Uveal and capsular biocompatibility after implantation of sharp-edged hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in eyes with pseudoexfoliation syndrome

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PURPOSE: To evaluate the uveal and capsular biocompatibility of 3 types of sharp-edged foldable intraocular lenses (IOLs) in eyes with pseudoexfoliation syndrome (PEX).

SETTING: Department of Ophthalmology, Medical University of Vienna, Vienna, Austria.

METHODS: Eighty-five eyes with PEX had implantation of 1 of the following sharp-edged 3-piece IOLs: hydrophilic acrylic (Injectacryl F3000, OphthalMed), hydrophobic acrylic (AcrySof MA60MB, Alcon), or silicone (CeeOn 911, AMO). Postoperative evaluation (flare, cellular reaction, and capsular reaction) was performed at 1, 3, and 7 days as well as 1, 3, 6, and 12 to 18 months.

RESULTS: One year after surgery, flare was comparable between the IOLs. In terms of uveal biocompatibility, whereas the Injectacryl had the highest deposition of debris on the IOL surface ($P = .04$), the CeeOn 911 had significantly more small round cells in the first 6 months ($P<.03$). The AcrySof had the highest number of foreign-body giant cells ($P = .01$). In terms of capsular biocompatibility, lens epithelial cell outgrowth was highest in the AcrySof group ($P<.02$). Anterior capsule opacification was comparable between the 3 groups. Posterior capsule opacification was mild in all groups but was significantly greater in the Injectacryl group ($P<.05$). There were no cases of clinically significant IOL decentration or capsule contraction.

CONCLUSIONS: In general, inflammatory cells accumulated more easily on hydrophobic IOLs than on hydrophilic IOLs; the AcrySof IOL had the highest prevalence of foreign-body giant cells. All 3 IOLs had good biocompatibility, although the AcrySof group had increased inflammatory signs.

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In eyes with pseudoexfoliation syndrome (PEX), fibrillin is deposited around the microvasculature, increasing the leakage of proteins into the aqueous humor and thus compromising the blood–aqueous barrier (BAB).[1–4] This implies a stronger immune reaction to intraocular lenses (IOLs) in these eyes. In addition, due to weakening of the zonular support, patients with PEX are predisposed to phacodonesis and spontaneous lens dislocation.[3,5] Accordingly, the number of intraoperative and postoperative complications has been reported to be higher in these eyes.[2,3] Commonly reported complications associated with intraocular surgery in eyes with PEX are postoperative inflammation, capsule opacification, and IOL luxation.[2,6]

The few studies that have examined the use of IOLs in eyes with PEX report high rates of capsule opacification.[7,8] However, 1 of these studies[7] used a heparin-surface-modified poly(methyl methacrylate) IOL that is no longer implanted. The IOL was placed through

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an enlarged clear corneal incision or sclerocorneal incision, which causes greater surgical trauma.

In a comparative study of a round-edged hydrophilic IOL and a sharp-edged hydrophobic IOL in patients with PEX, Abela-Formanek et al.[8] found that the hydrophilic IOL led to an increased rate of posterior capsule opacification (PCO). This might result in a higher incidence of neodymium:YAG laser capsulotomy with the associated potential risks for cystoid macular edema, capsule tear, and IOL subluxation. Because the hydrophilic IOL had a round-edged optic, a distinction between the effect of IOL material and the optic edge on PCO could not be established. However, several studies[1,4,9,10] have shown that IOLs with sharp-edged optics significantly reduce the incidence of PCO as they inhibit and delay the migration of lens epithelial cells (LECs) onto the posterior capsule.

In 1998, Naumann et al.[3] postulated that flexible silicone IOLs should not be implanted eyes with PEX as it might result in capsule contraction syndrome and vaulting of the IOL optic. However, more recent studies[4,11] of second-generation silicone IOLs with a sharp optic edge showed good uveal and capsular biocompatibility 1 year after surgery in patients without PEX.

The aim of the present study was to evaluate the uveal and capsular biocompatibility of 3 types of foldable IOLs of different materials with sharp-edged optics and a 3-piece design in eyes with PEX. As eyes with PEX have a stronger immune reaction to IOLs, the study served as a test model for biocompatibility of different IOL materials. We prospectively evaluated the progress of capsule opacification and cellular reaction on the IOL surface.

