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In vitro analysis of AcrySof intraocular lens glistening

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PURPOSE. *The authors studied the effects of changes in packaging solution temperature on the development of glistening in acrylic intraocular lenses (AcrySof, Alcon).*
METHODS. *Glistening was examined by slit lamp at each condition. In Experiment 1, AcrySof lenses were soaked in physiologic saline adjusted to 15°C and 37°C in an incubator. In Experiment 2, AcrySof lenses were soaked in physiologic saline adjusted to 37°C and 60°C for 5 min, then stored in physiologic saline adjusted to 15°C. In Experiment 3, glistening formation was induced in AcrySof lenses by soaking them in warm water (37°C). The lenses were allowed to dry at 15°C and then soaked in physiologic saline adjusted to 15°C. After storage of dry AcrySof lenses at 37°C in an incubator for 10 months followed by soaking in physiologic saline adjusted to 15°C, glistening formation was evaluated in Experiment 4.*
RESULTS. *Glistening became observable after 1 month, despite the temperature having been lowered to 15°C. No glistening was observed in the lenses soaked in physiologic saline adjusted to 37°C after 5 min, but glistening was observed 1 month after soaking. When allowed to dry at 15°C, the glistening decreased. After 1 month of soaking at 15°C, glistening was again observable.*
CONCLUSIONS. *AcrySof lenses soaked in warm water for a short time may change characteristics, and therefore, close monitoring of the temperature and time of soaking is necessary to prevent glistening formation. (Eur J Ophthalmol 2003; 13: 759-63)*

KEY WORDS. *Acrylic intraocular lenses, Glistening, Warm water*

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INTRODUCTION

In acrylic intraocular lenses (IOL) (AcrySof, Alcon), small shiny spots known as glistening are sometimes observed under slit-lamp evaluation. The nonuniformity of material in lenses produced by molding technology has been raised as a potential cause of glistening formation, but individual differences in the degree of glistening are observed in actual clinical situations; thus, the cause is not completely understood.

There are reports that glistening is a phenomenon that occurs only in AcrySof lenses packaged in Acry-Pak folders (1), on the effects of heating lenses prior to ocular implantation (2), and of a high frequency of glistening formation in diabetic patients (3).

We conducted a study on the effect of temperature changes of lens soaking solution on glistening formation in AcrySof lenses packaged in Wagon Wheel cases.

METHODS

We examined acrylic IOL by slit lamp in four experiments.

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Experiment 1: AcrySof lenses were soaked in physiologic saline adjusted to 15°C and 37°C in an incubator, and the lenses were examined by slit lamp at 5 min, 1 week, 1 month, 3 months, and 6 months (Fig. 1).

Experiment 2: AcrySof lenses were soaked in physiologic saline adjusted to 37°C and 60°C for 5 min, then stored in physiologic saline adjusted to 15°C. Glistening was examined by slit lamp at 1 week, 1 month, 3 months, and 6 months (Fig. 1).

Experiment 3: AcrySof lenses were soaked in physiologic saline adjusted to 37°C for 1 month in an incubator, and the lenses were allowed to dry at 15°C for 30 min and then soaked in physiologic saline adjusted to 15°C, and glistening was examined over time (Fig. 2).

Experiment 4: After storage of dry AcrySof lenses at 37°C in an incubator for 10 months followed by soaking in physiologic saline adjusted to 15°C, glistening formation was evaluated over time (Fig. 2).

Five AcrySof lenses (MA60BM, 23.0 D) were used for each experiment.

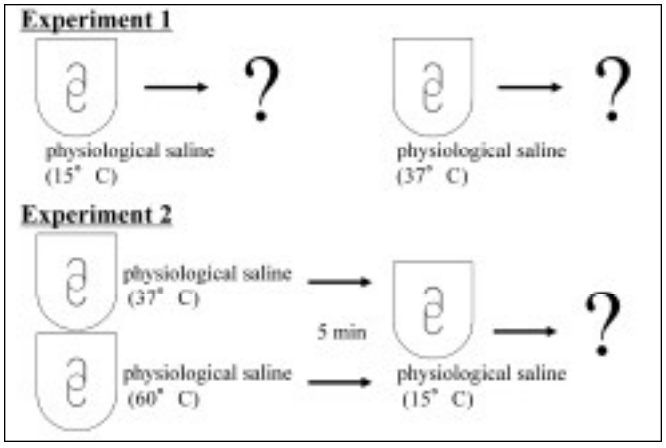

Fig. 1 - *Experiment 1: AcrySof lenses were soaked in physiologic saline adjusted to 15°C and 37°C in an incubator. Experiment 2: AcrySof lenses were soaked in physiologic saline adjusted to 37°C and 60°C for 5 min, then stored in physiologic saline adjusted to 15°C.*

