained by the more intense collagenous sealing of both capsules at the IOL optic edge compared with that of acrylic IOLs. This sealing better resists the proliferative pressure of Soemmering's ring (12). The results of the recent prospective study are controversial. Formanek et al. in their 7-year follow-up study showed the lowest Nd:YAG capsulotomy rate with silicone 3-piece sharp-edged IOLs (12.5% in the CeeOn IOL group and 40% in the AcrySof IOL group) in eyes with uveitis having cataract surgery (13). The results of a 7-year prospective study by Pozlerova et al. showed a higher capsulotomy rate in eyes with round-edged silicone optic IOLs compared with hydrophobic acrylic square optic edge IOLs (22).

According to our results, eyes with the square-edged acrylic hydrophobic optic IOL had a greater rate of Nd:YAG laser capsulotomy than eyes with the square-edged silicone optic IOL 3 years postoperatively, though the difference was not significant. However, during the first 2 years after cataract surgery, there was no case of PCO that required Nd:YAG laser capsulotomy in either of the group (7, 16, 23). All implanted IOLs in our study were with a square-edged biconvex optic, but both hydrophobic acrylic models had an optic 5.5 mm in diameter and silicone IOL had an optic 6.0 mm in diameter. Many surgeons believe that a larger IOL optic is advantageous in preventing PCO mainly because of easier achievement of complete contact of the anterior IOL optic surface with the anterior capsulorrhexis (2, 6). Our study only included those eyes where the anterior capsule overlapped the edges of the IOL optic by 360°. The overlapping area of capsulorrhexis on the IOL optic was similar in all 3 IOL groups, and no correlation between PCO value and overlapping of the capsulorrhexis area on the IOL optic was found. These findings allowed us to think that these differences in the IOL optics design had no influence on our study results. Therefore, the further continuation of this study should demonstrate differences in the PCO performance in these two IOLs of different materials.

The clinical introduction of single-piece acrylic hydrophobic IOLs with some differences in optic and haptic design compared with 3-piece acrylic hydrophobic IOLs was likely to have some differences in PCO prevention. The haptics of the 1-piece IOL extend directly from the posterior surface leaving a potential gap in the 360° sharp-edge optic. The more bulky haptic root of single-piece IOL could hinder the adhesion of the anterior and posterior lens capsule around the loop, and a discontinuous capsular bend may be formed. LECs may then progress through the broad haptic-optic junction toward the center of the posterior lens capsule (24). The results of our present study confirm that the modification of the IOL optic and haptic design of the acrylic hydrophobic sharp-edge optic IOL from a 3-piece to 1-piece design caused no significant change in the PCO development at 3-year follow-up similar to the previous results published after 2-year follow-up (7). These results can be explained only by the quality of acrylic hydrophobic biomaterial – adhesiveness – that results in a great IOL optic-capsule adhesion (25).

Anterior capsule opacification occurs in the portion of the anterior capsule in contact with the optic. Here, the LECs come into contact with the IOL surface, and the IOL material causes the LECs to undergo myofibroblastic metaplasia and produce extracellular matrix components (26). This study showed that the grade of ACO density was significantly greater in the 3-piece silicone IOL group than in the acrylic hydrophobic IOL groups, but there was no difference between 1-piece and 3-piece acrylic hydrophobic IOL models. These results are comparable with the other results that silicone IOLs cause the highest ACO grade (13).

Conclusions

The 3-year follow-up after cataract surgery showed very low and without difference PCO development comparing sharp-edged 3-piece and 1-piece acrylic hydrophobic IOLs and sharp-edged 3-piece silicone IOLs, which might be explained by the effect of sharp-edge optics and by the high-quality acrylic hydrophobic and silicone material. There was no difference in PCO prevention between 3-piece and 1-piece acrylic hydrophobic IOLs (AcrySof), which might be explained only by the effect of the acrylic hydrophobic biomaterial. The ACO development was the highest in 3-piece sharp-edged silicone IOLs compared with acrylic hydrophobic IOLs, and there was no difference in the ACO development between two different models of acrylic hydrophobic IOLs. These results primarily are dependent on differences in the IOL material.

Statement of Conflict of Interest

The authors state no conflict of interest.

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