Effects of 30-day Continuous Wear with Silicone Hydrogel Lenses on Corneal Epithelial Barrier Function

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ABSTRACT

Purpose. To examine the effects of 30-day continuous wear (CW) of high-Dk/t Si-H lenses on epithelial barrier function by measuring the permeability of the corneal epithelium to sodium fluorescein (P_{dc}).

Methods. 29 neophytes were adapted to Si-H lenses. Baseline P_{dc} measurements were then obtained (included afternoon (PM) followed by morning (AM) measurements, where one eye was patched overnight until the morning reading. Following baseline assessments, subjects wore their lenses continuously for 30 days; PM and AM P_{dc} measurements were then repeated. All P_{dc} measurements were obtained using an automated scanning fluorometer.

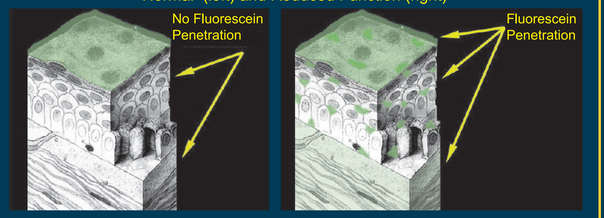
Results. There was no significant difference between eyes for baseline PM, baseline AM, and CW PM P_{dc} measurements ($p > 0.05$). However, the 30-Day Follow-up AM P_{dc} measurements were –2.187 (ln nm/sec) and –1.878 (ln nm/sec) for patched and unpatched eyes, respectively ($p = 0.0733$). This corresponds to a 13.09% and 49.86% increase in permeability from the baseline PM in the patched and unpatched eyes, respectively.

Conclusions. The results of this study show that there is a substantial decrease in epithelial barrier function during CW. Of interest and possible clinical importance, the disparity in the corneal epithelial barrier function between patched and unpatched eyes suggests that upon awakening, the accumulated debris/inflammatory cells in the post-lens tear film is mechanically agitated against the corneal epithelium with each lens movement. Therefore, timely tear flushing to remove trapped debris may be important in maintaining a normal corneal epithelium.

BACKGROUND

Epithelial Barrier Function

Normal (left) and Reduced Function (right)



The corneal epithelium plays an important role in maintaining the homeostasis of ocular surface. The normal human corneal epithelium is resistant to the flow of hydrophilic substances. However, a change in epithelial structure or function can allow unwanted substances to penetrate the epithelium. For example, a previous study showed a significant increase in corneal epithelial permeability to fluorescein after 8 hours of overnight-wear.[1] The effects of longer periods of continuous wear have not been reported.

STUDY AIM

To measure the effects of 30-day continuous-wear (CW) with silicone hydrogel lenses on epithelial permeability to fluorescein (P_{dc}).

METHODS

Subjects

29 subjects participated in the study. All subjects had no history of contact lens wear in the previous 12 months and were free from ocular and systemic diseases with eye manifestations.

Contact Lenses

Focus Night & Day™ lenses (Iotrafilcon A; 24% H_2O; 8.4 mm or 8.6 mm; 13.8 mm; 175 Dk/t)

Instrument

A Fluorotron Master® automated scanning fluorometer was used to perform all P_{dc} scans using single-drop fluorescein technique.[2]

Experimental Design and Procedures

- Prospective, randomized, single-masked study design.
- After CW adaptation, all subjects discontinued lens wear for at least one week prior to baseline measurements.
- Visits:

Baseline

Visit #1: Biomicroscopic evaluation, baseline PM P_{dc} measurement

Visit #2: Biomicroscopic evaluation, baseline AM P_{dc} measurement, contact lens dispensing

30-day Continuous-Wear Follow-Up

Visit #3: Biomicroscopic evaluation, PM P_{dc} measurement

Visit #4: Biomicroscopic evaluation, AM P_{dc} measurement

- Subjects patched one eye (randomized) on the evening prior to AM P_{dc} visits.*

* Patching simulated a closed-eye condition during which lens movement and tear exchange were minimized due to lid closure. Thus, P_{dc} measurements could be obtained immediately upon eye opening and lens removal.

RESULTS

- 29 subjects completed the study
- 22 subject data sets were analyzed
  - * 5 subject-data sets were not included in the analysis due to central corneal staining after overnight wear.
  - * 2 subject-data sets were outliers and were not included in analysis.

Table 1
Patched vs. Unpatched at each visit

N = 22	Mean ln (P_{dc}) + SE [ln(nm/sec)]			
	Baseline		30-Day Follow-up	
	PM	AM	PM	AM
Patched	-2.32 ± 0.14	-2.42 ± 0.13	-2.33 ± 0.15	-2.19 ± 0.21
Unpatched	-2.28 ± 0.11	-2.12 ± 0.17	-2.20 ± 0.14	-1.88 ± 0.17
p-value	0.882	0.215	0.337	0.073

Smaller negative values = higher epithelial permeability

Table 2
Baseline vs. 30-day follow-up visits
for patched and unpatched eyes

N = 22	Mean ln (P_{dc}) + SE [ln(nm/sec)]	
	Patched	Unpatched
Baseline (PM)	-2.32 ± 0.14	-2.28 ± 0.11
30-Day Follow-up (AM)	-2.19 ± 0.21	-1.88 ± 0.17
% Increase in Permeability from Baseline (PM) to 30-Day Follow-up (AM)	13% ⇑	50% ⇑
p-value	0.595	0.057

Smaller negative values = higher epithelial permeability

DISCUSSION

The results suggest that Continuous Wear reduces normal epithelial barrier function. Several factors, including post-lens tear thickness, physical lens fit, upper lid tension during closed- and open-eye conditions, tear chemistry, tarsal plate physiology, and corneal fragility, may contribute to the variability of the corneal epithelial permeability measurement. Larger sample-size studies are needed to validate the effects of individual or combined factors on corneal epithelial permeability.

CONCLUSIONS

The unpatched eye following 30 days of continuous wear showed an increase in P_{dc} compared with the patched eye. These overnight P_{dc} differences between the patched vs. unpatched eyes may be explained as follows:

Normally, without contact lens wear, the blink process clears accumulated debris directly from the corneal surface. However, with inefficient tear flushing, as is the case during soft contact lens wear, the debris remains trapped between the lens and cornea. As the lens moves during blinking (unpatched eye), there is mechanical trauma to the epithelium. However, for the patched eye, the lens does not move and thus the cornea is protected from lens-induced mechanical trauma.

Clinically, this observation suggests that adequate tear flushing after eye opening is a significant requisite in avoiding clinical adverse events during overnight CL wear.

REFERENCES

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2. McNamara NA, Fusaro RE, Brand RJ, Polse KA, Srinivas P. Measurement of corneal permeability to fluorescein: A repeatable study. *Invest Opthalmol & Vis Sci*, 1997; 38(9): 1930-1939.

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