**Introduction**

The maintenance of normal corneal function during contact lens wear is dependent on sufficient oxygen diffusing through the lens material. If corneal oxygen supply is sufficiently reduced, normal metabolic activity is adversely affected, causing the cornea to swell. One factor that determines the ultimate success of a contact lens when prescribed for continuous wear is the level of oxygen that reaches the cornea during the overnight closed-eye wearing period. The corneal swelling response is widely accepted as a meaningful index for evaluating the level of oxygen reaching the cornea. The overnight experimental paradigm most accurately represents the closed-eye circumstance under which continuous wear contact lenses are worn. The aim of this study was to evaluate the overnight corneal swelling response to a silicone-hydrogel hybrid contact lens material by comparison to conventional hydrogel and silicone elastomer materials.

**Methods**

Phase I was conducted at the premises of The Lodge at Woodcliff in Rochestor, New York, USA. All subjects were examined on a single night in November, 1987. Phase II was conducted at the premises of Optimum Vision Care in Rochester, New York, USA. All subjects were examined on a single night in February 8, 1999. Up to 6 subjects were used to assess differences in non-parametric variables.

Each phase was conducted using a contralateral eye study design holding lens identity (test versus control) as a within-subjects factor. Study phase I had an additional between-subjects factor of lens power. Subjects were masked to the lens identities and the identity receiving the test lens was randomly assigned.

Subjects:

- Phase I - 30 daily wear adapted soft contact lens wearers
- Phase II - 25 daily wear adapted soft contact lens wearers

**Lenses:**

- Material: Material
- Power: Power
- DK: DK
- Dk/L: Dk/L

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Control</th>
<th>Test</th>
<th>Test</th>
<th>Control</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>etafilcon A</td>
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<td>110</td>
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<tr>
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<td>silicone</td>
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<td>300</td>
<td>300</td>
<td>300</td>
<td>300</td>
</tr>
</tbody>
</table>

Phase I

- Test: balafilcon A +4.00, -3.00, -9.00 99 110 @ -3.00
- Control: silicone -3.00 300* 200

Phase II

- Test: balafilcon A -3.00 99 110
- Control: silicone -3.00 300

**Procedure:**

Subjects attended the examination suite on the evening of the overnight wearing period. Each subject was fitted with a test lens on one eye and a control lens on the contralateral eye. Both lenses were assessed for fit and comfort, anterior ocular physiology (using the slit lamp biomicroscope) and corneal thickness, with the slit lamp biomicroscope. Following the measurement of corneal thickness subjects were randomly fitted with a test lens on one eye and a control lens on the contralateral eye. Both lenses were assessed for fit and comfort after which patients entered for approximately 8 hour of closed eye sleep with the lenses in place. All measurements of lenses fit, lens comfort, anterior ocular physiology (using the slit lamp biomicroscope) and corneal thickness, were repeated immediately upon awakening the following morning.

**Results**

A 3-way ANOVA incorporating the factors of LENS, TIME, and POWER was used to test for differences in means for each of the parametric variables in Phase I. The Wilcoxon Matched Pairs test was used to assess differences in non-parametric variables. A 2-way ANOVA incorporating the factors of LENS, and TIME was used to test for differences in means for each of the parametric variables in Phase II. McNemar test and Wilcoxon signed-ranks test were used to assess differences in non-parametric variables.

**Discussion**

Improving the probability of success when designing a soft contact lens for continuous overnight wear requires a good balance between the material's oxygen transmissibility, physical/mechanical properties, and the lens design. The oxygen transmissibility of the silicone elastomer lens was sufficient to limit overnight swelling to an average of 2.62%. The mechanical properties and lens design, however, reduced comfort (presumably due to the high level of movement and corneal exposure) to levels that limit the usefulness of the lens in clinical practice. Clinically acceptable fit and comfort results were recorded with the hydrogel lens but an average of 9.14% swelling was measured. By balancing the oxygen transmissibility of silicone with the mechanical/physical properties of hydrogels, the balafilcon A lens was able to deliver good fit and comfort results while limiting swelling to levels similar to the silicone elastomer. Overnight central corneal swelling results are often reported as averages, which may not give the best representation of what one might expect to find in clinical practice. Due to variability in corneal oxygen demands it may be more appropriate to evaluate the swelling distribution rather than the average. The following figure shows swelling distributions from Phases I and II of the current study.

**Conclusion**

By balancing the relationship between silicone and hydrogel components, balafilcon A soft contact lenses are able to deliver the fit and comfort of a soft contact lens while maintaining corneal swelling levels similar to a silicone elastomer contact lens.

**References**