Some topographical changes associated with silicone hydrogel contact lenses may be due to inverted lenses

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**Recommended Citation**

Williams, Kyle J. and Westberg, Murry D., "Some topographical changes associated with silicone hydrogel contact lenses may be due to inverted lenses" (2004). *College of Optometry*. 1496.  
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Abstract
Purpose: It is possible that many reports of topographical and refractive changes associated with silicone hydrogel contact lens wear are the result of inadvertent wearing of inverted lenses. We wished to investigate differences in subjective, topographic, and refractive impact of wearing inverted silicone hydrogel lenses in comparison to wearing lenses in the normal (non-inverted) configuration.

Methods: Baseline uncorrected visual acuity and topographical maps were taken for 14 subjects, and a comfort survey was completed for each. The subjects were then fit with Focus Night & Day (Ciba Vision) silicone hydrogel contact lenses; one of the two lenses was inverted on each subject, as determined by a randomized, masked schedule. Lenses were removed after 12 hours that included overnight wear. Acuities, topographical maps and the comfort survey were then repeated.

Results: Significant change was noted from baseline for both lens conditions for acuities (p<0.01) and the topographical maps (p<0.05). The comfort of the two lenses did not significantly differ. Although the topographical maps were often distinctly different in appearance for the two conditions, numerical differences were small.

Conclusions: Subjects' inability to distinguish inverted from non-inverted lens comfort supports the suggestion that silicone hydrogel lenses may in fact often be worn insideout. Topographic changes occur with the lenses whether inverted or not, although the appearance of the maps are noticeably different. A potential exists for corneal reshaping with silicone hydrogel lenses.

Degree Type
Thesis

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Some Topographical Changes Associated With Silicone Hydrogel Contact Lenses May Be Due to Inverted Lenses

By

Kyle J. Williams
Murry D. Westberg

A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
May 2004

Advisors:
Peter Bergenske, O.D., F.A.A.O
Patrick Caroline, F.A.A.O
Some Topographical Changes Associated With Silicone Hydrogel Contact Lenses May Be Due to Inverted Lenses

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Biographies

Murry D. Westberg is from the small town of Warren, Minnesota. He attended the University of North Dakota, where he received his bachelor’s degree in Mathematics and secondary education certification in 2001. He and his wife Amie were married on June 29, 2002 in Coon Rapids, Minnesota. They currently live in Forest Grove, Oregon where Murry attends Pacific University College of Optometry, and Amie teaches high school math. They plan to move back to their home state of Minnesota when Murry graduates in 2005.

Kyle J. Williams was raised in a town in northwest Wyoming named Cody. Upon high school graduation in 1997, he attended Northwest College in Powell Wyoming for two years before transferring to the University of Wyoming in Laramie Wyoming. He graduated with a bachelor’s in Visual Science for Pacific University in May 2002. He is an avid outdoor enthusiast, who enjoys snow skiing, water skiing, mountain biking, fishing, rafting, camping, and running. Upon graduation in May 2005, he hopes to obtain an associate position, which will eventually lead to a partnership in a private practice in northern Wyoming, or western Montana.
Title: Some topographical changes associated with silicone hydrogel contact lenses may be due to inverted lenses

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Includes 4 tables and 15 figures.

Submitted on May 1, 2004.
Purpose: It is possible that many reports of topographical and refractive changes associated with silicone hydrogel contact lens wear are the result of inadvertent wearing of inverted lenses. We wished to investigate differences in subjective, topographic, and refractive impact of wearing inverted silicone hydrogel lenses in comparison to wearing lenses in the normal (non-inverted) configuration. Methods: Baseline uncorrected visual acuity and topographical maps were taken for 14 subjects, and a comfort survey was completed for each. The subjects were then fit with Focus Night & Day (Ciba Vision) silicone hydrogel contact lenses; one of the two lenses was inverted on each subject, as determined by a randomized, masked schedule. Lenses were removed after 12 hours that included overnight wear. Acuities, topographical maps and the comfort survey were then repeated. Results: Significant change was noted from baseline for both lens conditions for acuities ($p<0.01$) and the topographical maps ($p<0.05$). The comfort of the two lenses did not significantly differ. Although the topographical maps were often distinctly different in appearance for the two conditions, numerical differences were small. Conclusions: Subjects' inability to distinguish inverted from non-inverted lens comfort supports the suggestion that silicone hydrogel lenses may in fact often be worn inside-out. Topographic changes occur with the lenses whether inverted or not, although the appearance of the maps are noticeably different. A potential exists for corneal reshaping with silicone hydrogel lenses.

