Suppression of surface light scattering in intraocular lenses manufactured using an improved production process

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PURPOSE: To clinically examine the suppression of surface light scattering after implantation of an intraocular lens (IOL) manufactured using an improved production process.

SETTING: Miyata Eye Hospital, Miyazaki, Japan.

DESIGN: Comparative case series.

METHODS: The prospective case series comprised eyes receiving hydrophobic acrylic Acrysof SN60WF IOLs that were manufactured before and after the improvement. Light scattering on the anterior IOL surface was examined up to 3 years postoperatively using an EAS-1000 anterior segment analyzer. The changes during the postoperative period were evaluated and the 2 IOLs compared. The corrected distance visual acuity (CDVA) and contrast sensitivity under photopic and mesopic conditions were also examined 3 years postoperatively.

RESULTS: The case series comprised 24 eyes (received IOL before improvement) and 27 eyes (received IOL after improvement). After the improvement, the IOLs showed no increase in surface light scattering up to 2 years, while there were increases after 2 years in the other IOLs. The light scattering with the improved IOL was significantly reduced at all observations ($P < .048$, t test with Holm correction). No difference was found in the CDVA and contrast sensitivity.

CONCLUSIONS: The improvement in the production process effectively decreased and slowed the development of surface light scattering. The slower increase in the improved IOL 3 years postoperatively showed that the development of water aggregates would not be completely prevented.

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In hydrophobic acrylic intraocular lenses (IOLs), in particular Acrysof IOLs (Alcon Laboratories, Inc.), surface light scattering increases over time postoperatively.[1–5] Water aggregates in an IOL surface layer caused by phase separation are considered to be the etiology of surface light scattering.[6,7] Cryogenic-focused ion-beam scanning electron microscopy (SEM) observations of explanted Acrysof MA60BM IOLs identify nanometer-sized water aggregates that are similar to glistenings except for their size and location[8] and are referred to as subsurface nanoglistenings.[7] Progressive increases in surface light scattering[2,5] show the development of phase separation with aging of the IOL. Although the influence of the increased surface light scattering on visual function is not critical,[2,3,5,9] the risks of degradation remain a cause for concern.[4,10]

For suppressing the phenomena, the manufacturer refined the IOL production process for suppressing development of water aggregates within the IOL[11] by implementing tight environmental and process controls in the formulation, cast molding, and curing operations. The curing process was improved by increasing the temperature by approximately 40% and decreasing the cycle by 20%. The improved IOLs have been commercially available in Japan since 2012. An in vitro examination using accelerated aging showed significant suppression of surface light scattering.[12] Clinically, observations up to 1 year after implantation

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of the improved IOLs found no significant increase in surface light scattering.[13] Whereas significant increases were observed over 1 year postoperatively,[2] our study evaluated surface light scattering for 3 years postoperatively to verify that the improved production process suppresses surface light scattering.

PATIENTS AND METHODS

This study comprised 2 observational case series. In the first case series, Acrysof SN60WF hydrophobic acrylic IOLs manufactured using the improved production process (Q-code model) were implanted in eyes from January to July 2012. In the other case series, the same IOL manufactured before the improvement (J-code model) was implanted in eyes from September 2006 to July 2009. The study adhered to the tenets of the Declaration of Helsinki, and the Institutional Review Board, Miyata Eye Hospital, approved the study protocols. All patients provided informed consent. Eyes with posterior capsule opacification and other diseases influencing the corrected distance visual acuity (CDVA) and contrast sensitivity were excluded from the study.

Surgical Technique

In all cases, the cataract was removed with phacoemulsification after a continuous curvilinear capsulorhexis was created. The IOL was implanted in the capsular bags using an injector.

Patient Evaluations

Surface light scattering was examined 1, 3, and 6 months as well as 1, 2, and 3 years postoperatively using an anterior segment analyzer (EAS-1000, Nidek Co., Ltd.) as previously described.[2,4,5,9] A Scheimpflug image was captured under a perpendicular slit illumination with a flash intensity of 200 W. To avoid the effects of posterior capsule opacity, the light scattering intensity on the anterior IOL surface was analyzed with densitometry using the measurement unit of computer-compatible tape (CCT) ranging from 0 to 255 (maximum). The mean densitometry was measured in the central 3.0 mm area.[14] Light scattering caused by glistenings was also examined 1 month and 3 years postoperatively. Densitometry of the same area size was performed at the center of the IOL.[8]

The CDVA and contrast sensitivity were also examined. Contrast sensitivity was measured using the Functional Acuity Contrast Test chart (Stereo Optical, Inc.) under photopic and mesopic conditions. The area under the log contrast sensitivity function was calculated according to the method of Applegate et al.[15]

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Statistical Analysis

A statistical power of 0.94 was anticipated for detecting a difference of 10 CCT in surface light scattering for the sample sizes obtained. When a significance level was $P = .05$, the standard deviation in the CCT values was 10 CCT.[5]

The change in surface light scattering over time was examined using 1-way analysis of variance followed by the Tukey multiple comparison test. Comparisons between the 2 IOLs (J-code and Q-code models) were examined by the t test with the Holm correction. Comparisons of CDVA and contrast sensitivity between the 2 IOLs were examined using the Mann-Whitey test and t test with the Holm correction, respectively. A P value less than 0.05 was considered statistically significant. Results are presented as the mean $\pm$ SD unless otherwise specified.

RESULTS

The group receiving the improved IOL (Q-code model) comprised 27 eyes of 27 patients. The mean age of the patients was 68.2 $\pm$ 5.4 years. The group receiving the IOL manufactured before the improvement in the production process (J-code model) comprised of 24 eyes of 24 patients. The mean age of the patients was 70.3 $\pm$ 6.7 years.

Figure 1 shows typical Scheimpflug images of 2 IOLs 1 month and 1 and 3 years postoperatively. While the J-code IOL showed increased light scattering on the IOL surfaces, the scattering was reduced in the Q-code IOL. Figure 2 shows the changes in surface light scattering. In the Q-code IOLs, there was no change until 2 years postoperatively and a significant increase was found at 3 years ($P < .001$). In contrast, the J-code IOLs showed no increase until 2 years postoperatively and there were significant increases at 2 years or later compared with the earlier observations ($P < .005$, Tukey multiple comparison). Comparisons between the 2 IOL groups resulted in significantly lower surface light scattering in the Q-code model ($P < .048$, t test with Holm correction).

The mean scattering values associated with glistenings in the J-code IOLs and Q-code IOLs 1 month postoperatively were 18.0 $\pm$ 2.4 CCT and 15.5 $\pm$ 1.1 CCT, respectively. They increased to 34.0 $\pm$ 10.5 CCT and 19.9 $\pm$ 3.0 CCT, respectively, 3 years after surgery. The scatterings associated with glistenings in the Q-code IOL were significantly less that those in the J-code IOL ($P < .001$, t test).

Although the difference in surface light scattering was the greatest 3 years postoperatively, the mean CDVA with the Q-code IOLs (-0.11 ± 0.09 logMAR) did not differ significantly from that with the J-code IOLs (-0.12 ± 0.10 logMAR) ($P = .58$).

Figure 3 shows contrast sensitivity under photopic and mesopic conditions. There were no significant differences ($P > .14$) between the J-code IOLs and Q-code IOLs. The mean area under the log contrast sensitivity