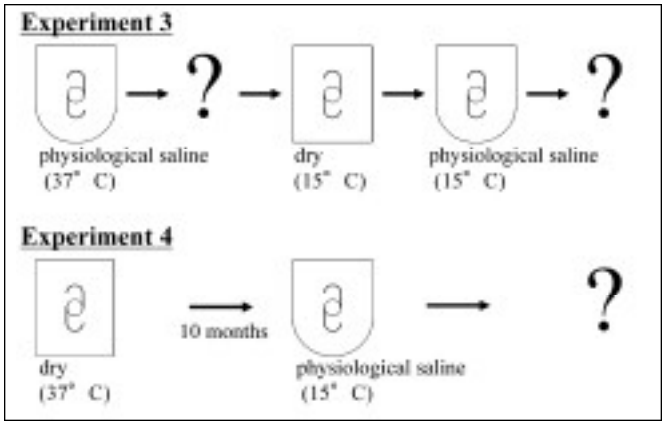

Fig. 2 - *Experiment 3: AcrySof lenses were soaked in physiologic saline adjusted to 37°C for 1 month in an incubator, and the lenses were allowed to dry at 15°C for 30 min and then soaked in physiologic saline adjusted to 15°C. Experiment 4: Storage of dry AcrySof lenses at 37°C in an incubator for 10 months was followed by soaking in physiologic saline adjusted to 15°C.*

RESULTS

Experiment 1

No glistening was observed in the AcrySof lenses soaked in physiologic saline adjusted to 15°C at any time (Fig. 3). No glistening was observed in the AcrySof lenses soaked in physiologic saline adjusted to 37°C after 5 min. However, glistening of grades 1 and 2 (4) was observed 1 month after soaking (Fig. 4). This glistening remained at the same degree at 3 and 6 months, showing no particular changes. Similar results were obtained in all five lenses used in this experiment.

Experiment 2

No glistening was observed after soaking the lenses at 37°C for 5 min, as in Experiment 1. Glistening became clearly observable after 1 month had passed, despite the temperature having been lowered to 15°C. No particular changes in glistening were observed until 6 months after soaking (Fig. 5), whereas grade 3 (4) glistening was observed in AcrySof lenses soaked in physiologic saline adjusted to 60°C after 5 min. The lenses were then soaked in physiologic saline adjusted to 15°C, resulting in no particular changes in the degree of glistening (Fig. 6). Similar results were obtained in all five lenses used in this experiment.

Experiment 3

Glistening was observed at 1 month when the lenses were soaked at 37°C, as in Experiment 1. When al-

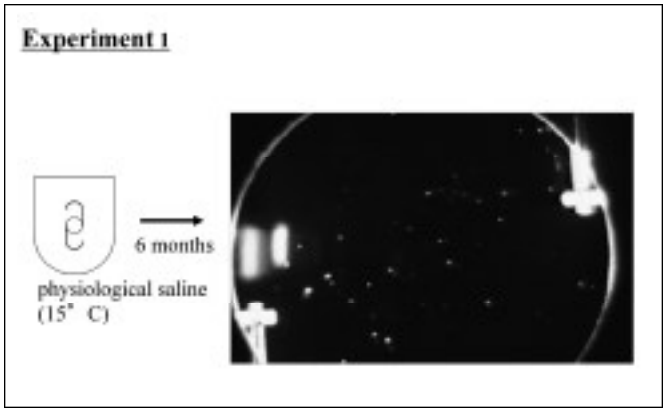

Fig. 3 - *No glistening was observed in the AcrySof lenses soaked in physiologic saline adjusted to 15°C at any time.*

