The Effect of 30-Day Continuous Wear on Corneal Epithelial Barrier Function: Gas-Permeable vs. Silicone Hydrogel Lenses

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BACKGROUND & STUDY AIM

- Previous work has shown that one-night of overnight wear of HEMA or silicone-hydrogel (Si-H) lens wear causes significant changes to epithelial barrier function (EBF).[1]
- The lowered EBF associated with soft lens wear may be due to insufficient tear flow.[1-4]
- To further explore the effect of reduced tear flow on EBF, we hypothesize that gas-permeable (GP) lenses will have less effect on EBF because GP lenses have much greater tear flow compared with soft lenses.
- To test our hypothesis, we measured the effects of 30-day continuous wear (CW) on EBF for subjects fitted with high-Dk/t GP or Si-H lenses.

STUDY METHOD

Study Design
- Randomized parallel-group study

Subjects
- Randomized to GP (tisilfocon A; Dk = 175) or Si-H (lotrafilcon A; Dk = 140) and then adapted to day- and overnight-wear
- 18-39 years of age
- No contact lens wear within 12 months before the 1st visit
- No clinically significant dry eyes, ocular pathology, and systemic condition with ocular manifestation
- Spectacle prescription between -1.00 to -5.75DS and cylinder < -0.75D or -6.00 to -10.00 and cylinder < -1.25D
- Corneal toricity < 1.25D; asymmetry < 1.00D

Lens-Fitting Criteria
- Si-H lenses fitted according to manufacturer's fitting guide
- Near-alignment fit for most GP lenses (Average OAD = 9.5 mm)
- Both lens types fitted by experienced clinicians

EBF Assessment
- Assessed with automated scanning fluorometer by measuring permeability of epithelium to sodium fluorescence (P_{dc})

Study Protocol
- P_{dc} measurements: afternoon (PM) followed by next-day morning (AM) measurements
- A set of PM and AM measurements after a wash-out period (no lens wear) & repeated after 30-day CW
- PM and AM P_{dc} measured at minimum of 4 hours and within 2 hours after awakening, respectively
- The night before AM P_{dc} measurements, subjects patched one eye; patch removed immediately before the P_{dc} measurements
- Patching simulates closed-eye condition with lens movement & tear exchange minimized due to lid closure. Thus, P_{dc} measurements obtained immediately after eye opening & lens removal.

Figure 1. Flowchart of study visits
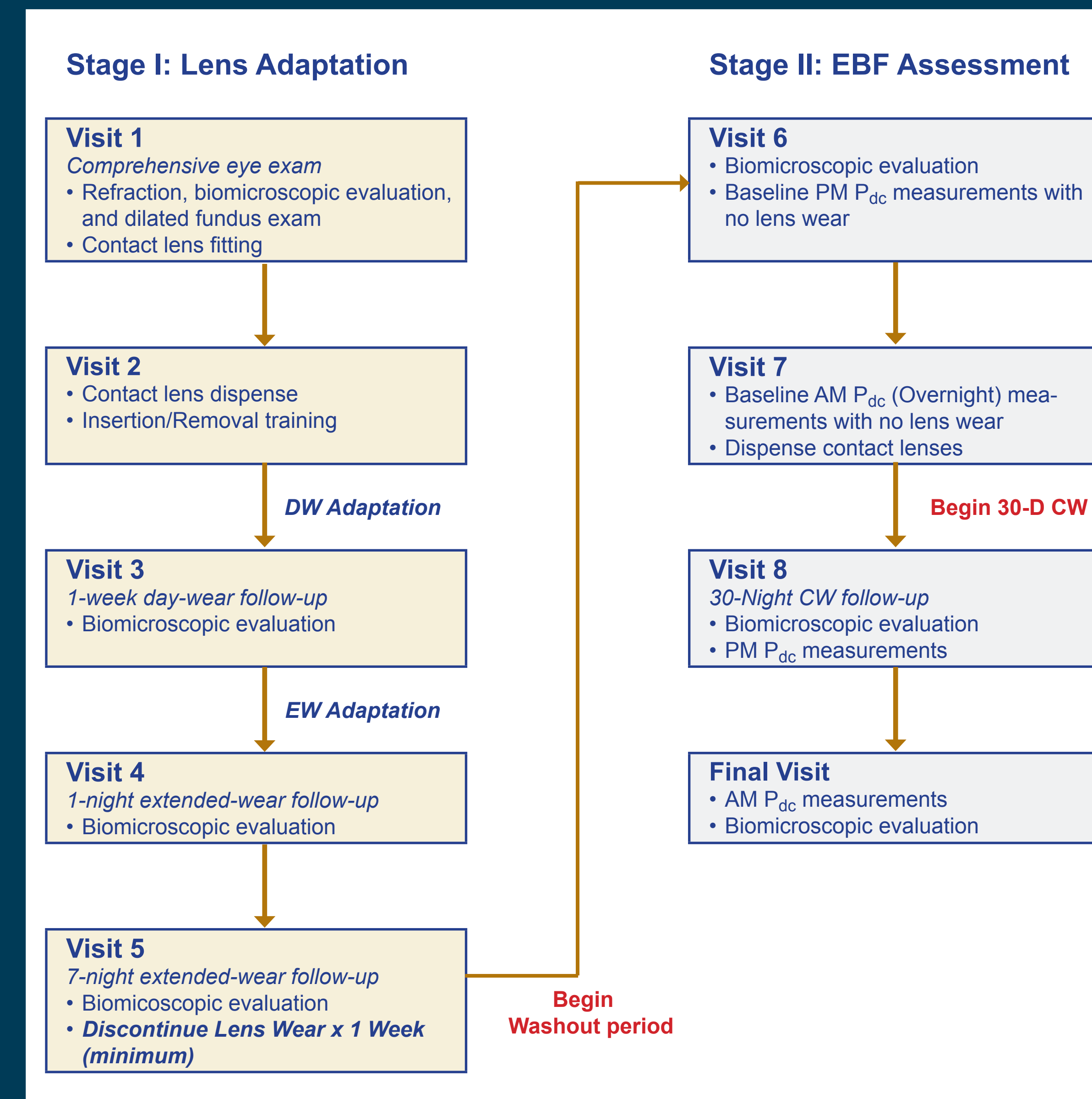
RESULTS

