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ARTICLE

Posterior capsule opacification with two similar-design hydrophobic acrylic intraocular lenses: 3-year results of a randomized controlled trial

Christina Leydolt, MD, Daniel Schartmüller, MD, Luca Schwarzenbacher, MD, Veronika Prenner, MD, Victor Danzinger, MD, Marcus Lisy, MD, Claudette Abela-Formanek, MD, Rupert Menapace, MD

Purpose: To compare intraindividually the incidence and intensity of posterior capsule opacification (PCO) and Nd:YAG capsulotomy rates between 2 similar open-loop single-piece hydrophobic acrylic intraocular lenses (IOLs) differing slightly in their particular material, optic surface, and sharp posterior edge design over a period of 3 years.

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

Design: Randomized, prospective, patient-masked and examiner-masked clinical trial with intraindividual comparison.

Methods: 100 patients randomly received a Vivinex XY1 IOL in 1 eye and a Clareon CNA0T0 IOL in the fellow eye. The amount of PCO (score 0 to 10) was assessed subjectively and objectively with digital retroillumination pictures using automated image analysis software (Automated Quantification of After-Cataract). Corrected distance visual acuity and the presence of glistenings, subjective visual symptoms, and Nd:YAG laser capsulotomy rate were noted.

Results: 67 of 100 patients were available for the 3-year follow-up examination. The objective PCO score of the Vivinex XY1 IOLs was 1.0 ± 1.0 compared with the PCO score of 1.5 ± 1.2 for the Clareon CNA0T0 IOLs ($P < .001$). 7.5% of patients had a Nd:YAG capsulotomy in the Vivinex XY1 eye, and 9.0% had a capsulotomy in the Clareon CNA0T0 eye ($P = 1.0$).

Conclusions: Both hydrophobic acrylic IOLs showed low PCO and YAG rates with a small but significant favor of the Vivinex XY1 IOL compared with the Clareon CNA0T0 IOL. The interaction of various factors such as hydrophobic material, smooth optic surface, and sharp posterior optic edge is the major key for PCO prevention.

Clinical Trial Number: NCT 04369482.

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The optical quality demands on modern intraocular lenses (IOLs) are high. A multitude of different IOLs are available, with sometimes only small differences in IOL design and surface properties or chemical composition of the material. However, the problem of posterior capsule opacification (PCO) formation is not fully solved.[1–4] Small amounts of PCO already lead to decreased contrast sensitivity which is getting even more visually relevant with the increasing number of implanted presbyopia correcting IOLs nowadays (eg, trifocal IOLs or extended depth-of-focus IOLs) with primarily reduced contrast sensitivity at a certain amount.[5] Reduced visual acuity can also increase the incidence of falling particularly in elderly patients though.[6] Treatment of PCO by Nd:YAG laser capsulotomy is effective, but may not be readily accessible to the patient, can lead to further complications such as intraocular pressure (IOP) rise, ocular inflammation, cystoid macular edema, retinal detachment, and is associated with additional costs.[7]

The present prospective, randomized, controlled study intraindividually compares 2 similar hydrophobic acrylic IOLs: the Vivinex XY1 and the Clareon CNA0T0 IOL within a follow-up period of 3 years. These IOLs differ slightly in their particular material, optic surface, and sharp posterior edge design. Thus, the aim of the study was to identify any resulting differences in PCO development.

METHODS

Patient Recruitment, Randomization, IOL Assignment, and Surgical Technique

One hundred patients (200 eyes) were included in this prospective, randomized clinical trial for intraindividual comparison. The

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From the Department of Ophthalmology, Medical University of Vienna, Vienna, Austria.

Corresponding author: Christina Leydolt, MD, Department of Ophthalmology, Medical University Vienna, Waehringer Guertel 18-20, A-1090 Vienna, Austria. Email: christina.leydolt@meduniwien.ac.at.