PATIENTS AND METHODS

Eighty-six eyes of 78 patients with PEX were prospectively recruited for cataract surgery. Beginning of enrollment was June 2001. In a nonrandomized protocol, the patients received a hydrophilic acrylic IOL (Injectacryl F3000, OphthalMed), hydrophobic acrylic IOL (AcrySof MA60MB, Alcon), or silicone IOL (CeeOn 911, Pharmacia). The study design adhered to the tenets of the Declaration of Helsinki. Patients gave informed consent before inclusion in the study. Exclusion criteria were diabetes mellitus, systemic anticoagulant use, and antiphlogistic therapy.

All surgery was performed by 1 of 2 surgeons (C.A.F., M.A.) using a standardized protocol. After a 3.2 mm temporal clear cornea incision and continuous curvilinear capsulorhexis (diameter 4.5 to 5.0 mm) were created, phacoemulsification was performed. Remaining cortex was aspirated and the capsular bag expanded under sodium hyaluronate 1% (Healon). The foldable IOL was implanted in the bag.

Postoperatively, all patients received betamethasone–neomycin ointment (Betnesol N) the night after surgery and betamethasone 0.1–neomycin 0.5% eyedrops (Betnesol N) and diclofenac 1% eyedrops (Voltaren Ophtha) 4 times daily for 4 weeks. Postoperative evaluation was performed at 1, 3, and 7 days as well as 1, 3, 6, and 12 to 18 months.

Table 1. Patient demographics.

IOL Group	Number of Eyes	Mean Age (Y) ± SD	Women/Men
Injectacryl	26	76.1 ± 6.9	16/10
AcrySof	33	76.3 ± 7.6	22/11
CeeOn	27	74.3 ± 7.1	17/10

IOL = intraocular lens

Flare was assessed with a laser flare–cell meter (FC-1000, Kowa) 30 minutes after pupil dilation. Seven measurements were taken with a background scatter of less than 10%. The highest and lowest readings were discarded, and the remaining 5 were averaged. Laser flare values were expressed in photons/millisecond. Cellular reaction was evaluated by specular microscopy and capsular reaction by biomicroscopy. Grading of small round cells, foreign-body giant cells, and LECs and semiquantitative analysis of anterior capsule opacification (ACO) and posterior capsule opacification (PCO) were performed as previously described.[8]

For statistical analysis, all pairwise comparisons were by the Wilcoxon rank sum test. A P value less than 0.05 was considered statistically significant. SPSS 11.0 for Windows (SPSS, Inc.) was used for statistical analysis.

RESULTS

The mean age of all patients was 76.1 years ± 6.7 (SD). Table 1 shows the patient demographics by IOL group. Of the 86 eyes enrolled, 18 were lost to follow-up 1 year after surgery. Reasons were death (3 patients, 4 eyes) and change of address with loss of contact (12 patients, 14 eyes). Twenty-six eyes received an Injectacryl IOL, 33 an AcrySof IOL, and 27 a CeeOn 911 IOL.

Flare

Preoperative flare values were comparable in the 3 IOL groups. In the first month after surgery, all groups had an increase in flare values, which were significantly higher in the AcrySof IOL group ($P < .03$). After 1 month, the values decreased to normal levels; over 6 to 18 months, flare was comparable between the groups (Figure 1).

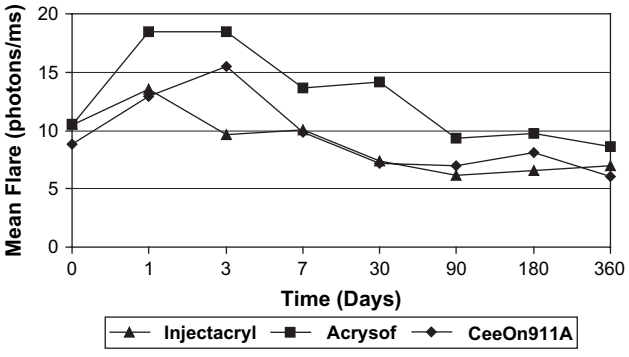

Figure 1. Mean flare values.

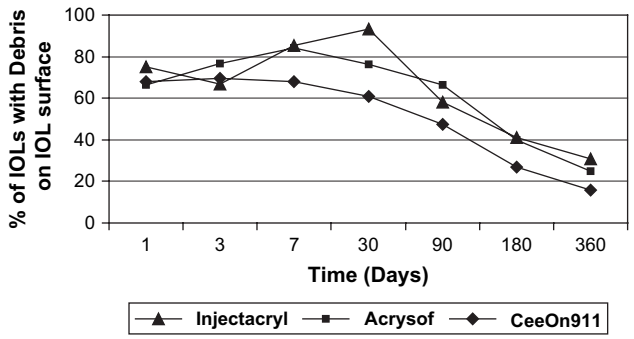

Figure 2. Percentage of IOLs with debris on the surface.

