Tokai J Exp Clin Med., Vol. 47, No. 1, pp. 9-12, 2022

Long-term Stability of New Acrylic Intraocular Lens Materials by Accelerated Severe Aging Test

Akira TSUJI and Kenji KAWAI

Department of Ophthalmology, Tokai University School of Medicine

(Received September 22, 2021; Accepted November 2, 2021)

Objective: In this study, we examined the long-term stability of recently marketed acrylic intraocular lens (IOL) materials using accelerated severe aging tests.
Methods: LENTIS Comfort (LS-313MF15) and Clareon (SY60WF) were selected as the study materials, and Nex-Acri AA 1P (NS-60YS) was used as the reference material. Severe accelerated aging test was performed by immersing the IOLs in screw-cap vials filled with ultrapure water at 100°C for 115 days. After the pre-determined periods, the appearance, dimensions, weight, and transmittance of each of the IOLs were examined. The absorbance of the storage solution was measured, and the presence or the absence of the eluted ingredients was examined. In addition, changes in the chemical structure were examined using FT-IR.
Results: SY60WF showed white turbidity, change in color, decrease in dimensions and weight, and reduced transmittance in the region 400–850 nm. These changes intensified over longer period of time. Among the two IOLs used for the study, the absorbance of the storage solution of only SY60WF increased with time. In the FT-IR spectrum, only SY60WF showed a shift of the peak around near 1700 cm^{-1}, owing to the presence of carbonyl group, indicating a change in the chemical structure.
Conclusion: Although no change was observed for the LS-313MF15 or NS-60YS after accelerated testing simulation performed for 10 or 20 years. SY60WF showed structural changes, which could be due to hydrolysis.

Key words: acrylic intraocular lens (IOL), accelerated deterioration test, glistening, hydrophobic, hydrophilic

INTRODUCTION

The first report of an intraocular lens (IOL) was made to be in the middle of the 18th century, but it was actually in 1949 when Harold Ridley inserted a small lens made of acrylic (PMMA) as an IOL. The IOL material was later changed by replacing PMMA with silicone in 1984 and again to acrylic in 1994.

In recent years, glistening and sub-surface nano-glistening (SSNG) have been reported with acrylic IOLs inserted for a long time [1–8]. For a long-term IOL implantation, manufacturers are constantly urged to improve the material to maintain the transparency of the material.

Therefore, secular changes made by conducting reproducibility experiments on the deterioration of soft acrylic intraocular lenses have been observed, starting several years after their insertion [9, 10].

In this study, we examined the long-term stability of recently marketed acrylic IOL materials, which have been manufactured using different methods and materials from the IOLs available in the market that have not been clinically evaluated by accelerated aging tests.

MATERIALS AND METHODS

The following three types of IOLs were selected as materials for this experiment.

1. Product name: Clareon, model name: SY60WF, hydrophobic acrylic lens, cast molding method, which was launched in 2020 by Alcon.
2. Product name: LENTIS Comfort, model name: LS-313 MF15, hydrophilic acrylic lens, and lath-cut method, which was launched in 2019 by Santen.
3. Product name: Nex-Acri AA 1P, model name: NS-60YS, hydrophobic acrylic lens, cast molding method, which was launched in 2016 by Nidek. (Used as a reference material)

Severe accelerated aging testing was performed by immersing the IOLs in screw-cap vials filled with ultrapure water followed by maintaining the vial at 100°C for 115 days (assuming that 100°C for 23 days corresponds to 37°C for 4 years and that 57.5% and 115 days at 100°C correspond to 10 and 20 years, respectively, at 37°C).

EVALUATION PARAMETERS

Appearance, lens weight, lens dimension (overall diameter, optic), transmittance, infrared spectrum (FT-IR), light absorption of preservation solution.

