Senior Research Project

Saline-Induced Hydrogel Lens Brunescence

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Introduction

There have been many documented cases whereby hydrogel contact lenses have turned brown as a result of being stored in certain preserved saline solutions (see photo #1). The overwhelming majority of the color changes have been noted with the F.D.A. Group IV (high water, ionic) lenses. Many possible causes have been speculated, such as: heating of extended-wear lenses in sorbate-containing solutions, storage or disinfection of dirty lenses in sorbate-containing solutions, and use of topical vasoconstrictors.[1] It has further been speculated that interaction of tear film proteins with saline preservatives or the particular disinfection system may also be a contributing factor.[2]

This study was designed to determine if sorbic acid is indeed the underlying cause of the induced hydrogel lens brunescence and the significance the particular F.D.A. lens group has in the process. The study also attempts to determine whether or not the particular disinfection system or the interaction of tear film proteins play a role in the discoloration of hydrogel lenses.

Study Design

Twelve hydrogel contact lenses were utilized in the study; six lenses were Bausch & Lomb Optima 38 daily wear lenses, the remaining six were Barnes Hind Hydrocurve II (55% water content) extended-wear lenses. The B & L lenses were chosen to represent the F.D.A. Group I

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1 Aquavella JV, Rao GN, eds: Contact Lenses. Chapter 10. J.B. Lippencott, Phila, pp. 226-262, 1987.

2 Gerald Lowther, O.D., Ph.D.; Contact Lens Lecture Notes, Course 557, F.S.C.O., Fall 1987

(low water, nonionic) class while the Hydrocurve lenses were chosen to represent the F.D.A. Group IV (high water, ionic) class of lenses.

The experimental design of the study is illustrated in Fig.1. Three disinfection systems were utilized in this study. Two lenses from both F.D.A. Groups I and IV were disinfected with each type of system, with one lens in each group being coated with tear proteins and the other being a clean, uncoated lens. The tear coated lenses were obtained by placing them in the experimenter's eyes for a period of fifteen minutes; after the lenses were coated, they were then placed directly into the designated disinfection system (see Fig.1).

The lenses were removed from the disinfection system after the appropriate disinfection period (see Fig.2) and all were placed into identical contact lens cases, each of which contained a designated preserved saline solution (as outlined in Fig.1), and stored. The study was designed so as to have sorbic acid well represented because of the seemingly well-held notion of it being the most likely cause. Fig.3 illustrates the various saline preservatives involved in the study and the brand names of the solutions that the various lenses were stored in.

The lenses were stored at room temperature for three weeks in their respective solutions. After three weeks, all of the lenses were removed and cleaned with the same hydrogel cleaning solution (Pliagel). Once cleaned, the lenses which were marked to be coated with tear proteins were placed in the researcher's eyes in the same manner and duration as was described earlier to provide the necessary coating. Each lens was then disinfected in the same manner as was done previously and placed back into it's respective case containing the appropriately

preserved saline solution. The lenses were then allowed to remain stored for approximately another three week period.

The above cleaning/disinfection/storage process was repeated for a duration of six months (see Fig.4). After every cleaning, the lenses which were designated to be coated with tear proteins were coated in the manner outlined earlier. No enzyme cleaner was utilized throughout the course of the study. Lens coloration was monitored by visual inspection to detect any changes. White contact lens cases were used as storage cases to aid in detecting subtle color changes. Photographs were taken at the conclusion of the study to document the long term changes in lens coloration, if any, which may occur throughout the course of the study.

Results

Throughout the course of the research study (July, 1988- January, 1989) no visible coloration changes were observed to have taken place in any of the lenses involved in the study. Photographs taken at the conclusion of the study also fail to show any appreciable change in lens coloration throughout the duration of the study (see photos 2-7). Upon conclusion of the study, the lenses were allowed to remain stored in their respective cases for an additional three month period without even being removed for cleaning or replacing the storage saline. Photographs fail to show any color change in any of the lenses, however, visual inspection shows a slight brunescent color change in the Group IV lens which was chemically disinfected (Polyquad disinfectant), coated with tear proteins, and stored in sorbic acid preserved saline for the prolonged period.