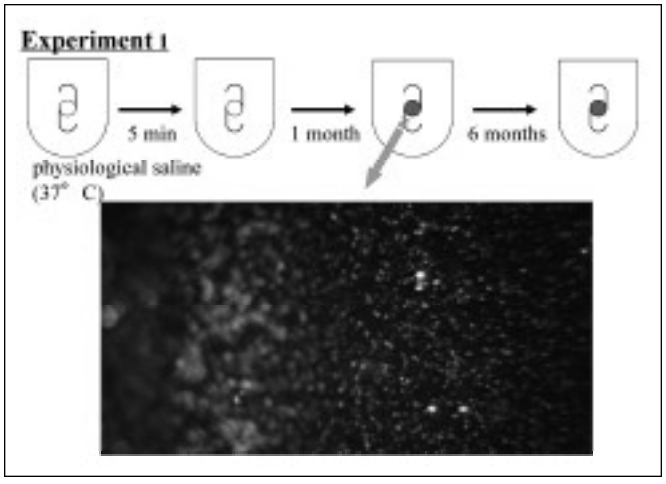

Fig. 4 - *No glistening was observed in the AcrySof lenses soaked in physiologic saline adjusted to 37°C after 5 min. However, glistening was observed 1 month after soaking.*

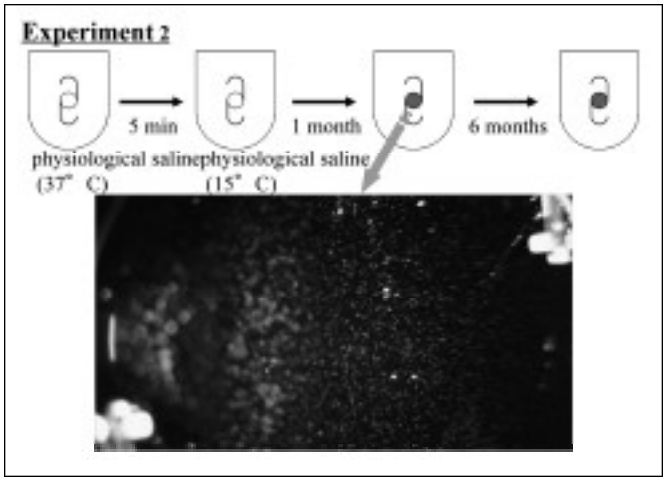

Fig. 5 - *No glistening was observed after soaking the lenses at 37°C for 5 min. Glistening became clearly observable after 1 month had passed. No particular changes in glistening were observed until 6 months after soaking.*

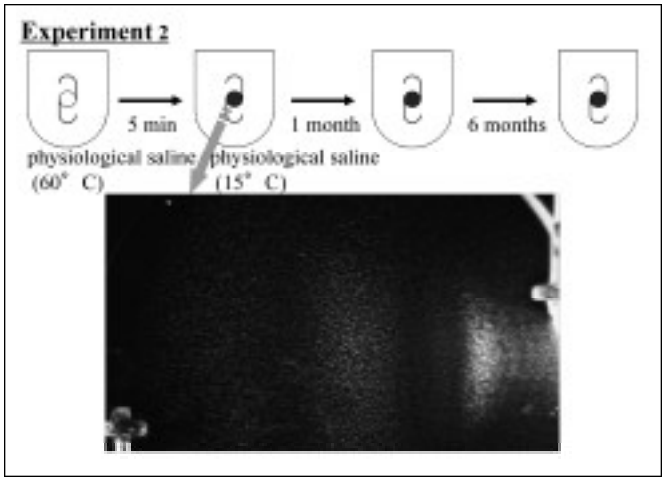

Fig. 6 - *Grade 3 glistening was observed in AcrySof lenses soaked in physiologic saline adjusted to 60°C after 5 min. The lenses were then soaked in physiologic saline adjusted to 15°C, resulting in no particular changes in the degree of glistening.*

lowed to dry at 15°C, the glistening gradually decreased and was not observable 30 min later. Then, after 1 month of soaking at 15°C, the glistening was again observable (Fig. 7).

Experiment 4

No glistening was observed at any time.

