Comparison of topographical changes associated with overnight wear of inverted silicone hydrogel contact lenses of different powers

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Comparison of topographical changes associated with overnight wear of inverted silicone hydrogel contact lenses of different powers

Abstract
Purpose: Previously conducted studies have demonstrated significant topographical changes following overnight wear of both normally configured (non-inverted) and inverted -6.00D silicone hydrogel lenses. Further, a distinct difference in topography was realized between eyes wearing the inverted vs non-inverted lenses. These results suggest that silicone hydrogel lenses may be sufficiently rigid to potentially effect predictable changes in corneal topography following overnight wear. This investigation was designed to study the effects of overnight wear of -9.00D silicone hydrogel lenses to evaluate changes in corneal topography and to compare these results with previously collected data to determine if they result in greater changes in topography due to increased rigidity of the lenses.

Methods: Baseline corneal topography data was collected for N = 11 subjects. The subjects were then fit with -9.00D Focus Night & Day (CibaVision) silicone hydrogel lenses. All subjects, who were recruited based on their participation in the initial study, wore a non-inverted lens on one eye and an inverted lens on the other eye, to match the conditions of the previous study, which was determined by a randomization schedule. Lenses were removed following 12hrs of continuous wear, including 8hrs of overnight wear. Following removal of the contact lenses, corneal topography data was collected, and a comfort survey was completed comparing the subjects' perception of comfort with both the non-inverted and inverted contact lenses.

Results: The inverted -9.00D lens resulted in significantly (p

Conclusions: Greater corneal flattening was realized with inverted silicone hydrogel contact lenses vs non-inverted lenses. Further, the effect was greater with higher powered minus lenses. These data suggest that planned corneal reshaping to correct for refractive error may occur with appropriately designed silicone hydrogel lenses. Both inverted and non-inverted contact lenses were well-tolerated during overnight wear.

Degree Type
Thesis

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Comparison of Topographical Changes Associated with Overnight Wear of Inverted Silicone Hydrogel Contact Lenses of Different Powers

Felicia Popowski, BS
LeRoy Popowski, MS
Shauna Bendele, BS

A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
May 2005

Advisors:
Peter Bergenske, OD, FAAO
Patrick Caroline, FAAO
Comparison of Topographical Changes Associated with Overnight Wear of Inverted Silicone Hydrogel Contact Lenses of Different Powers

Authors:

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Biographies

Felicia Popowski earned her BS degree at the University of Washington (Seattle, WA) in August of 2001. As an undergraduate student, she conducted research in child development and psychology while working full-time as a clinic manager for an ophthalmology/optometry practice. She derived great satisfaction from interacting directly with patients and wanted to further her clinical skills with a career in optometry. She discovered a fondness for educating others while lecturing for continuing education classes at both the local and state level. During optometry school, she has served as an assistant instructor for clinical procedures labs, worked as the ocular disease department technician and been employed as a dispensing optician and contact lens technician in a local private practice. Felicia enjoys an active lifestyle with her pro-athlete husband LeRoy and their two sons. They run, bike, hike, and take full advantage of all the beautiful scenery the Northwest has to offer. After graduation, Felicia will focus her career in disease and hospital based optometry.

LeRoy Popowski earned his BA at St. John’s University (Collegeville, MN) in May of 1997. While an undergraduate student, he competed in both cross country and track & field, earning All-Conference honors multiple times and running in the NCAA XC National Championships. He then attended the University of Iowa, where he completed a Master’s degree in Exercise Physiology in December of 2000. While a graduate student, he published studies evaluating the effects of progressive hypohydration on plasma and urinary parameters, cognitive ability, and utilized positron emission tomography imaging to identify cerebral structures involved in thermoregulation and body fluid balance. LeRoy has competed as a professional duathlete for five years, placed 3rd at the US Pro Duathlon Championships, recorded several top ten finishes at Duathlon World Cup Team, and competed in the World Duathlon Championships in Austria. He married an incredible woman, Felicia, in May of 2004 and is enjoying a wonderful marriage. LeRoy is presently enjoying time spent with Felicia and is earnestly training for his first Ironman Triathlon.

Shauna R. Bendele is from Oakland, OR. She attended Pacific University in Forest Grove, Oregon where she received her bachelor’s degree in Visual Science in May 2002. She currently lives in Clackamas, Oregon and attends Pacific University College of Optometry. Upon graduation in May 2005, she plans to remain in the Pacific Northwest.
Title: Comparison of Topographical Changes Associated with Overnight Wear of Inverted Silicone Hydrogel Contact Lenses

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Includes 4 tables and 3 figures.