Conclusions

With respect to the duration of the study, the results support the notion that storage of clean hydrogel lenses in sorbate-preserved salines is no more a cause of induced brunescence than storage in salines preserved with other agents. Furthermore, the Group IV lenses seem to be no more appreciably susceptable to coloration changes than the Group I lenses, and the particular disinfection system seems to play no significant role in the discoloration process. There appears to be no catalytic effect caused by the interaction of tear film proteins in the discoloration process as well.

While the study falls short of identifying the exact cause of induced hydrogel lens brunescence, it does provide valuable insight into the problem. The beginning coloration change which was noted in one of the lenses during the extended storage period (after the actual conclusion of the "designed" study) leads to the speculation that sorbate-preserved saline solutions do play a major role in the discoloration process, as was believed at the outset of the study. The changes observed after the extended storage period brings into question the time factor involved in the process. In addition, the results of the study raise additional questions: whether or not the exact concentration of sorbic acid in various saline solutions needs tobe looked at more closely, the significance the power or thickness of the lens has in the process, and whether or not storage of dirty lenses in sorbate-containing saline solutions contributes significantly to the problem. These questions need to be looked at in more detail, and could possibly provide the basis for a follow-up study to further examine the problem of induced hydrogel lens brunescence.

References

Review of Optometry / May, 1988. p.56.

Aquavella JV, Rao GN, eds: Contact Lenses. Chapter 10, J.B. Lippincott, Phila, pp.226-262, 1987

Lowther, Gerald, O.D., Ph.D.: Contact Lens Lecture Notes, Course #557 (Contact Lenses), F.S.C.O., Fall 1987

Fig. 1

FDA Hydrogel Classification

Disinfection System	Group I		Group II	Group III	Group IV	
H_2O_2	Sorbic Acid C	Non-pres. N	—	—	Dymed C	Sorbic Acid N
Chemical	Polyquad C	Sorbic Acid N	—	—	Sorbic Acid C	Non-pres. N
Heat	Sorbic Acid C	Thimerosol N	—	—	Non-pres. C	Sorbic Acid N

Key

C - tear coated lens

N - New lens

Fig. 2 Disinfection System Utilized

Disinfection System	System Brand Name	Disinfection Period
Hydrogen peroxide	Lensept (Ciba)	2 hrs. disinfection 10 min. neutralization
Chemical	Opti-soft (Alcon)	4 hrs.
Heat	Thermal disinfec. unit (Barnes Hind)	Duration of unit operation (approx. 20 min.)

Fig. 3 Saline Solutions Utilized for Storage

Preservative	Saline Brand Name
Non-preserved	Lens Plus Saline Solution (aerosol-Allergan)
Sorbic acid	Murine Saline Solution (Murine)
Polyquad	Opti-soft Disinfection/Saline Solution (Alcon)
Thimerosol	Boil-n-Soak Saline Solution (Alcon)
Dymed	Renu Saline Solution (Bausch&Lomb)

Fig. 4 Record of Cleaning/Disinfection Schedule

Cleaning #	Date of Cleaning/Disinfection
0 (Starting date)	July 18, 1988
1	August 10, 1988
2	September 1, 1988
3	September 23, 1988
4	October 15, 1988
5	November 6, 1988
6	November 30, 1988
7	December 20, 1988
8 (Study concl.)	January 10, 1989

