EXTENDED REPORT

Influence of three-piece and single-piece designs of two sharp-edge optic hydrophobic acrylic intraocular lenses on the prevention of posterior capsule opacification: a prospective, randomised, long-term clinical trial

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Background: Posterior capsule opacification (PCO) is still a major long-term complication of modern cataract surgery. We evaluated the impact of sharp-edged intraocular lenses (IOLs) with different haptic designs made from the same hydrophobic acrylic material on posterior and anterior lens capsule opacification.

Setting: Eye clinic of Kaunas University of Medicine, Lithuania. Prospective randomised clinical study.

Methods: Seventy-four eyes of 74 patients scheduled for cataract surgery were included in a prospective randomised clinical study. Thirty-seven eyes of 37 patients received a three-piece acrylic hydrophobic (AcrySof, MA3OBA, Alcon) IOL; and thirty-seven eyes of 37 patients received a one-piece acrylic hydrophobic (AcrySof, SA3OAL, Alcon) IOL. Visual acuity, anterior capsule opacification (ACO), capsular folds, capsulorrhexis/optic overlapping and posterior capsule opacification (PCO) were evaluated. ACO was assessed subjectively. PCO values in the entire IOL optic area and in the central 3 mm optic zone were assessed using a photographic image-analysis system (EPCO2000). Follow-ups were performed post-operatively at 1 day, 6 months, 1 year and 2 years.

Results: There were no significant differences in best corrected visual acuity, grade of ACO and capsulorrhexis/optic overlapping between IOL types during the follow-up period. Patients in the one-piece acrylic hydrophobic IOL group more frequently presented with capsular folds behind the IOL optic area than those in the three-piece IOL group. In the three-piece acrylic hydrophobic IOL group, PCO values (mean (SD)) of the entire IOL optic area were significantly lower six months postoperative (three-piece: 0.002 (0.009); one-piece: 0.007 (0.017); $p=0.04$), one year postoperative (three-piece: 0.004 (0.016); one-piece: 0.026 (0.041); $p=0.001$) as well as one year postoperative in the central 3 mm optic zone (three-piece: 0.000 (0.0002); one-piece: 0.019 (0.049); $p=0.001$). However, two years postoperative, the PCO values of the groups did not show significant differences (entire IOL optic area: three-piece, 0.136 (0.223); one-piece, 0.154 (0.190); $p=0.18$; central zone: three-piece, 0.023 (0.065); one-piece: 0.020 (0.039); $p=0.44$).

Conclusion: The 2 year follow-up after cataract surgery showed no significant difference in ACO and PCO development between three-piece and one-piece acrylic hydrophobic intraocular lenses.

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Posterior capsule opacification (PCO) is still a major long-term complication of cataract surgery and likely the most common cause of non-refractive decreased postoperative vision.^{1,2} The pathogenesis of PCO is multifactorial, meaning that it is not sufficient to influence one specific pathway of its pathogenesis to eliminate or decrease PCO development.^{1,3}

Many techniques have been advocated to prevent PCO including intraocular lens material and design,^{4–12} surgical techniques,^{13–17} pharmacologic methods,¹⁸ physical techniques to destroy lens epithelial cells (LECs),¹⁹ and the use of antibodies against LECs.²⁰

Many scientific studies have attempted to find an answer to the following question: how does intraocular lens (IOL) design influence PCO?^{4–9,12} Nishi demonstrated that the PCO-reducing effect is mainly related to a sharp-edge optic IOL design and the formation of a capsular bend.^{4–9} Adhesiveness of IOL material with the lens capsules helps to create a sharp capsular bend.^{8–10,21–23} The clinical introduction of single-piece acrylic hydrophobic IOLs with some optic and haptic design differences compared with three-piece acrylic hydrophobic IOLs enabled us to determine the influence of design on PCO prevention. So far, there have been few prospective, randomised, clinical studies on long-term (2 year) clinical results of single and three-piece acrylic hydrophobic foldable IOLs.^{24–25}

MATERIALS AND METHODS

This study was a prospective, randomised, non-masked clinical trial. After approval of the regional ethics committees was obtained, 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 of age, in which the same well-experienced surgeon performed a cataract phacoemulsification procedure with the same technique including anterior capsule overlapping of the IOL optic for 360°.