Abstract

Purpose: Previously conducted studies have demonstrated significant topographical changes following overnight wear of both normally configured (non-inverted) and inverted -6.00D silicone hydrogel lenses. Further, a distinct difference in topography was realized between eyes wearing the inverted vs non-inverted lenses. These results suggest that silicone hydrogel lenses may be sufficiently rigid to potentially effect predictable changes in corneal topography following overnight wear. This investigation was designed to study the effects of overnight wear of -9.00D silicone hydrogel lenses to evaluate changes in corneal topography and to compare these results with previously collected data to determine if they result in greater changes in topography due to increased rigidity of the lenses. Methods: Baseline corneal topography data was collected for N = 11 subjects. The subjects were then fit with -9.00D Focus Night & Day (CibaVision) silicone hydrogel lenses. All subjects, who were recruited based on their participation in the initial study, wore a non-inverted lens on one eye and an inverted lens on the other eye, to match the conditions of the previous study, which was determined by a randomization schedule. Lenses were removed following 12hrs of continuous wear, including 8hrs of overnight wear. Following removal of the contact lenses, corneal topography data was collected, and a comfort survey was completed comparing the subjects' perception of comfort with both the non-inverted and inverted contact lenses. Results: The inverted -9.00D lens resulted in significantly (p<0.010) greater corneal flattening nasally compared to the non-inverted contact lens. A greater flattening (p<0.005) of the corneal topography occurred with the inverted -9.00D lens vs the -6.00D lens. Comfort between the inverted and non-inverted lenses was not significantly different. Conclusions: Greater corneal flattening was realized with inverted silicone hydrogel contact lenses vs non-inverted lenses. Further, the effect was greater with higher powered minus lenses. These data suggest that planned corneal reshaping to correct for refractive error may occur with appropriately designed silicone hydrogel lenses. Both inverted and non-inverted contact lenses were well-tolerated during overnight wear.

Key Words: Corneal reshaping, silicone hydrogel lenses, refractive error, corneal topography, contact lens comfort, overnight contact lens wear.
Introduction

A previous study, conducted at the Pacific University College of Optometry, demonstrated orthokeratology effects following overnight wear of -6.00D silicone hydrogel contact lenses. Corneal topography changes resulted from wearing these lenses both inverted and non-inverted, although greater changes at some corneal positions were demonstrated with the inverted lenses compared to the non-inverted lenses. Most notably, there was a significant change nasally, with a mean increased corneal flattening of 0.26D with the inverted contact lens vs the non-inverted contact lens. Additionally, topography changes following inverted overnight contact lens wear appeared to demonstrate a similar pattern when the subjects' corneal topography maps were compared. Subjects also reported similar comfort wearing contact lenses both inverted and non-inverted. Mountford noted similar changes with plus powered silicone hydrogel lenses.

The present study was designed to evaluate the effects of overnight wear of silicone hydrogel lenses of higher power with assumed increased thickness and rigidity. Silicone hydrogels are stiffer than conventional hydrogels due to the incorporation of silicone. The modulus is 4-6 times greater than low rigidity materials like etafilcon A. The materials with the highest ratio of silicone to water are the stiffest and the CibaVision Focus Night & Day lens has the highest modulus of silicone hydrogels available on the market. Given this, it was important to determine if a thicker lens design would have a deleterious effect of patient comfort when worn in the inverted configuration. The
investigators theorized that contact lenses of higher powers would result in an increase in the magnitude of corneal flattening with overnight wear.

The introduction of a soft contact lens to be used as a corneal re-shaping modality for the correction of refractive error would be a significant development. The use of a highly oxygen permeable lens with great comfort would likely significantly increase the number of patients to engage in orthokeratology for the correction of refractive error.
Methods

The protocol for this study was submitted to and approved by the IRB of Pacific University. Eleven of the original fourteen subjects from the initial study\(^1\), ages 22-35 were recruited to participate. All subjects were myopic, with the range of refractive error from -0.50D to -8.00D. Informed consent was obtained from all subjects.

Subjects were fit with a pair of Focus Night & Day (Ciba Vision) silicone hydrogel contact lenses (8.4 BC, 13.8mm diameter, -9.00D). Each patient was fit with contact lenses on both eyes, one contact lens inverted and one non-inverted, corresponding with the initial study randomization, to enable comparison between different contact lens powers. Subjects were not informed which eye was fit with the inverted lens. Biomicroscopy examination was used to confirm the proper orientation of the contact lenses. Subjects then wore the contact lenses continuously for 12 hours (including 8 hours of sleep time) and reported back to the clinic the following morning. Due to the presence of refractive error, subjects were driven home and picked up the following morning.