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study was performed at the Department of Ophthalmology at the Vienna General Hospital (Medical University of Vienna, Vienna, Austria). Inclusion criteria were bilateral age-related cataract, age 40 and older, visual potential in both eyes of 20/30 or better, and normal findings in medical history and physical examination. Exclusion criteria were a history of ocular disease, preceding ocular surgery or trauma, relevant other ophthalmic diseases (such as pseudoexfoliation and retinal degenerations), uncontrolled systemic or ocular disease, and any intraoperative complication. The study was approved by the local ethics committee of the Medical University of Vienna, Austria (EK 1560/2014). All the research and measurements followed the tenets of the Declaration of Helsinki, and informed consent was obtained from all participants in this study.

Before the start of the study, a randomization list was generated with the DataInf RandList v. 2.0 software for a simple randomization procedure. A sequentially numbered sealed envelope was opened in the operating room and presented to the surgeon after phacoemulsification. The envelope contained the participant's right eye randomization assignment to one of the IOLs (Vivinex XY1 or Clareon CNA0T0). The randomly assigned IOL was implanted in the participant's first eye. The second eye was implanted with the other IOL to allow for intraindividual comparison. Patients and investigators were masked to IOL type. After the end of the study, all data were entered and the participant's implanted IOLs were unblinded with the randomization list for statistical analysis thereafter.

Surgery was performed by 3 experienced surgeons (R.M., C.L., C.A.) between January 2019 and January 2020 using a standardized, small-incision phacoemulsification technique. Most surgeries were immediate sequential cataract surgeries. At the end of surgery, the status of the overlap of the anterior capsule onto the IOL optic was documented by the surgeon and any surgical complications that would have led to patient exclusion.

The Vivinex XY1 IOL (Hoya Surgical Optics, Inc.) is a preloaded 1-piece hydrophobic acrylic blue-light filtering IOL with a biconvex aspheric optic and a sharp posterior optic edge. It has an optic diameter of 6.0 mm, an overall length of 13.0 mm, and haptics of the same acrylic material as the optic with a C-loop configuration with no angulation. The Clareon CNA0T0 IOL (Alcon Laboratories, Inc.) is made of an acrylate–methacrylate copolymer. The IOLs have an asymmetric biconvex optic and a posterior sharp edge interrupted at the optic–haptic junction. It also features an optic diameter of 6.0 mm, an overall length of 13.0 mm, and supporting haptics of the same acrylic material as the optic with no haptic angulation.

Follow-Up Examinations and Image Acquisition

Follow-up examinations were performed 3 years postoperatively. On each visit, corrected distance visual acuity (CDVA) in logMAR was assessed with Early Treatment Diabetic Retinopathy Study charts. IOP measurements were taken; thereafter, patients received phenylephrine 2.5% and tropicamide 0.5% for pharmacological mydriasis. The amount and type of regeneratory PCO (score 0 to 10) was evaluated subjectively at the slitlamp. A subjective score of 0 to 10 was used, where 0 stands for a clear capsule and 10 stands for severe regeneratory PCO. The presence of glistenings, as well as a semiquantitative slitlamp grading of glistening density was assessed: With the slitlamp beam set at 10.0 mm by 2.0 mm, the glistenings were graded as trace = fewer than 10, 1+ = 10 to 20, 2+ = 20 to 30, 3+ = 30 to 40, and 4+ = more than 40.[8] Patients were also asked about any disturbing visual symptoms such as edge glare or dysphotopsia (yes/no), and a full retinal examination was performed. Finally, the need for an Nd:YAG laser capsulotomy was noted, based on CDVA >logMAR 0.1 and subjective patient complaint of reduced visual acuity, as well as the presence of regeneratory after-cataract in the central optic–capsule interspace as judged under retroillumination and slitbeam illumination. If patients have had a Nd:YAG laser capsulotomy before the 3-year follow-up, this was also noted—these eyes were excluded for PCO analysis. Digital retroillumination images for documentation of regeneratory PCO were taken from the posterior capsule as described in detail previously.[9]

Data Evaluation and Image Analysis

All data from case report forms were entered into a Microsoft Excel sheet, and further statistical evaluation was performed with standard software (MS Excel and SPSS). As the amount of PCO was of primary interest for this study, we also used automated image analysis software for objective PCO evaluation (Automated Quantification of After-Cataract [AQUA]). The system has been shown to correlate well with subjective scoring of PCO.[10] However, it is fully automated, and there is no subjective bias to the evaluation process. The AQUA software calculates the entropy (grade of disorder) of a bitmap. This value is converted into a score between 0 and 10 (where 0 stands for a "clear" capsule and 10 for exceptionally severe PCO). Mean objective PCO scores were calculated with this software for the Vivinex XY1 and Clareon CNA0T0 IOL groups using the 3-year retroillumination images.