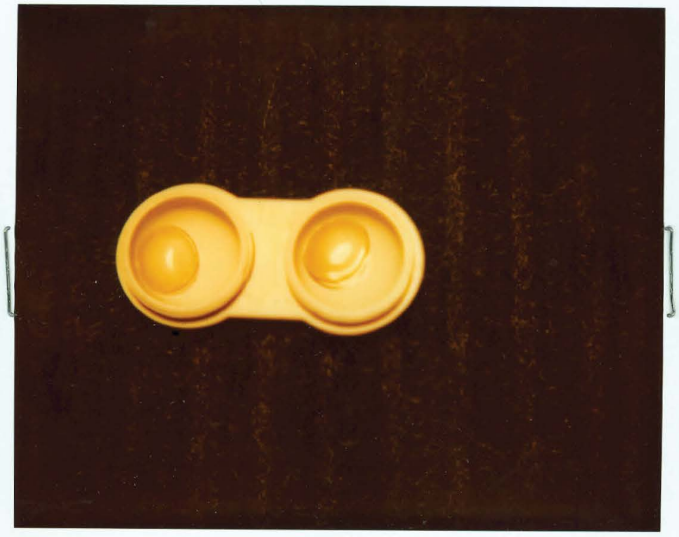

Photo #1

Demonstrative Photograph

Lenses are BARNES-HIND Hydrocurve II 55% H_2O extended WEAK hydrogels which have significantly brunesced during storage

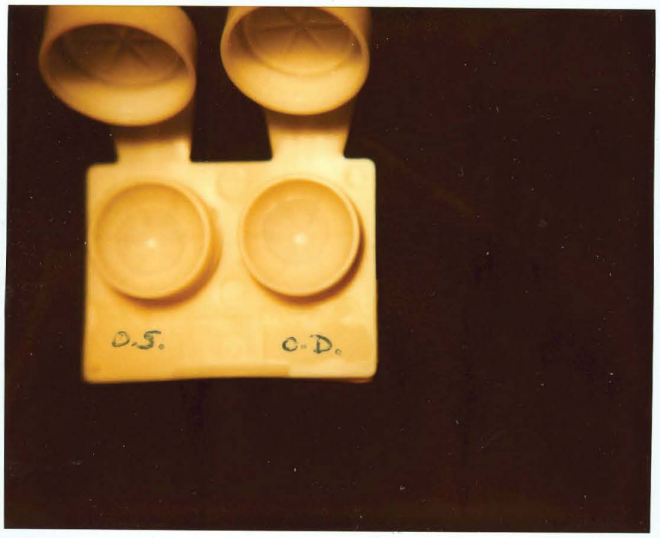

Photo #2

O.S.
Group I
H_2O_2 Disinfected
Sorbic Acid Storage
Tear coated lens

O.D.
Group I
H_2O_2 Disinfected
Non-preserved Saline-Storage
Non-Tear coated

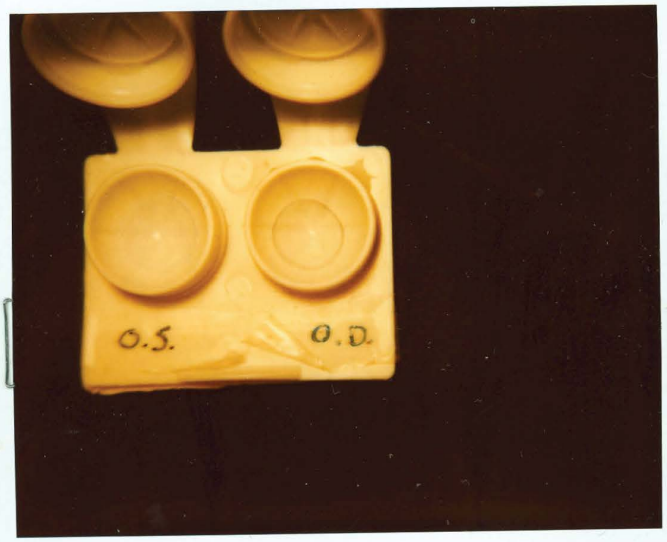

Photo #3

O.S.

GROUP I
Chemically disinfected
(Polyquad)
Stored in Polyquad
TEAL coated

O.D.