DISCUSSION

Small incision cataract surgery is the main type of cataract surgery performed. Because there is minimal risk of postoperative inflammation or corneal astigmatism after surgery, patients undergoing this procedure may experience an early return to normal life (5). Along those lines, various foldable lenses have been developed, and the demand for these lenses continues to increase. AcrySof IOL, made of a material

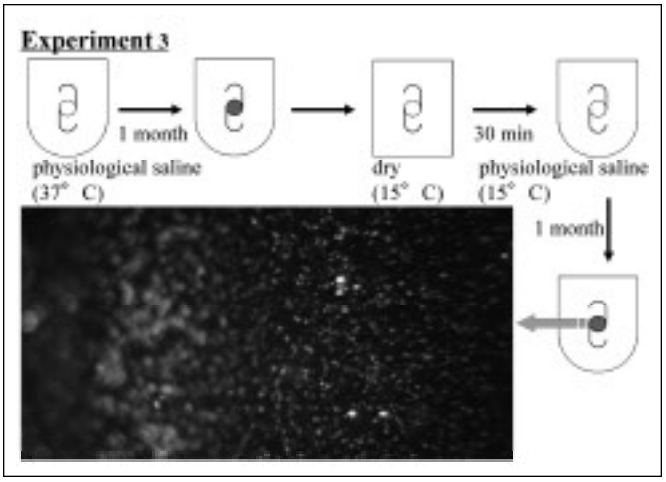

Fig. 7 - *Glistening was observed in 1 month when the lenses were soaked at 37°C. When allowed to dry at 15°C, the glistening gradually decreased and was not observable 30 min later. After 1 month of soaking at 15°C, the glistening was again observable.*

similar to PMMA, are the most commonly used lenses, having the advantages of low frequency postoperative inflammation or recurrence of cataracts (6-9). However, it has been reported that shiny spots, known as glistening, were observed in AcrySof lenses by slit-lamp evaluation after a certain period postimplantation. This glistening had been believed to be induced by sterilization of lenses in the AcryPak lens case sold in the United States, but not in lens cases sold in Japan and Europe (1). In addition, it was originally thought that shiny spots in lenses had no effect on ocular function, and were only a cosmetic issue. Recently, this issue has moved back into the spotlight by reports of high frequency of glistening formation in AcrySof packaged in Wagon Wheel cases (4) in patients with lowered contrast sensitivity (10) and in patients in which a YAG laser target light does not converge (11).

The nonuniformity of the material in lenses produced by molding technology has been raised as a mechanism for glistening formation. It is thought that tiny vacuoles, called microvoids, are formed in AcrySof lenses produced by this method and that aqueous humor is taken into these spaces and observed as tiny glistening spots. AcrySof IOL are believed to contain 0.3% water at 37°C. Observations of glistening formation not occurring in 15°C solution but occurring in 37°C solution in Experiment 1, and no glistening formation in Experiment 4, suggest either an increase in microvoids or an increase in penetration of solution into microvoids in AcrySof lenses soaked in 37°C solution over a period of time. The observation in Experiment 2 that no glistening formation occurred in AcrySof lenses soaked in 15°C solution for 6 months, but glistening formation occurred in lenses soaked in 37°C for 5 min, despite the soaking temperature having been lowered to 15°C for 1 month, suggests that microvoid formation will be induced or increased in as short a time as 5 min when the temperature is set at 37°C. However, it is thought that liquid sufficient to be observed as shiny spots has not been taken into vacuoles at this point. More liquid will gradually be taken into microvoids as the lenses are soaked for a certain length of time, and the amount of liquid reaches a certain threshold after 1 month. Additionally, in Experiment 3, glistening was not observable after AcrySof lenses were allowed to dry for approximately 30 min, and were again observable after 1 month of soaking at 15°C, suggesting that the amount of water taken into microvoids gradually decreases when the lenses are dried, rendering glistening unobservable. However, because microvoids have already been formed, the amount of water taken into the microvoids gradually increases even when the lenses are soaked in low temperatures around 15°C, reaching a certain threshold after 1 month. Soaking of AcrySof lenses in warm physiologic saline immediately prior to folding has been the practice. Soaking AcrySof lenses in warm water for a short time may change their characteristics, and therefore, close monitoring of the temperature and time of soaking is necessary to prevent glistening formation. In clinical situations, not all cases exhibit glistening formation, suggesting that nonuniformity of material due to the manufacturing process, handling of lenses prior to implantation, and postimplantation temperature changes in the anterior chamber all may be factors. Future studies should be conducted on diabetic cases and cases of strong postoperative inflammation, in which glistening formation is frequently observed, focusing on temperature changes in the anterior chamber.

It is said that glistening has no effect on ocular function, but glistening higher than grade 3 may cause issues more serious than cosmetic. The long-term stability of AcrySof lenses, as well as methods of prevention of glistening formation, need to continue to be closely investigated.

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