Sample Size Calculation and Statistics

Two hundred eyes of 100 patients with bilateral cataract were included in this prospective randomized comparative study. The number was selected to detect a clinically relevant difference in PCO (AQUA score) of 0.5 between groups after 3 years using a standard deviation of 1.5 from our previous long-term PCO studies with the Acrysof IOL.[11] Using a paired *t* test and 1-sided testing, the type I and type II errors were set to 0.05 and 0.2, respectively. Therefore, at least 58 patients are necessary for a power of 0.8. To account for a drop-out rate of about 40% (mean drop-out rate of our previous long-term PCO studies) after 3 years in this elderly population, 100 patients were included in the study.

The results from the Vivinex XY1 and Acrysof SN60WF IOL groups were compared, and the differences between the 2 groups were calculated. Normally distributed data were compared using a paired *t* test, not normally distributed data were analyzed using the Wilcoxon signed-rank test. Binominal data were compared using the McNemar test. A *P* value of 0.05 or less was considered significant. Data are presented as mean ± SD.

RESULTS

Sixty-seven patients (67%) of the 100 patients included in the study could be examined after 3 years. Thirty-three patients were not available for the 3-year follow-up examination: 11 patients did not show up at the arranged appointment associated with COVID-19 restrictions, 9 patients suffered from chronic illness or immobility, 6 patients died, 7 patients could not be contacted, that is, returned mail because of change of address or possibly death, or they could not be reached through telephone. Therefore, it is not known whether these patients died, or moved to a nursing home. Mean postoperative follow-up was 35.6 ± 1.9 months. No serious adverse event occurred in any group. Preoperative demographic data of patients are presented in Table 1. At the completion of surgery, all optics were circumferentially overlapped by the anterior capsule leaf. No primary fibrosis was noted on the posterior capsule in any case. There were no surgical complications that would have led to patient exclusion.

PCO was evaluated objectively with digital retroillumination images and the AQUA software. Three years postoperatively, a mean objective PCO score (scale 0 to 10) of 1.0 ± 1.0 was found for the Vivinex XY1 group and a score of 1.5 ± 1.2 for the Clareon CNA0T0 group (*P* <

Table 1. Preoperative demographic data of patients

IOL	Vivinex XY1	Clareon CNA0T0
Age (y)	73.0 ± 8.6	
Sex (F/M)	77/23	
Refraction (SE) (D)	0.06 ± 2.5	−0.03 ± 2.9
CDVA (Snellen)	0.59 ± 0.16	0.60 ± 0.17
ACD (mm)	3.12 ± 0.37	3.11 ± 0.36
AL (mm)	23.58 ± 1.16	23.58 ± 1.22

ACD = anterior chamber depth; AL = axial length; SE = spherical equivalent
There was no statistical difference between IOL groups

.001) (n = 62) (Figure 1). 1.6% (n = 1) showed the same amount of regeneratory PCO in both eyes, whereas 30.6% (n = 19) showed more regeneratory PCO in the Vivinex XY1 eye and 67.7% (n = 42) showed more regeneratory PCO in the Clareon CNA0T0 eye (Figure 2). In 14.5% (n = 9) of the Vivinex XY1 eyes and 9.7% (n = 6) of the Clareon CNA0T0 eyes, no regeneratory PCO was seen at 3 years.

Before the 3-year follow-up, 6.0% (4 patients) had a Nd:YAG laser capsulotomy in their Vivinex XY1 eye and 7.5% (5 patients) in their Clareon CNA0T0 eye (P = 1.000), respectively. After the 3-year examination, 1 additional patient had a capsulotomy in the Vivinex XY1 eye and in the Clareon CNA0T0 eye, resulting in an overall capsulotomy rate of 7.5% (5 eyes) in the Vivinex XY1 and 9.0% (6 eyes) in the Clareon CNA0T0 group (P = 1.00), respectively.