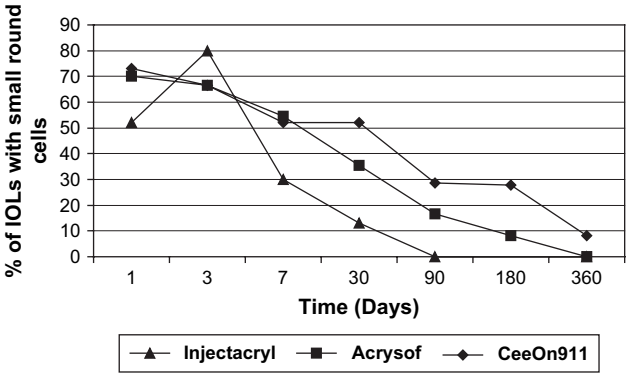

Figure 3. Percentage of IOLs with small round cells on the surface.

Uveal Biocompatibility

Debris Deposition of debris on the IOL surface was comparable in all 3 groups in the first 6 months postoperatively. After 12 to 18 months, values were significantly higher in the Injectacryl group ($P = .04$) (Figure 2).

Small Round Cells After the immediate high postoperative small round cell reaction on all IOLs (less pronounced in the Injectacryl group; $P = .032$), there was a decrease in all 3 groups. Up to 3 months postoperatively, grade 3 small round cells were found in all groups. The reaction was slightly stronger in the CeeOn 911 group; the difference between the CeeOn group and the Injectacryl group was significant at 1 to 6 months ($P > .05$) (Figure 3).

Foreign-body giant cells increased 1 month after surgery. The highest grade in the AcrySof group was 3; the maximum in the other groups was 1. After 12 to 18 months, the AcrySof group had a statistically significantly higher number of foreign-body giant cells than the other IOL groups ($P = .01$) (Figure 4).

Capsular Biocompatibility

Lens epithelial cell outgrowth was highest in the AcrySof group. Values were significantly increased 7 days and 1 month postoperatively ($P < .02$). In the Injectacryl group, almost no LEC growth was observed. The CeeOn group had significantly higher LEC outgrowth than the Injectacryl group 7 days postoperatively ($P = .04$) (Figure 5).

One year after surgery, ACO of the capsulorhexis rim and central optic areas was comparable between the 3 IOL groups (Figure 6). Posterior capsule opacification was mild in all groups but was significantly greater in the Injectacryl group ($P < .05$) (Figure 7). There were no cases of clinically significant IOL decentration or capsule contraction in any group.

DISCUSSION

The present study evaluated the uveal and capsular biocompatibility of 3 types of 3-piece IOLs in patients with PEX. All IOLs were similar in diameter and thickness and had sharp optic edges, but they were of different material. Eyes with PEX have a higher postoperative inflammatory reaction than eyes with senile cataract and no other ocular disease; therefore, eyes with PEX can serve as a test model for IOL biocompatibility. In our study, we chose IOLs with a sharp optic edge as they inhibit and delay the migration of LECs onto the posterior capsule.[9,10,12]

Previous studies report that inflammatory cells accumulate more easily on hydrophobic IOLs than on

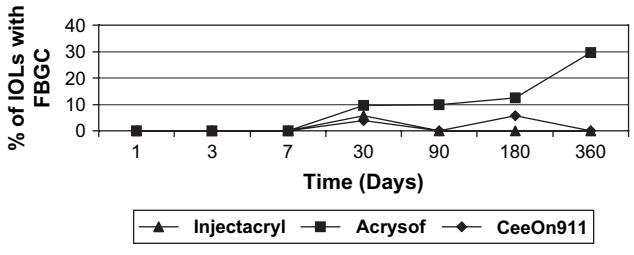

Figure 4. Percentage of IOLs with foreign-body giant cells on the surface.

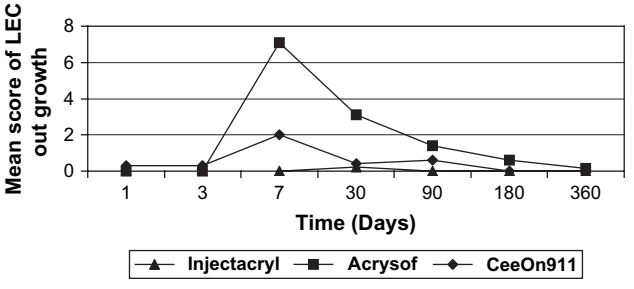

Figure 5. Mean LEC outgrowth score.