USED EQUIPMENT

▶ Appearance
Nikon Optical Microscope (SMZ1500)
Nikon Digital Microscope Camera (DXM1200)
▶ Lens weight
SHIMADZU Analytical Balance (AP324X)
▶ Dimension (Overall diameter, optic)
NIKON measuring microscope (MM-400)

Akira TSUJI, Department of Ophthalmology, Tokai University School of Medicine,143 Shimokasuya, Isehara, Kanagawa 259-1193, Japan
Tel: +81-463-93-1121 Fax: +81-463-91-9328 E-mail: tsujiakira@pop16.odn.ne.jp

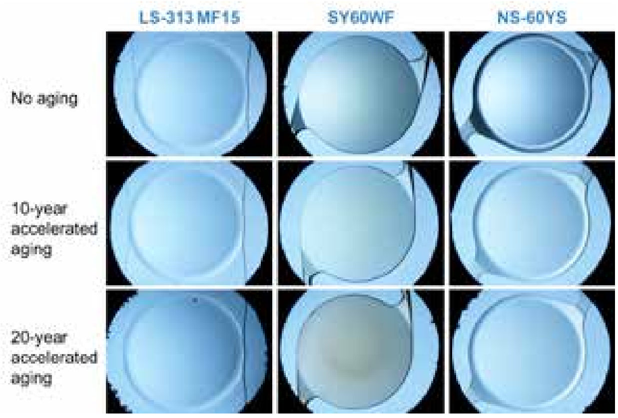

Fig. 1 Result of Bright-field appearance in water field

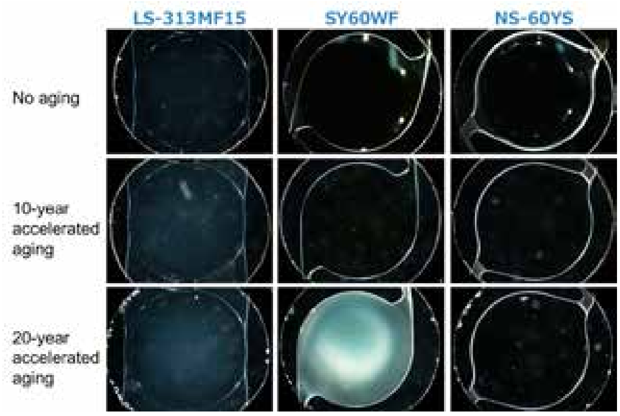

Fig. 2 Result of Dark-field appearance in water

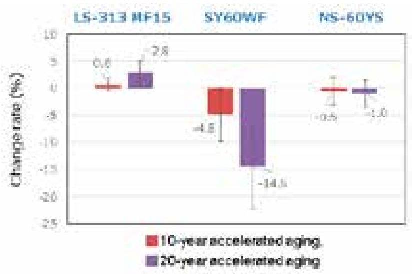

Fig. 3 Lens weight

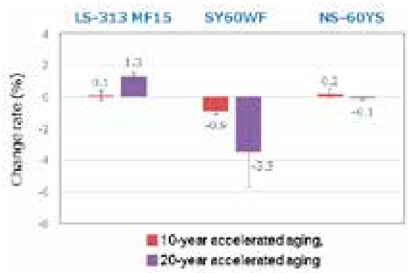

Fig. 4 Overall length

Fig. 5 Optic diameter

Table 1 Lens weight

	10-year accelerated aging		20-year accelerated aging	
	No aging(mg)	10-year accelerated aging(mg)	No aging(mg)	20-year accelerated aging(mg)
LS-313 MF15	31.8 ± 0.8	32.0 ± 0.6	31.4 ± 0.5	32.2 ± 0.5
SY60WF	16.2 ± 0.8	15.4 ± 0.2	16.5 ± 1.4	14.0 ± 0.3
NS-60YS	17.1 ± 0.5	17.0 ± 0.1	17.2 ± 0.4	17.0 ± 0.1

Table 2 Overall length

	10-year accelerated aging		20-year accelerated aging	
	No aging(mm)	10-year accelerated aging(mm)	No aging(mm)	20-year accelerated aging(mm)
LS-313 MF15	10.69 ± 0.03	10.70 ± 0.05	10.72 ± 0.05	10.86 ± 0.03
SY60WF	12.89 ± 0.02	12.78 ± 0.03	12.89 ± 0.03	12.45 ± 0.34
NS-60YS	12.99 ± 0.03	13.00 ± 0.01	13.03 ± 0.01	13.02 ± 0.04