- 74 subjects, 35 GP and 39 Si-H, completed the study.
- P_{dc} analyzed for the cornea without central staining
- Raw values of P_{dc} transformed to a log scale to ensure normal distribution of data: 5 and 3 outliers in GP and SiH groups, respectively, excluded from the data analysis
- Higher negative value of $\ln(P_{dc})$ = Less disruption or compromise in the EBF

Part I: Difference in EBF between eyes at each visit for different lens types

Table 1. $\ln(P_{dc}) \pm$ SE [ln(nm/sec)] values at each visit for each eye in the GP group (n = 30)

n = 30	$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]		$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]	
	PM Baseline	AM Baseline	PM Post 30-D CW	AM Post 30-D CW
Eye #1	-2.29±0.12 (unpatched)	-2.27±0.15 (patched)	-2.32±0.16 (unpatched)	-2.01±0.09 (patched)
Eye #2	-2.22±0.13 (unpatched)	-2.18±0.15 (unpatched)	-2.39±0.14 (unpatched)	-2.38±0.15 (unpatched)
p-value (between-eye diff)	0.6184	0.5541	0.604	0.0685

There was no significant difference in the integrity of EBF between eyes at baseline visits and at the PM visit after 30-day CW (p values > 0.05). At AM visit after 30-day CW, **the EBF was more reduced in the patched** than in the unpatched eye; this trend was not statistically significant (p = 0.0685).

Table 2. $\ln(P_{dc}) \pm$ SE [ln(nm/sec)] values at each visit for each eye in the Si-H group (n = 36)

n = 36	$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]		$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]	
	PM Baseline	AM Baseline	PM Post 30-D CW	AM Post 30-D CW
Eye #1	-2.31±0.11 (unpatched)	-2.47±0.13 (patched)	-2.24±0.12 (unpatched)	-2.27±0.15 (patched)
Eye #2	-2.47±0.11 (unpatched)	-2.18±0.14 (patched)	-2.25±0.11 (unpatched)	-1.90±0.13 (unpatched)
p-value (between-eye diff)	0.2448	0.1108	0.9507	0.0173

There was no significant difference in the integrity of EBF between eyes at baseline visits and at the PM visit after 30-day CW (p values > 0.05). At AM visit after 30-day CW, there was **more change in EBF in the unpatched** than in the patched eye; this trend was statistically significant (p = 0.0173).

Part II: The overall impact of lens wear on EBF

Table 3. $\ln(P_{dc}) \pm$ SE [ln(nm/sec)] values before and after lens wear with GP lenses, using baseline PM visit as a reference.

$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]		% increase in $\ln(P_{dc})$	p-value
PM Baseline	AM Post 30-D CW		
-2.29±0.12	-2.01±0.09 (patched)	32% ↑	0.0747
-2.22±0.13	-2.38±0.15 (unpatched)	15% ↓	0.4402

There were no significant differences between before and after 30-day CW with high-Dk GP lenses for both eyes, using baseline PM visit as a reference. The same comparison, using the baseline AM visit as a reference, also did not show statistically significant difference (p = 0.386 patched; p = 0.0975 unpatched).

Table 4. $\ln(P_{dc}) \pm$ SE [ln(nm/sec)] values before and after lens wear with Si-H lenses, using baseline PM visit as a reference.

$\ln(P_{dc}) \pm$ SE [ln(nm/sec)]		% increase in $\ln(P_{dc})$	p-value
PM Baseline	AM Post 30-D CW		
-2.31±0.11	-2.27±0.15 (patched)	4% ↑	0.8042
-2.47±0.11	-1.90±0.13 (unpatched)	77% ↑	0.0009

After 30-day CW with Si-H lenses, there was no significant effect on the integrity of EBF in the patched eyes (p = 0.8042). The same wearing modality, however, had significantly compromised EBF in the unpatched eyes by 77% (p = 0.0009). The same trend was observed (but not with statistical significance for either eye) when the comparison was referenced to the baseline AM visit (p = 0.386 patched; p = 0.0975 unpatched).

CONCLUSIONS

This is the first parallel-group study to assess the effect of high-Dk GP and Si-H lenses on the integrity of corneal epithelium after 30-day CW. The results of this study suggest the following:

- There was a substantial decrease in EBF during 30-day CW with Si-H lenses, compared with GP lenses. However, it is unclear why the baseline permeability was much lower (although not statistically significant) in one eye wearing Si-H at the PM visit. Additional matched-pair multivariate analyses will be performed to confirm this finding to account for potential confounding factors.
- Upon eye opening, subjects wearing GP lenses showed rapid recovery, which was opposite in effect from soft lens wearers.
  - Possible explanation: Upon awakening, normal ocular surface was quickly restored for GP wearers and effects of lens-epithelial trauma were rapidly reversed. However, due to tear stagnation under a soft lens, the epithelium continued to be traumatized until all debris was removed from under the lens.
- These findings suggest that restoration of normal ocular surface may be an important requisite in avoiding adverse clinical events in overnight lens wear. It seems that adequate tear flow under a lens upon eye opening may be necessary to decrease ocular morbidity associated with continuous wear.

REFERENCES

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ACKNOWLEDGEMENTS