Two patients (3.0%) showed IOL glistening (density: trace: 1.5% [n = 1]; 1+: 1.5% [n = 1]; 2+: 0% [n = 0]; 3+: 0% [n = 0]; and 4+: 0% [n = 0]) in the Vivinex XY1 eye, whereas in 9 patients (13.4%) of the Clareon CNA0T0 eyes, glistening was detected 3 years postoperatively (P < .039). The density of glistenings in the Clareon CNA0T0 IOLs was as follows: trace: 9.0% (n = 6); 1+: 3.0% (n = 2); 2+: 1.5% (n = 1); 3+: 0% (n = 0); and 4+: 0% (n = 0).

Similar to the objective image analysis findings, the subjective PCO score from slitlamp examination (scale 0 to 10) was 1.3 ± 1.4 for the Vivinex XY1 group and 1.8 ± 1.6 for the Clareon CNA0T0 group (P = .005). Concerning CDVA, both IOLs showed no difference 3 years postoperatively (Vivinex XY1: logMAR −0.03 ± 0.08, Clareon CNA0T0: logMAR −0.03 ± 0.08; n = 61; P = .746) (Figure 3). We also found no significant difference in

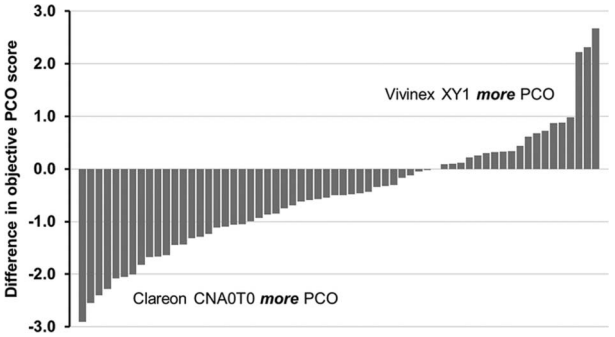

Figure 2. Individual differences of regeneratory PCO (AQUA score) 3 years postoperatively. AQUA = Automated Quantification of After-Cataract; PCO = posterior capsule opacification

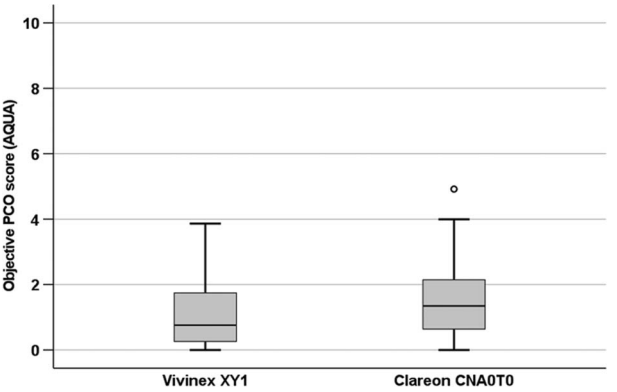

Figure 1. Objective PCO score (AQUA) of the Vivinex XY1 and Clareon CNA0T0 IOL 3 years postoperatively represented with boxplots. Boxes show the interquartile range, whiskers the non-outlier minimum and maximum. There was a significant difference between the 2 IOLs (P < .001). AQUA = Automated Quantification of After-Cataract; PCO = posterior capsule opacification

subjective optical symptoms such as edge glare or dysphotopsia described by the patients (Vivinex XY1: 0%, n = 0; Clareon CNA0T0: 0%, n = 0).

DISCUSSION

Three years postoperatively, we found a small but significant difference in the objective PCO score (0 to 10) of 1.0 ± 1.0 for the Vivinex XY1 group and 1.5 ± 1.2 for the Clareon CNA0T0 group (P < .001) in this intraindividually compared randomized controlled trial. The YAG capsulotomy rate was found to be very similar with 7.5% in Vivinex XY1 eyes compared with 9.0% in Clareon CNA0T0 eyes (P = 1.00).