Table 3 Optic diameter

	10-year accelerated aging		20-year accelerated aging	
	No aging(mm)	10-year accelerated aging(mm)	No aging(mm)	20-year accelerated aging(mm)
LS-313 MF15	6.01 ± 0.02	5.97 ± 0.02	6.00 ± 0.02	6.05 ± 0.03
SY60WF	5.94 ± 0.02	5.91 ± 0.02	5.95 ± 0.01	5.63 ± 0.11
NS-60YS	6.00 ± 0.01	5.99 ± 0.01	6.00 ± 0.01	6.00 ± 0.01

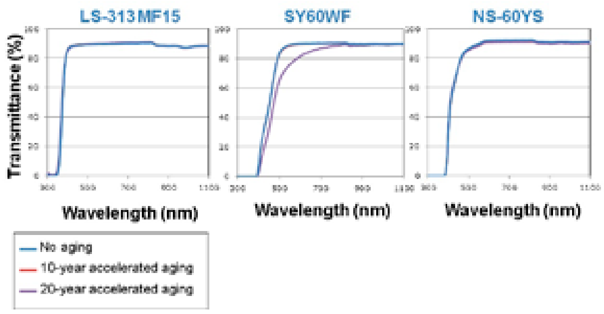

Fig. 6 Transmittance

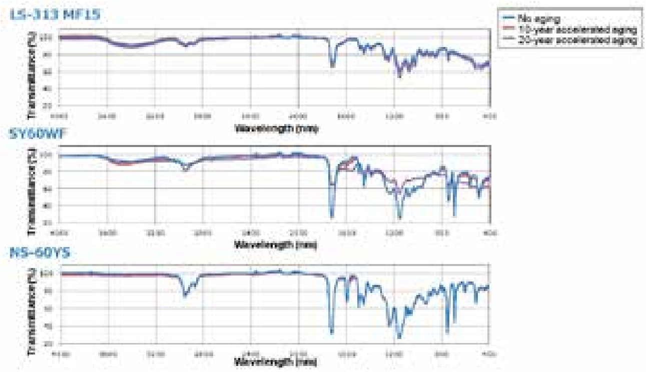

Fig. 7 Fourier-transform infrared Spectrum

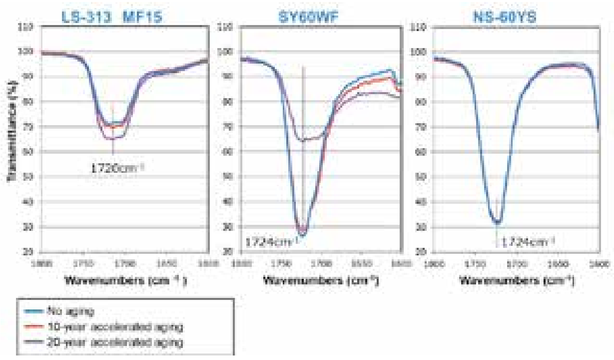

Fig. 8 Fourier-transform infrared Spectrum
Wavenumbers 1600 cm^{-1} to 1800 cm^{-1}

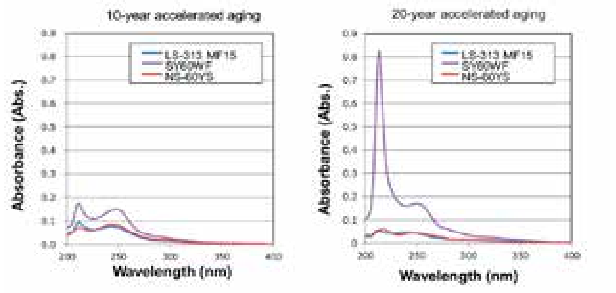

Fig. 9 Absorbance of preservation solution

▶ Transmittance
SHIMADZU UV-VIS spectrophotometer (UV-2600)
▶ Infrared light spectrum
SHIMADZU Fourier Transform Infrared Spectrophotometer (IRAffnity-1)
▶ Light absorption of preservation solution
SHIMADZU UV-VIS spectrophotometer (UV-2600)

The IR spectra was recorded only once whereas for all other evaluation parameters measurements were performed 5 times each.