The following morning, upon arrival to the clinic, the contact lenses were removed from both eyes of each subject. Corneal topography maps were acquired for each eye to assess changes in slope utilizing a Medmont E300 Corneal Topographer with Medmont Studio version 3.9.8 software (Camberwell, Australia). All topography data was acquired by an investigator who was unaware of which eye contained the experimental (inverted) lens. Analysis of change included subjective generalized changes in topography and changes at
three points on the horizontal axis including: 1) the centermost point 2) 1.5mm nasal to center, and 3) 1.5mm temporal to center. Subjects then completed a comfort questionnaire by providing verbal responses to questions read aloud by an investigator. The comfort questionnaire required subjects to grade comfort on a scale of 1 to 10, with 1 representing “not at all comfortable” and 10 representing “very comfortable”. Comfort was graded upon insertion of the contact lens, immediately upon awakening in the morning following overnight wear, and following removal of the contact lenses. Subjects were thanked for their time and released.
Results

Results are reported for corneal topography changes from baseline to an experimental condition following 12 hours continuous wear (8 hrs of sleep time) of -9.00D silicone hydrogel contact lenses. The experimental condition of the present investigation, overnight wear of -9.00D was also compared to a previously conducted study in which patients’ topography was assessed following overnight wear of -6.00D silicone hydrogel contact lenses. These two experimental conditions were compared to evaluate for an increased change in corneal topography with contact lenses of increased power with assumed increased thickness and rigidity. Subjective comfort data regarding patient tolerance of the inverted and non-inverted contact lenses was also collected.

Statistical analysis was performed comparing corneal topography at baseline, following overnight wear of -6.00D contact lenses (one inverted and the other non-inverted), and following overnight wear of -9.00D contact lenses (one inverted and the other non-inverted). Comparison between the inverted and non-inverted lens topography changes at each of the experimental conditions was also performed. Paired t-tests were performed to determine statistical differences between conditions.

Baseline versus -9.00D

The data for each individual subject are contained in tables 1 and 2. Significant change was noted only at the nasal location. The mean difference at the nasal location between the non-inverted and inverted lens was 0.693 D (95%CI 0.244 to 1.142). Paired t test yields \( p = 0.0063 \), \( t = 3.441 \), with \( DF = 10 \). Differences at other locations were not found to
be statistically significant. Figures 1 and 2 show the magnitude of corneal flattening at the nasal location with -6.00D and -9.00D contact lenses, respectively.

**-6.00D versus -9.00D**

The mean difference at the nasal location between the -9.00D and -6.00D inverted lenses was 0.527 D (95%CI 0.222 to 0.833). Paired t test yields $p=0.0032$. $t = 3.84$ with DF = 10. Figure 3 compares the degree of nasal corneal flattening between -6.00D and -9.00D contact lenses. Differences at the other locations were not found to be statistically significant. Table 3 contains the difference data between the -6.00D lens and the -9.00D lens for each of the subjects.

**Subjective Comfort**

Overall comfort between the inverted and non-inverted lenses was assessed on three measures: comfort immediately after lens insertion, comfort immediately upon awakening, and comfort immediately following lens removal. Additionally, habitual comfort upon awakening without contact lens wear was recorded for comparison. On all three measures, subjective comfort was not significantly different. These results coincide with the study by Williams and Westberg. Individual comfort data are displayed in table 4.
Discussion

Presently, orthokeratology is utilized to reshape the cornea with overnight rigid contact lens wear. The goal of corneal reshaping is to flatten the corneal curvature sufficiently to effect changes in refractive error to achieve emmetropia and realize adequate daytime visual acuity without the use of spectacle or contact lens wear. The present study shows that statistically, but not clinically, significant topography changes occur at the 1.5mm nasal location following overnight wear of inverted silicone hydrogel contact lenses.

The results show topographical differences between inverted and non-inverted lenses as well as differences correlated with the increased thickness of the -9.00D contact lens versus the -6.00D contact lens. Greater corneal flattening was realized with inverted silicone hydrogel contact lenses vs non-inverted lenses. Further, the effect was greater with higher powered minus lenses. Notably, the only significant degree of corneal flattening occurred at a nasal position. This was an interesting finding that suggests that the location of corneal topography change is predictable. The study by Williams and Westberg drew this same conclusion. It is not clear why the effect occurs here not at other locations, perhaps it is due to a nasal decentration effect that occurs when sleeping.