In a previous study, we found significantly lower PCO and YAG rates with Vivinex XY1 IOLs compared with Acrysof SN60WF IOLs as well as a significantly higher amount of glistenings with Acrysof SN60WF IOLs in a prospective randomized controlled fellow-eye clinical trial.[11] The Acrysof IOL was the first hydrophobic acrylic foldable lens introduced in 1993 with variations in design and also material launched since then. It is made of a hydrophobic acrylate–methacrylate copolymer and plasma etching of the optic. The newer Clareon material is a cross-linked acrylic optic biomaterial combining a hydrophilic polymer (2-hydroxyethyl-methacrylate) and a hydrophobic component (phenylethyl acrylate) with a water content of 1.5%, which is supposed to show reduced glistening and surface inhomogeneities.[12]

Plasma treatment of the optic is a method of hydrophilization and increases adhesive forces between the IOL and the capsular bag known as sandwich theory proposed by Linnola.[13] The so-called sandwich pattern of IOL, a single lens epithelial cells (LECs) layer acting as an adhesive to promote a biological glue between the IOL and posterior capsule and the posterior capsule itself promotes adhesion after surgery, thus inhibiting PCO. Proteins making up the extracellular matrix, including fibronectin, vitronectin, laminin, and collagen IV, play a role in this adhesion. Another treatment to promote the adhesion between the IOL optic and posterior capsule to prevent

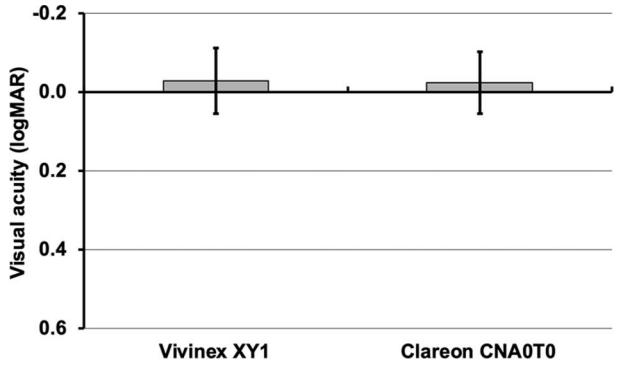

Figure 3. CDVA in logMAR of the Vivinex XY1 and Clareon CNA0T0 IOL 3 years postoperatively represented with boxplots. Boxes show the interquartile range, whiskers the nonoutlier minimum and maximum. There was no significant difference between the 2 IOLs (P = .75).

PCO is UV–ozone (O_3) irradiation that produces active species and introduces nitrogen substituents and functional OH and COOH groups on the IOL posterior surface. The COOH groups are highly adhesive to the adhesion protein fibronectin.[14] This UV–O_3 irradiation is applied on the posterior surface of the Vivinex XY1 IOL. The IOL surface modification improves adhesion between the IOL and the posterior capsule through a single layer of LECs and adhesion proteins, such as fibronectin preventing LEC migration and therefore PCO. Comparing surface-treatment methods, argon plasma—as used with the Acrysof IOL as well as Clareon IOLs—was associated with an etching effect that can promote surface deterioration, whereas UV–O3 treatment produced little damage to the lens surface. UV–O_3 treatment was shown to be more effective than argon plasma treatment in preventing PCO in a rabbit study.[14] Despite bioadhesive aspects in the early postoperative period, material hydrophobicity and surface roughness to inhibit cell adhesion and migration seem to play a major role in preventing the second invasion of LEC that might lead to regeneratory PCO years after cataract surgery. Reduced cell adhesion on hydrophobic acrylic IOLs correlates with a lower surface roughness and higher water contact angle.[15] In an in vitro study by Giacinto et al. analyzing surface properties of various IOLs, the Vivinex XY1 and Clareon SY60WF IOLs exhibited the lowest surface roughness (mean surface roughness: Vivinex XY1: 0.63 nm; Clareon SY60WF: 1.01 nm) and a higher mean contact angle value than other IOL models indicating a high hydrophobicity of the IOL material.[16] A smooth regular IOL surface might reduce cell adhesion and therefore lower the incidence of PCO.