RESULTS

Appearance

Bright-field appearance in water field and Dark-field appearance in water.

As shown in Figs. 1 and 2, SY60WF only turned yellow after 115 days (20 years), and the optics turned cloudy in water (Fig. 1, 2). (5/5 example)

Lens weight

The weight loss of SY60WF was confirmed from 10 years of acceleration, and it further increased after 20 years of acceleration.

A weight loss occurred from 16.2 ± 0.8 mg to 15.4 ± 0.2 mg in case of 10 years of acceleration compared to no aging. In case of 20 years of acceleration a weight loss of 16.5 ± 1.4 mg to 14.0 ± 0.3. mg occurred (Fig. 3, Table 1) compared to No aging.

Overall length

The overall length of LS-313 MF15 increased after 20 years of acceleration.

The overall length of the SY60WF decreased after 10 years of acceleration and was found to be even less after 20 years of acceleration (Fig. 4, Table 2).

Optic diameter

In SY60WF, no change in the optical diameter was observed after 10 years of acceleration, but the optical diameter was found to decrease after 20 years of acceleration (Fig. 5, Table 3).

Transmittance

10-year accelerated aging

There were no noticeable changes observed in the transmittance of any of the IOLs.

20-year accelerated aging

SY60WF: The transmittance of the lens decreased after acceleration.

(Wavelength in the range of 400 to 850 nm) (Fig. 6).

Fourier-transform infrared Spectrum

SY60WF: The structure is different from that before acceleration (Fig. 7).

In Fig. 8, the region of the wave numbers between 1600 cm^{-1} – 1800 cm^{-1} of the FT-IR in Fig. 7 is enlarged (Fig. 7, 8).

No changes in transmittance were observed for the

LS-313 MF15 and NS-60YS.

A shift in the peak attributed to the presence of carbonyl group at approximately 1700 cm^{-1} was detected for SY60WF.

Absorbance of preservation solution

The LS-313MF15 and NS-60YS did not show any significant changes in the acceleration spectrum over 10 years.

With SY60WF, an eluted component was observed in all the preservation solutions compared with acceleration over 10 years (Fig. 9).

DISCUSSION

A deterioration of polymer materials and consequent coloring occurs when they are exposed to heat, light, oxygen, water, etc. for a long periods of time owing to various reactions such as oxidation, hydrolysis, depolymerization, and cross-linking of the polymer.

It has been reported that the deterioration of polymer materials may involve swelling, cloudiness, surface cracks, etc. and may result in a significance reduction of the strength [11].

Hydrolysis is one of the ways to determine the deterioration of IOLs. The method involves immersing the test material in a vial containing water at 37°C or 50 °C for 30 or 90 days.

The evaluation parameters considered for the study are weight, transmittance, and SEM to observe the changes that have occurred with respect to the untreated material. The test solution is screened quantitatively and hydrolysates such as UV absorbers, additives, and decomposition products are quantified [12, 13].

If an acrylic resin based IOL, used as a medical material, is implanted in the eye for a long period of time, material deterioration cannot be avoided.

To determine the clinical deterioration, it is necessary to remove and examine the implanted IOL, which is difficult in real life.

Therefore, we used a method in which each IOL was kept immersed in a screwcap bottle containing ultrapure water at 100°C for 115 days for severe accelerated deterioration.

We hypothesized that 23 days in an oven at 100°C would be equivalent to 37°C for 4 years, and hence, 10 years would be equivalent to 57.5 days while 20 years would be equivalent to 115 days. We have previously reported the hydrolysis of IOL using this method [9].

From the experimental results obtained from the previous reports it can be concluded that some IOLs produced by the cast molding process can suffer from turbidity, which affects the visibility.