After patients provided informed consent, they were randomly assigned to receive a three-piece AcrySof MA3OBA or one-piece AcrySof SA3OAL hydrophobic acrylic IOL. Thirty seven eyes of 37 patients received a MA3OBA IOL (group 1), and 37 eyes of 37 patients a SA3OAL IOL (group 2). Both IOLs are foldable hydrophobic acrylic, with a biconvex square-edged 5.5 mm optic, and an overall diameter of 12.5 mm. The MA3OBA has poly (methyl methacrylate) (PMMA) haptics angled at 5°, resulting in posterior vaulting of the optic. The SA3OAL is a one-piece lens with no haptic angulation.

Abbreviations: ACO, anterior capsule opacification; IOL, intraocular lens; LEC, lens epithelial cell; PCO, posterior capsule opacification.

Figure 1 Grade of anterior capsule opacification density (mean (SD)) of the capsulorrhexis rim area and its comparison between the intraocular lens (IOL) groups.

All patients were operated under topical and intravenous anaesthesia. Clear cornea phacoemulsification using the “divide and conquer” technique and in the bag injection (Monarch) of the two foldable IOLs were performed using the same viscoelastic material (Provisc). 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 an irrigation/aspiration tip. Intracameral injections of cefuroxime 2 mg, subconjunctival injections of dexamethasone 2 mg and application of tobramycin 0.3% into the conjunctival sac were performed. Any surgical complications led to patient exclusion from the study.

Patients were examined on the first day, six months, one year and two years after surgery. During each examination (under maximum pupil dilation) the lens capsules were evaluated using a slit lamp. To evaluate anterior capsule opacification (ACO), the anterior capsule leaf on the IOL optics was divided into two parts: capsulorrhexis rim area and capsule/optic area. Capsule opacification was graded as follows: 0, no detectable ACO, 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, standardised retroillumination images of the posterior lens capsule were taken using a TOPCON SL 8 Z digital slit-lamp. Several images of each eye were taken. The flashlight reflex was slightly decentred on the IOL's optic edge, and pictures with reflexes on the right and left side were captured. Images were then analysed using the EPCO 2000 program.²⁶ 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 as 0 (none), 1 (minimal), 2 (mild), 3 (moderate) or 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 the 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 retroillumination images were analysed to determine the presence of folds in the posterior capsule.

Statistical analysis

All variables were checked for normal distribution using the Kolmogorov Smirnov one-sample test. Data are shown as mean

Figure 2 Grade of anterior capsule opacification density (mean (SD)) of the capsule/optic area and its comparison between the IOL groups.

(SD). Non-parametric tests were used (Mann Whitney U test) to compare differences between with skewed distribution. We assessed the statistical significance of differences in frequencies using the χ^2 test. The relation between investigated variables was estimated using Spearman's correlation coefficients. SPSS 12.0 (Chicago, USA) software was used for the statistical analysis. A two-sided value of $p < 0.05$ was considered statistically significant.

RESULTS

Seventy-four patients were enrolled (37 three-piece and 37 one-piece IOLs). Mean age at the time of cataract surgery in the three-piece IOL group was 66.7 (SD 8) years and 66.92 (SD 7.7) years in the one-piece group ($p > 0.05$). There was no difference in gender distribution and follow-up time from surgery to examination between the groups. Ten patients (4 (10.8%) from group 1, and 6 (16.2%) from group 2) were not able to participate in the last examination (2 years after surgery). Two patients were known to have died and four patients were too ill or frail to attend. It was not possible to contact one patient. Three patients refused to participate in the study.

For visual acuity, there was no significant difference between patients with three-piece and one-piece AcrySof IOLs for preoperative best-corrected visual acuity and postoperative at 2 years.

For ACO, the only difference ($p > 0.05$) between the groups was in fibrosis of the capsulorrhexis rim area 6 months and

Figure 3 Posterior capsule opacification values (mean (SD)) in the entire IOL optic area and its comparison between the IOL groups.

Figure 4 Posterior capsule opacification values (mean (SD)) in the central 3 mm IOL optic zone and its comparison between the IOL groups.