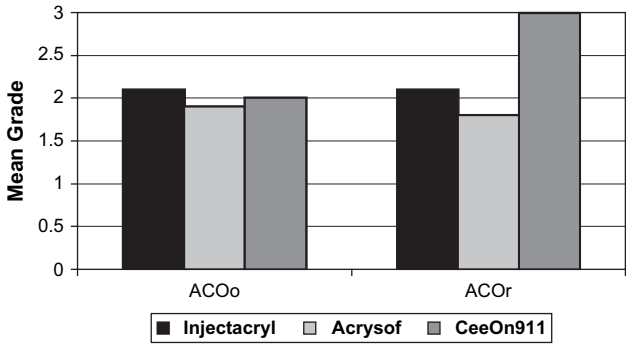

Figure 6. The mean ACO grade (ACOo = ACO of the optic zone; ACOr = ACO of the capsulorhexis rim).

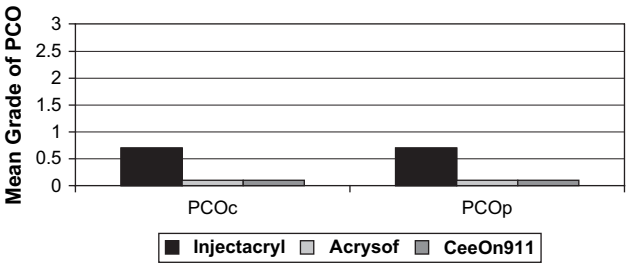

Figure 7. The mean PCO grade (PCOc = PCO in the central 3.0 mm zone; PCOp = PCO in the 3.0 to 6.0 mm zone).

hydrophilic IOLs.[8] This agrees with the results in our study, in which the AcrySof IOL had the highest prevalence of foreign-body giant cells 1 year after surgery. These cells are a sign of persistent inflammation and are a good marker of uveal biocompatibility. Small round cells, a sign of nonspecific inflammatory reaction after surgical trauma, were seen on all IOLs but were greater in the CeeOn IOL group up to 6 months after surgery. In contrast, a study of eyes without PEX[12] found almost no small round cells postoperatively. We therefore conclude that the increased immune reaction in our study reflects the underlying disease and resulting damage to the BAB. However, the clinical relevance of small round cells seems low as the cells tend to disappear after 6 months postoperatively.

Lens epithelial cell outgrowth is more common on hydrophilic materials.[13,14] However, in our study, the Injectacryl group had almost no LEC outgrowth. Schild et al.[15] report a similar protective effect of the Injectacryl IOL in eyes without PEX. This is in contrast to the hydrophilic Hydroview IOL in eyes with PEX or uveitis. [8,16] In this study, LEC outgrowth persisted on the IOL, even 1 year after surgery. This shows that LEC outgrowth is mainly material dependent and that more recently produced IOLs have improved capsular biocompatibility. In our study, the AcrySof group had increased LEC outgrowth in the first month after surgery, a result that is likely material dependent.

Anterior chamber opacification was comparable between all 3 groups; fibrosis of the capsulorhexis rim was strongest in the silicone group. In addition, the PCO grade was mild in all 3 groups, although PCO was significantly greater in the Injectacryl group. A former study found a high prevalence of PCO with the hydrophilic Hydroview IOL.[8] However, the Hydroview had a round optic edge. The advantages of the sharp optic edge design of the hydrophilic Injectacryl IOL are shown in our results.

Nishi and Nishi[11] report that second-generation silicone IOLs help prevent PCO. Strong capsular reaction can lead to decentration and phimosis in the presence of PEX. Our results showed no decentration or development of phimosis, which agrees with the findings of Nishi and Nishi.

High flare values in eyes with PEX have been described.[17,18] Postoperatively, these values rise after surgery because of the inflammatory effect of the procedure. In our study, the AcrySof IOL group had higher flare values than the other 2 IOL groups until 1 month after surgery; levels returned to normal in the Injectacryl group and CeeOn group after 3 to 7 days. This agrees with the results in a study by Abela-Formanek et al.[16] However, the reasons for this reaction remain unclear as the surgical trauma and IOL designs were similar in the study.

Jehan et al.[6] report late IOL dislocation within the capsular bag in patients with PEX. In our study, no dislocation was observed; however, the mean follow-up was much shorter than the follow-up in the Jehan et al. study (7 years).

In conclusion, our study found that capsular biocompatibility depends on IOL material and optic edge design, especially in eyes with chronic disease. It also showed the advantages of a sharp optic edge design and the good biocompatibility of currently available IOLs in eyes with PEX as evidenced by the markedly decreased inflammatory signs (flare, foreign-body giant cells) in the silicone IOL group and hydrophilic acrylic IOL group.

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