GROUP I
Chemically disinfected
(Polyquad)
Sorbic acid storage
NON-TEAL COATED

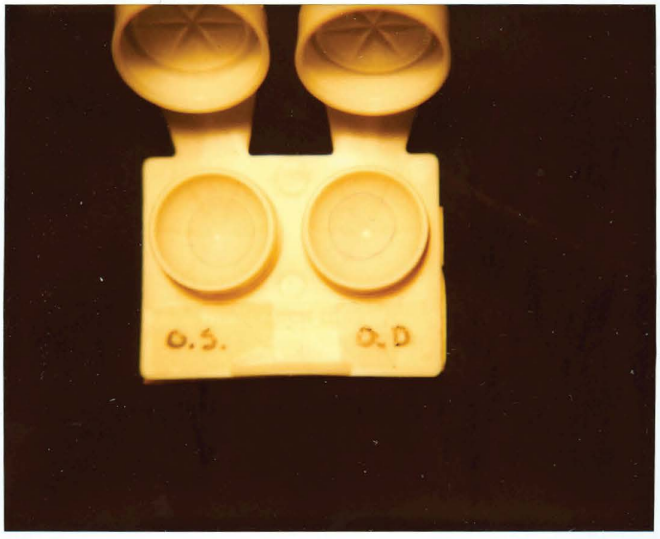

Photo # 4

O.S.	O.D.
Group I	Group I
Heat disinfected	Heat disinfected
Sorbic Acid Storage	Thimerosol Storage
Tear coated	Non-tear coated

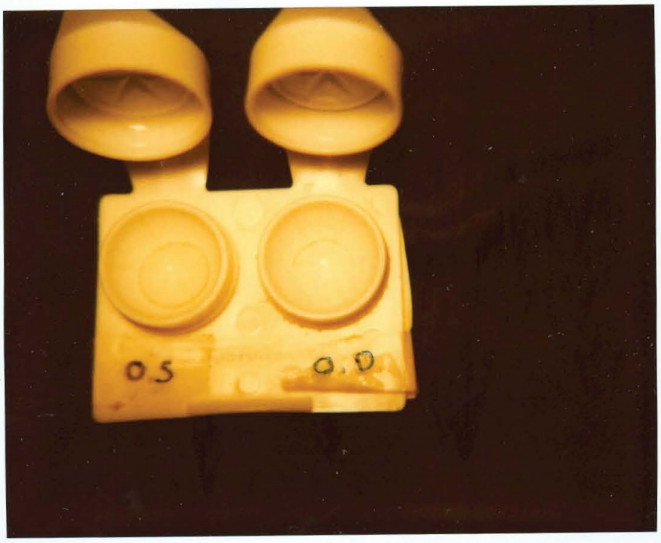

Photo #5

O.S.

Group IV
Chemically disinfected
(Polyquad)
Sorbic Acid Storage
Tear coated

O.D.

Group IV
Chemically disinfected
(Polyquad)
Non-preserved Saline-Storage
Non-tear coated

Photo #6

O.S.

GROUP IV
H_2O_2 Disinfected
Dymed storage
TEAR coated

O.D.

GROUP IV
H_2O_2 Disinfected
Sorbic Acid Storage
NON-TEAR coated

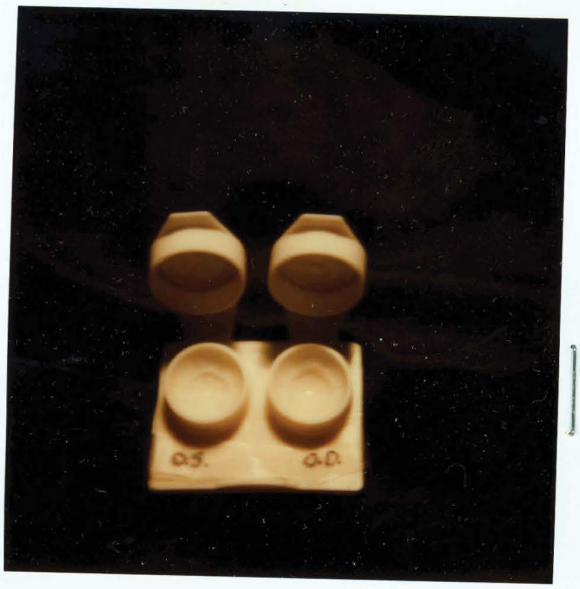

Photo #7

O.S.

Group IV

Heat Disinfected

Non-preserved Saline-Storage

Tear Coated

O.D.

Group IV

Heat Disinfected

Sorbic Acid Storage

Non-tear coated