1 year after surgery (the grade of ACO density was higher in eyes with one-piece AcrySof IOL). However, the differences were not statistically significant ($p = 0.14$ and 0.16 respectively) (figs 1 and 2).

During the first postoperative year (6 months and 1 year), PCO values in the three-piece AcrySof IOL group were lower than in the one-piece AcrySof IOL group (figs 3 and 4). Six months after surgery, a significant difference between the means of PCO values in the entire IOL optic area was determined ($p = 0.04$). One year postoperative, there were significant differences between the means of PCO values in the entire IOL optic area and in the central 3 mm optic zone ($p = 0.001$ and $p = 0.001$ respectively). However, 2 years after surgery, PCO values in both groups were no longer different.

This study included only those eyes where the anterior capsule overlapped the edges of the IOL optic 360° . The average overlap of the capsulorrhexis on the intraocular lens optic was 34.38% (SD 12.1) in the three-piece AcrySof IOL group, and 34.15% (SD 13.2) in the one-piece AcrySof IOL group ($p = 0.99$) on the first postoperative day and did not differ during the entire follow-up period (table 1). Negative correlation was established between PCO values and overlapping in both IOL groups, but was higher in the three-piece AcrySof IOL group (6 months after surgery, $r = -0.26$, $p = 0.12$; 1 year after, $r = -0.43$, $p = 0.008$; 2 years after, $r = -0.16$, $p = 0.38$).

There was no correlation between ACO density degree and PCO values during the 2 year follow-up.

During the entire follow-up period, we found capsular folds behind the IOL optic area more often in the one-piece AcrySof IOL group. The difference between the IOL groups was significant during all follow-ups (fig 5). In the one-piece AcrySof IOL group, we found a dynamic correlation between PCO values (in the entire IOL optic area and in the central optic zone) and capsular fold presence behind the IOL optic area

Table 1 Overlapping of capsulorrhexis on intraocular lens optic (mean (SD)) in the IOL groups during the 2-years follow-up period

Capsulorrhexis/ optic overlap	Three-piece AcrySof (%)	One-piece AcrySof (%)	p Value
First day	34.38 (12.1)	34.15 (13.2)	0.99
6 months	36.50 (12.8)	33.76 (12.7)	0.43
1 year	36.85 (11.9)	34.34 (14.0)	0.45
2 years	38.15 (11.6)	31.09 (13.5)	0.05

(6 months after surgery, $r = 0.17$, $p = 0.31$ and $r = 0.15$; $p = 0.37$ respectively; 1 year after, $r = 0.24$, $p = 0.15$ and $r = 0.50$, $p = 0.002$ respectively; 2 years after, $r = 0.47$, $p = 0.008$ and $r = 0.50$, $p = 0.004$ respectively) during the follow-up period.

During the 2 year follow-up, there was no case of PCO with a decrease of two or more lines of visual acuity that required Nd:YAG laser capsulotomy in either of the groups.

DISCUSSION

The results of the present study confirm that the modification of the acrylic hydrophobic sharp-edge optic IOL from a three-piece to one-piece design caused no significant change in PCO at 2 years and no significant difference in ACO during the 2 year follow-up.

Three-piece sharp-edge optic hydrophobic acrylic (AcrySof, Alcon) IOLs have been widely accepted in the ophthalmic community, largely because of the excellent prevention of PCO.^{3 5 10 11}

Nishi et al demonstrated that the PCO-reducing effect is related to the truncated sharp-edge IOL design. In their experimental animal studies, they used sharp-edge IOLs made of various materials (hydrophobic acrylic (AcrySof), PMMA and silicone^{4 6-8}), and histologically determined the same sharp capsular bend. These studies allowed Nishi et al to conclude that the preventative effect of an IOL on PCO is dependent on IOL sharp-edge optic design. On the other hand, acrylic hydrophobic material has an adhesive surface that results in greater IOL optic-capsule adhesion,²¹ and more rapid capsular bend formation,⁹ which create a tight fit of the posterior lens capsule against the back of the IOL optic (a form of "shrink wrap"). Linnola et al demonstrated the greatest binding of fibronectin and laminin to acrylic hydrophobic IOLs (AcrySof). The strong adhesion between lens capsules and the AcrySof IOL could be explained by the fact that fibronectin plays a major role in the adhesion of IOLs and the lens capsule, which may in turn be a reason for the lower PCO values with an AcrySof lens.^{22 23}