Besides optic material and surface treatment, the role of a square posterior optic edge as a major factor for prevention of PCO formation by inhibiting migration of LECs behind the IOL optic is indisputable.[2,17–25] The effect is caused by a mechanical barrier of a sharp optic edge, by contact inhibition of migrating LECs at the capsular bend by the square edge, and a high pressure exerted by IOLs with a square-edged optic profile on the posterior capsule bend.[26–29] The successful PCO preventing effect of a sharp posterior optic edge resulted in the almost exclusively implementation in various IOL models nowadays. It has been postulated that the sharper the optic edge the more effective the barrier effect against migration of LECs.[25] Nevertheless, the sharpness of the posterior edges varies not only among different materials in a way that hydrophilic acrylic exhibits rounder edge design due to post-processing hydration and swelling but also among similar hydrophobic materials.[30,31] Nanavaty et al. scanned several IOLs with a standardized technique using environmental scanning electron microscopy. The posterior optic edges of commercially available IOLs were scanned at a magnification of x500 and x200 to measure the radius of curvature of the posterior optic edges and the optic edge thickness. They stated that IOLs with a radius of curvature of less than 10.0 mm seem to have good PCO inhibiting performance. The Vivinex XY1 was shown to have a very sharp posterior edge of 7.6 µm radius of curvature, and one of the thinnest edge profiles of 150.5 µm compared with the Clareon (radius of curvature: 7.9 µm; edge thickness: 167.2 µm) and the previously investigated Acrysof SN60WF (radius of curvature: 8.5 µm; edge thickness: 197.7 µm).[30]

The disrupted posterior square edge at the optic–haptic junction is a drawback in both Vivinex XY1 and Clareon IOLs. In this area, the impeded fusion of the capsule leaves interrupts the continuous bending of the posterior capsule around the posterior optic edge. The optic–haptic junction may serve as a gateway for LECs to access the retro-optical space, resulting in potentially more PCO. The square posterior optic edge has mostly been considered as the major factor for prevention of PCO formation, but the IOL material continues to play an important but still not fully clarified role in this complication. In our previous study comparing the Vivinex IOL with the Acrysof IOL, a significantly higher amount of glistenings in 92.8% of eyes with an Acrysof IOL compared with 1.5% with a Vivinex IOL was found.[11] Glistenings are microvacuoles within the IOL material and may occur when the IOL is in an aqueous environment and water fills microscopic openings within the optic material, which can impair the optical quality. Higher density of the acrylic polymer network may prevent the formation of microvacuoles and provide better visual outcomes.[32] Newer hydrophobic acrylic materials, such as the Vivinex XY1 and the Clareon material, should overcome that problem as demonstrated in the low rate of glistenings in this study (Vivinex XY1: 3.0%; Clareon: 13.4%; $P < .039$) as well as in in vitro studies with the Vivinex XY1 IOL.[33] Although PCO grades were generally low with both IOLs, one must consider that also small amounts of PCO, for example, thin continuous cell layers of regeneratory or fibrotic PCO on the posterior capsule remain undetected by retroillumination which compromise contrast sensitivity before high-contrast visual acuity. This can definitely affect visual performance specially with newer presbyopia-correcting IOL platforms, such as multifocal or extended–range-of-vision IOLs that feature reduced contrast sensitivity.

In conclusion, this is the first long-term prospective randomized controlled clinical study comparing the hydrophobic acrylic Vivinex XY1 IOL and Clareon CNA0T0 IOL. Both IOLs showed good performance regarding PCO and YAG capsulotomy rate 3 years postoperatively with

a slightly but significantly more favorable results with the Vivinex IOL over the Clareon IOL. This is possibly due to differences in sharpness of the posterior optic edge, surface smoothness, and other factors such as hydrophobicity and optic surface treatment indicating that they still remain major keys for PCO prevention.

WHAT WAS KNOWN

- Hydrophobic acrylic 1-piece IOLs with sharp posterior optic edge and C-loop haptics are one of the most popular IOLs nowadays.
- Variations of similar IOLs in their particular material, optic surface, and sharp posterior edge design affect posterior capsule opacification (PCO) prevention.

WHAT THIS PAPER ADDS

- Sharpness of the posterior optic edge, surface smoothness, hydrophobicity, and optic surface treatment remain major keys for PCO prevention.
- Low incidence of PCO is still important affecting visual performance specially with newer presbyopia correcting IOLs.

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First author:
Christina Leydolt, MD

Department of Ophthalmology, Medical University of Vienna, Vienna, Austria