Key Words: Corneal Topography, silicone hydrogel contact lenses, refractive error, visual acuity, corneal reshaping.
Purpose/Justification:

A number of reports have appeared in the contact lens literature indicating observation of unintentional topographic and consequently, refractive, changes in some patients wearing silicone hydrogel contact lenses \(^1\)\(^2\). The mechanism by which this occurs is poorly understood, and such findings can be disturbing to both the clinician and patient.

We have noted, quite serendipitously, that patients wearing high minus silicone hydrogel lenses in the inverted state show topographic changes similar to those seen in orthokeratology (Figure 1). Mountford has described similar changes with plus powered silicone hydrogel lenses \(^3\). A surprising aspect of the inverted minus lens phenomenon is that patients seem to be unaware the lenses are being worn incorrectly. It is common that a lens of substantial power worn inside out causes significant movement and lens awareness with conventional hydrogels.

It is possible that many reports of topographical and refractive changes associated with silicone hydrogel contact lens wear are the result of inadvertent wearing of inverted lenses. We wished to investigate differences in subjective, topographic, and refractive impact of wearing inverted silicone hydrogel lenses in comparison to wearing lenses in the normal (non-inverted) configuration.


**Methods:**

The protocol for this study was submitted to and approved by the IRB of Pacific University. Fourteen subjects, ages 22-35, were recruited to participate. All subjects were myopic, the range of refractive error being $-0.50$ to $-8.00$. Informed consent was obtained for all subjects.

Baseline uncorrected visual acuity was determined for each eye using high contrast Bailey-Lovie logMAR chart (University of California, Berkeley) with standard room lighting. All subjects were fit with 8.4 radius, 13.8mm diameter, $-6.00$ Focus Night & Day (CibaVision) silicone hydrogel contact lenses. One lens for each patient was placed on in the inverted state, the other in the normal non-inverted state. A randomization schedule was used to determine the eye wearing the inverted lens. Subjects were not told that one lens was being intentionally placed on inside out. Satisfactory fit and comfort were established and subjects completed a survey regarding initial comfort of each lens.

As most subjects were wearing lenses of incorrect power for their own refractive error, they were escorted home, asked to sleep overnight with the lenses, and were brought back for evaluation after twelve hours. Lenses were removed and topography, and uncorrected visual acuities were again obtained. The comfort survey was repeated for each lens. The investigator administering surveys and follow-up visual acuity testing were masked as to which eye wore the inverted lens.
**Results:**

Results are reported regarding subjective comfort, topographic changes, and uncorrected visual acuity.

**Subjective Comfort:**

Comfort was graded an analogue visual scale. Grading was a 1-10 scale, with 1 representing poorest comfort, and 10 representing best comfort. Comfort scores were obtained for each in the following categories:

- Immediately after insertion
- Immediately upon awakening
- Immediately following removal

For comparison, subject also scored their habitual (no contact lens wear) comfort upon awakening.

No significant difference was found between the two eyes for any of the conditions listed above. Comfort upon awakening was significantly different for both lens-wearing conditions compared to habitual comfort upon awakening. Descriptive statistics for each condition are listed in table 1.

**Topographic Change:**

For purpose of analysis, change in slope (compared to baseline) at three points of each cornea was considered. The three points were the centermost reading, and at 1.5 mm temporal and nasal along the horizontal meridian.
Changes in measured corneal radius, expressed in diopters, are shown in Table 2. Changes at the central and temporal locations were not found to be significant. There was significantly different change at the nasal location with a mean difference of .26 D greater flattening with the inverted lens. \( t= 2.5165, P = 0.025. \) degrees of freedom = 13. 95\% CI -0.57 to 1.09).

**Visual Acuity Change:**

Both conditions created significant difference in uncorrected visual acuity. For the non-inverted lens, mean change was .12 units \( (t= 3.005, P = 0.01. \) 95 \% CI -0.05 to 0.29). For the inverted lens mean change was .11 units. \( (t= 5.288. P = 0.0001. \) 95\% CI -0.06 to 0.28). No difference was detected between the two conditions.

Table 3 displays the change in acuity for the non-inverted lenses. Table 4 displays the change for the inverted lens condition.
Discussion:

These results indicate that there are topographical and acuity changes associated with both the normal and inverted lenses. Appearance of the difference map displays for the eyes wearing the inverted lenses is suggestive of patterns seen in rigid lens corneal reshaping. (See Figures 2-15), and in fact was the observation on which the current study was based.

It is interesting to note that subjects could not distinguish a comfort difference between the two conditions of wear. These were relatively high-minus (-6.00) lenses, which, based on experience with conventional hydrogel lenses, would be expected to create significant degradation in fit and comfort. The fact the these subjects were not any more aware of the inverted than the non-inverted lens supports our contention that silicone hydrogel lenses may often be worn inside out without comfort difference. Topographical difference maps indicate this may lead to corneal distortion and refractive shift.