However, from the time that one-piece AcrySof IOLs with different designs rather than three-piece AcrySof IOLs were introduced, it has remained unclear how the modification of IOL design influences the PCO prevention performance of AcrySof IOLs. The haptics of the one-piece AcrySof extend directly from the posterior surface, leaving a potential gap in the 360° sharp-edge optic. The more bulky haptic root (0.30 mm thick and 2.57 mm wide at its root) could hinder the adhesion of the anterior and posterior lens capsule around

Figure 5 Percentage of patients with postoperative capsular folds and comparison of proportions between the IOL groups during the 2 year follow-up.

the loop, and a discontinuous capsular bend may not be formed. LECs may then progress through the broad haptic-optic junction towards the centre of the posterior lens capsule.^{27–29}

Wallin et al reported results of a retrospective study showing that 2 years after cataract surgery, one-piece AcrySof IOLs showed less ACO, but more PCO.³⁰ Bender et al³¹ reported results of a 1 year follow-up prospective study, and Nejima et al²⁴ results of 18 months follow-up, in which both showed that one-piece and three-piece AcrySof IOLs are equal for PCO prevention. Mian et al retrospectively reviewed 434 eyes of patients who received AcrySof lenses and found a greater incidence of Nd:YAG capsulotomy with single piece lenses 6, 12 and 24 months after surgery.³² Only Sacu et al reported the results of a 2 year follow-up, randomised, prospective clinical study.²⁵ In their study, the difference between the groups was statistically significant at 1 year follow-up, with the three-piece AcrySof having less PCO; however, the 2 year follow-up showed no difference in PCO between the groups. Sacu et al's AcrySof IOL study²⁵ used 6 mm optics as opposed to the 5.5 mm optics of our study.

According to our 2 year follow-up study results, three-piece AcrySof IOLs showed significantly lower PCO values than one-piece AcrySof IOLs during the first postoperative year (6 months after surgery only in the entire IOL optic area, 1 year after in the entire IOL optic area and in the central 3 mm IOL optic zone). However, the 2 year follow-up after cataract surgery showed no difference between the two differently designed acrylic hydrophobic IOLs for PCO prevention, like the results of Sacu et al.²⁵ We did not find a difference in visual acuity during the entire follow-up period. There was no Nd:YAG laser treatment required.

The pathogenesis of PCO is multifactorial, including patient factors, surgical technique, and IOL design and biomaterial.^{1–3} The effectiveness of a sharp-edge concept depends on the relationship between capsulorhexis and optic.³³ According to the data from recent studies, a 360° overlapping of the capsulorhexis centred on the optic of the IOL is important for the creation of a square, sharp-edge effect. If the capsulorhexis is decentred and off the optic edge, an ingrowth of LECs behind the IOL optic is facilitated and strong negative correlation between anterior capsule overlapping and PCO development exists.^{3–11–17} Our study only included those eyes where the anterior capsule overlapped the edges of the IOL optic 360°. The overlapping area of capsulorhexis on the IOL optic was very similar in both IOL groups. The negative correlation between PCO value and overlapping of the capsulorhexis area on the IOL optic was higher in the three-piece IOL group during the entire follow-up period (the highest 1 year after surgery, $r = -0.43$, $p = 0.008$). This could be explained by the design differences in acrylic hydrophobic IOLs.

In conclusion, the current 2 year follow-up, prospective, randomised study showed that three-piece and one-piece acrylic hydrophobic IOLs were very similar for visual acuity and ACO development. One-piece acrylic hydrophobic IOLs were associated with more capsular folds. Long follow-up (2 years) showed no difference in PCO prevention between three-piece and one-piece acrylic hydrophobic IOLs (AcrySof), which might be explained by the quality of the acrylic hydrophobic biomaterial. Both sharp-edge optic acrylic hydrophobic IOLs ensured PCO prevention without requiring treatment with Nd:YAG laser capsulotomy during the 2 year follow-up.

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