Additionally, the demonstration of an increase in magnitude of corneal flattening with the presumed thicker and more rigid contact lenses provides further support for the possibility of designing a silicone hydrogel lens to be capable of effecting predictable corneal topographical changes. These data suggest that an appropriately designed silicone hydrogel lens may be able to effect predictable changes in corneal topography.
Both inverted and non-inverted contact lenses were well-tolerated during overnight wear. No significant difference in comfort was reported, which is a finding that surprises most experienced clinicians. Conventional soft lenses that accidentally are inserted inside out are not as tolerable, as patients clinically report immediate discomfort.

It is important to note that simply wearing inverted lenses can cause unwanted changes in both visual acuity and corneal topography. The present investigation provides support for further studies to address the ability of appropriately designed silicone hydrogel lenses to be utilized as an orthokeratology modality. Additional variables of significance include increasing the duration of overnight wear, lens centration, and effects of different contact lens curvatures.


Figures

Figure 1. Change from baseline with the non-inverted and inverted -6.00D lens, measured 1.5 mm nasal of center on the tangential topography map.

Figure 2. Change from baseline with the non-inverted and inverted -9.00D lens, measured 1.5 mm nasal of center on the tangential topography map.

Figure 3. Change at the nasal location with the inverted lens was significantly greater with the -9.00D than with the -6.00D lens.
Tables

Table 1. Corneal Topography Changes in Diopters from Baseline with Overnight Wear of -6.00D Silicone Hydrogel Contact Lenses.

Table 2. Corneal Topography Changes in Diopters from Baseline with Overnight Wear of -9.00D Silicone Hydrogel Contact Lenses.

Table 3. Corneal Topography Difference (in Diopters) from Overnight Wear of -6.00D to -9.00D Silicone Hydrogel Contact Lenses.

Table 4. Ocular comfort grading (1=not at all comfortable, 10=very comfortable).
Figure 1. Change from baseline with the non-inverted and inverted -6.00D lens, measured 1.5 mm nasal of center on the tangential topography map.
Figure 2. Change from baseline with the non-inverted and inverted -9.00D lens, measured 1.5 mm nasal of center on the tangential topography map.
Figure 3. Change at the nasal location with the inverted lens was significantly greater with the -9.00D than with the -6.00D lens.
Table 1. Corneal Topography Changes in Diopters from Baseline with Overnight Wear of -6.00D Silicone Hydrogel Contact Lenses.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Nasal 1.5mm Non-Inverted</th>
<th>Nasal 1.5mm Inverted</th>
<th>Central Non-Inverted</th>
<th>Central Inverted</th>
<th>Temporal 1.5mm Non-Inverted</th>
<th>Temporal 1.5mm Inverted</th>
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<td>1</td>
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<td>0.000</td>
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Mean Change
-0.109 -0.400 -0.309 -0.291 -0.227 -0.345

SD
0.164 0.316 0.487 0.342 0.185 0.216
Table 2. Corneal Topography Changes in Diopters from Baseline with Overnight Wear of -9.00D Silicone Hydrogel Contact Lenses.

<table>
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<tr>
<th>Subject</th>
<th>Nasal 1.5mm</th>
<th>Nasal 1.5mm</th>
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<th>Central</th>
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Mean Change | -0.234 | -0.927 | -0.384 | -0.361 | -0.295 | -0.370 |
SD          | 0.197   | 0.587  | 0.394  | 0.402  | 0.204  | 0.200  |
Table 3. Corneal Topography Difference (in Diopters) from Overnight Wear of -6.00D to -9.00D Silicone Hydrogel Contact Lenses. (Minus sign indicates more flattening)

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<tr>
<th>Subject</th>
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<td>-0.070</td>
<td>-0.068</td>
<td>-0.025</td>
</tr>
<tr>
<td>SD</td>
<td>0.175</td>
<td>0.455</td>
<td>0.505</td>
<td>0.380</td>
<td>0.303</td>
<td>0.261</td>
</tr>
</tbody>
</table>
Table 4. Ocular comfort grading (1=not at all comfortable, 10=very comfortable).

<table>
<thead>
<tr>
<th></th>
<th>Comfort Upon Insertion</th>
<th>Comfort Upon Awakening</th>
<th>Comfort Immediately Following Removal</th>
<th>Habitual Comfort Upon Awakening</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Inverted</td>
<td>Normal</td>
<td>Inverted</td>
</tr>
<tr>
<td>Mean</td>
<td>8.82</td>
<td>7.45</td>
<td>8.36</td>
<td>7.23</td>
</tr>
<tr>
<td>SD</td>
<td>1.25</td>
<td>1.44</td>
<td>1.57</td>
<td>2.04</td>
</tr>
</tbody>
</table>