In addition, lens produced the cast molding method, were also found to undergo structural changes and an increase in the eluate concentration in the preservative solution [10].

Of the IOLs selected this time, SY60WF is manufactured by the cast molding method, and the lace cut method is used for the manufacture of the LS-313 MF15 and NS-60YS. No noticeable change was observed in any of the lenses at 10 years of acceleration. However, after 20 years of acceleration, the lens of SY60WF turned yellow, and weight reduction and dimensional reduction were confirmed. This was reflected in the change in the spectral transmittance and the increase in the eluate concentration in the preservation solution.

In addition, since the peak shift was confirmed by FT-IR, it is considered that the material structure of SY60WF changed owing to acceleration process. In a previous report, we reported that the materials used in the cast molding method are easily hydrolyzed [9, 10]. The same result was obtained in this study. However, the fact that SY60WF did not show any noticeable change after 57.5 days (equivalent to 10 years), suggests that the conventional lens material AcrySof had been replaced with a hydrolysis resistant lens material. The resistance to hydrolysis is attributed to the higher water content ~1.5% of the lens material compared to a water content of 0.4% of conventional AcrySof [8].

In fact, LS-313 MF15 has a water content of 26% and as a future study, we plan to conduct a comparative study on the effects of different quantities of water content on the long-term stability of various IOLs [14].

ACKNOWLEDGMENTS

We express our gratitude to the intraocular lens manufacturers, who graciously provided us with the intraocular lenses studied.

REFERENCES

1) Miyata A, Uchida N, Nakajima K, *et al.* Clinical and Experimental Observation of Glistening in Acrylic Intraocular Lenses. J PN J Ophthalmol 2001; 45: 564–569.
2) Miyata A and Yaguchi S. Equilibrium water content and glistenings in acrylic intraocular lenses. J Cataract Refract Surg 2004; 30(8): 1768–1772.
3) Mamalis N. Intraocular lens glistenings. J Cataract Refract Surg 2012; 38(7): 1119–1120.
4) Werner L. Glistenings and surface light scattering in intraocular lenses. J Cataract Refract Surg 2010; 36(8): 1398–1420.
5) Matsushima H, Mukai K, Nagata M, *et al.* Analysis of surface whitening of extracted hydrophobic acrylic intraocular lenses. J Cataract Refract Surg 2009; 35(11): 1927–1934.
6) Miyata K, Honbo M, Otani S, *et al.* Effect on visual acuity of increased surface light scattering in intraocular lenses. J Cataract Refract Surg 2012; 38(2): 221–226.
7) Ong MD, Callaghan TA, Pei R, *et al.* Etiology of surface light scattering on hydrophobic acrylic intraocular lenses. J Cataract Refract Surg 2012; 38(10): 1833–1844.
8) Shiba T, Mitooka K and Tsuneoka H. In vitro analysis of AcrySof intraocular lens glistening. Eur J Ophthalmol 2003; 13(9–10): 759–763.
9) Kawai K, Hayakawa K and Suzuki T. Simulation of 20-year deterioration of acrylic IOLs using severe accelerated deterioration tests. Tokai J Exp Clin Med 2012; 37(3): 62–65.
10) Kawai K. An evaluation of glistening and stability of intraocular lens material manufactured by different methods. Eur J Ophthalmol 2021; 31(2): 427–435.
11) Okuda S. Chemical deterioration and reliability of plastics [in Japanese]. J Soc Rubber Sci Technol, Japan 1987; 60(8): 447–456.
12) International Organization for Standardization. Ophthalmic Implants–Intraocular Lenses–Part 5: Biocompatibility, ISO, Geneva, Switzerland, 2020 (ISO 11979-5).
13) Intraocular lenses--on the basis of high polymers. Nippon Ganka Gakkai Zasshi 1986; 90(1): 25–42.
14) Gurabardhi M, Häberle H, Aurich H, *et al.* Serial intraocular lens opacifications of different designs from the same manufacturer: Clinical and light microscopic results of 71 explant cases. J Cataract Refract Surg 2018; 44(11): 1326–1332.