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# Overnight Clinical Performance of a High Dk Silicone Hydrogel Soft Contact Lens

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**T.L. Comstock, O.D., M.S., M.W. Robboy, O.D., I.G. Cox, Ph.D.**
**N.A. Brennan, Ph.D.**

**Bausch & Lomb, Rochester, NY, USA**
**MOST enterprises Pty Ltd., Melbourne, Australia**

## 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 effected, causing the cornea to swell.[1] 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 comparisons to conventional hydrogel and silicone elastomer materials.

## Methods

Phase I was conducted at the premises of The Lodge at Woodcliff in Rochester, 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 Melbourne, AUSTRALIA. Subjects were examined at the site between January 20 and February 8, 1999. Up to 6 subjects were evaluated per night.

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 eye 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 | Power | Dk | Dk/t |
|---|---|---|---|---|---|
| Phase I | Test | balafilcon A | +4.00, -3.00, -9.00 | 99 | 110 @ -3.00 |
| | Control | etafilcon A | +4.00, -3.00, -9.00 | 21 | 30 @ -3.00 |
| Phase II | Test | balafilcon A | -3.00 | 99 | 110 |
| | Control | silicone | -3.00 | 300* | 200 |

* Visser reports in the 1997 Contact Lens and Anterior Eye (Supplement) 20 pp S19-S25 that silicone elastomers have a Dk of 300 to 400. Bausch & Lomb reports a Dk of 300 for the SilSoft® (silicone elastomer) Aphakic Extended Wear lens.

**Procedure**:

Subjects attended the examination suite on the evening of the overnight having ceased contact lens wear and abstained from alcohol intake for at least 24 hours. Baseline slit lamp biomicroscopy was performed and baseline corneal thickness measured. Corneal thickness in the US study was measured using a Payor-Holden micropachometer consisting of a Haag-Streit pachometer adapted to a Rodenstock model 2000 biomicroscope. The design and operation of the pachometer have been described elsewhere.[2] Corneal thickness in the Australian study was measured using Pacscan, an analytical software component that interfaces with the Orbscan instrument. A minimum of 3 repeat measurements for each data set was collected with additional images taken and processed if the central 3 values in the initial set were not within 10µm. 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 retired for approximately 8 hour of closed eye sleep with the lenses in place. All measurements of lens 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.

**Subjective Lens Comfort:**

The difference between test and control lens mean subjective comfort was not statistically significant in phase I ($F_{1,27}$=4.0, p<0.06) and was statistically significant ($F_{1,23}$=121, p≤0.001) in phase II.

Subjective Lens Comfort (0-100)

| | Phase I | | | | Phase II | | | |
|---|---|---|---|---|---|---|---|---|
| | PM | | AM | | PM | | AM | |
| | Test | Control | Test | Control | Test | Control | Test | Control |
| Mean | 90.5 | 80.7 | 85.9 | 81.4 | 79.4 | 14.5 | 74.0 | 23.2 |
| Std Dev | 12.7 | 20.0 | 14.3 | 18.3 | 18.0 | 16.5 | 21.3 | 18.7 |

**Lens Fit:**

Test lenses moved more than control lenses in Phase I (0.25 vs 0.17mm) and the difference was statistically significant, $F_{1,29}$=12.2, p≤0.005). In Phase II, test lenses moved less than control lenses (0.52 vs 1.33mm) and the difference was also statistically significant, $F_{1,24}$=17.9, p≤0.0005.

Lens centration and corneal coverage were evaluated in Phase II only. The difference in centration was not statistically significant, F1,24=3.5, p<0.08, and the difference in corneal coverage was significantly better with test lenses at both the dispensing visit, Z=2.78, p≤0.01, and the morning visit, Z=2.35, p≤0.05.

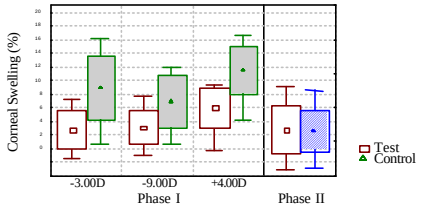
**Overnight Corneal Swelling:**

The difference between test and control lens mean overnight corneal swelling was statistically significant in phase I ($F_{1,27}$=77.5, p≤0.001) and was not statistically significant ($F_{1,24}$=0.4, p<0.52) in phase II.

Overnight Corneal Swelling (%)

| | Phase I | | | | | | Phase II | |
|---|---|---|---|---|---|---|---|---|
| | -3.00D | | -9.00D | | +4.00D | | | |
| | Test | Control | Test | Control | Test | Control | Test | Control |
| Mean | 2.87 | 8.94 | 3.15 | 6.95 | 6.14 | 11.52 | 2.89 | 2.62 |
| Std Dev | 2.71 | 4.58 | 2.40 | 3.68 | 2.81 | 3.35 | 3.35 | 2.93 |
| Min | -1.51 | 0.72 | -0.91 | 0.55 | -0.36 | 4.16 | -3.14 | -2.97 |
| Max | 7.24 | 16.23 | 7.65 | 11.82 | 9.30 | 16.64 | 9.10 | 8.51 |

Overnight Corneal Swelling (Mean, S.D. [Box], Range [Whisker])

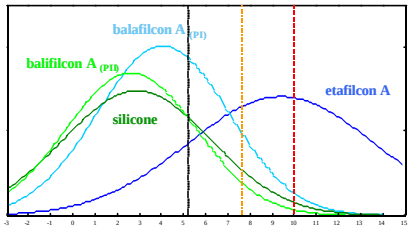



## Discussion

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.

Overnight Corneal Swelling (%)




Structural changes in the cornea have been shown to occur at 5.2% swelling in the form of striae and at 7.7% swelling in the form of endothelial folds.[3] 10% corneal swelling has been labeled dangerous.[4] From the above distributions the frequency with which these levels of corneal swelling can be expected can be calculated as follows:

| | | Swelling Greater Than | | |
|---|---|---|---|---|
| | | 5.2% | 7.7% | 10.0% |
| Phase I | etafilcon A | 82% | 63% | 42% |
| | balafilcon A | 34% | 11% | 2% |
| Phase II | silicone | 19% | 4% | 1% |
| | balafilcon A | 24% | 7% | 2% |

Clearly these rates are slightly overestimated in Phase I and may be slightly underestimated in Phase II as a result of the powers tested. They do, however, give a more relevant perspective of the potential clinical impact, relative to corneal edema, of continuous wear of these lenses.

## 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

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2. Holden BA, Polse KA, Fonn D, Mertz, GW: Effects of cataract surgery on corneal function. Invest Ophthal Vis Sci 1982; 22:343-350.

3. La Hood D, Grant T: Striae and folds as indicators of corneal edema. AAO Poster.

4. Efron N: Understanding oxygen: Dk/L, EOP, Oedema. J Br. Contact Lens Assoc., 1991; 14(2):65-69.