Future studies using lenses of higher dioptic power (i.e. −10.00 D) may show more dramatic topographical and visual acuity changes. Extending the wearing time of the silicone hydrogel lens to more than one night (possibly to one week or month of continuous wear) may also show more dramatic and consistent topographical and visual acuity changes. Ultimately, potential exists for creating specific lens geometries that might allow intentional, controlled corneal reshaping with silicone hydrogel lenses.


Table 1. Comfort grading on an analogue visual scale; 1 representing poorest comfort, 10 representing best comfort.

<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>8.5</td>
<td>7.28</td>
<td>6.57</td>
<td>6.28</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>1.78</td>
<td>2.02</td>
<td>2.02</td>
<td>2.37</td>
</tr>
</tbody>
</table>
Table 2. Topographical changes, indicated in diopters.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Normal</th>
<th>Inverted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.5 mm Nasal</td>
<td>Central</td>
</tr>
<tr>
<td>1</td>
<td>0.120</td>
<td>-0.125</td>
</tr>
<tr>
<td>2</td>
<td>-0.120</td>
<td>-0.500</td>
</tr>
<tr>
<td>3</td>
<td>-0.500</td>
<td>-0.250</td>
</tr>
<tr>
<td>4</td>
<td>0.120</td>
<td>-0.120</td>
</tr>
<tr>
<td>5</td>
<td>-0.250</td>
<td>0.500</td>
</tr>
<tr>
<td>6</td>
<td>0.250</td>
<td>-0.370</td>
</tr>
<tr>
<td>7</td>
<td>-0.120</td>
<td>-0.870</td>
</tr>
<tr>
<td>8</td>
<td>-0.370</td>
<td>-1.250</td>
</tr>
<tr>
<td>9</td>
<td>-0.250</td>
<td>-0.370</td>
</tr>
<tr>
<td>10</td>
<td>-0.370</td>
<td>-0.500</td>
</tr>
<tr>
<td>11</td>
<td>-0.120</td>
<td>-0.620</td>
</tr>
<tr>
<td>12</td>
<td>-0.370</td>
<td>0.370</td>
</tr>
<tr>
<td>13</td>
<td>-0.250</td>
<td>0.870</td>
</tr>
<tr>
<td>14</td>
<td>-0.120</td>
<td>-0.250</td>
</tr>
</tbody>
</table>
Table 3. Pre- and Post-overnight lens wear uncorrected visual acuities for the eye with the normal fit lens, measured in logMAR units.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Before</th>
<th>After</th>
<th>Difference (+ indicates improvement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.10</td>
<td>1.12</td>
<td>-0.02</td>
</tr>
<tr>
<td>2</td>
<td>0.70</td>
<td>0.60</td>
<td>0.10</td>
</tr>
<tr>
<td>3</td>
<td>0.52</td>
<td>0.32</td>
<td>0.20</td>
</tr>
<tr>
<td>4</td>
<td>0.20</td>
<td>0.16</td>
<td>0.04</td>
</tr>
<tr>
<td>5</td>
<td>0.22</td>
<td>0.12</td>
<td>0.10</td>
</tr>
<tr>
<td>6</td>
<td>0.74</td>
<td>0.64</td>
<td>0.10</td>
</tr>
<tr>
<td>7</td>
<td>0.74</td>
<td>0.76</td>
<td>-0.02</td>
</tr>
<tr>
<td>8</td>
<td>0.80</td>
<td>0.50</td>
<td>0.30</td>
</tr>
<tr>
<td>9</td>
<td>1.18</td>
<td>0.96</td>
<td>0.22</td>
</tr>
<tr>
<td>10</td>
<td>0.72</td>
<td>0.70</td>
<td>0.02</td>
</tr>
<tr>
<td>11</td>
<td>0.12</td>
<td>0.00</td>
<td>0.12</td>
</tr>
<tr>
<td>12</td>
<td>0.38</td>
<td>-0.20</td>
<td>0.58</td>
</tr>
<tr>
<td>13</td>
<td>1.46</td>
<td>1.46</td>
<td>0.00</td>
</tr>
<tr>
<td>14</td>
<td>1.30</td>
<td>1.24</td>
<td>0.06</td>
</tr>
</tbody>
</table>
Table 4. Pre- and Post-overnight lens wear uncorrected acuities for the eye with the inverted lens, measured in logMAR units.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Before</th>
<th>After</th>
<th>Difference (+ indicates improvement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.94</td>
<td>0.92</td>
<td>0.02</td>
</tr>
<tr>
<td>2</td>
<td>1.08</td>
<td>0.92</td>
<td>0.16</td>
</tr>
<tr>
<td>3</td>
<td>0.24</td>
<td>0.06</td>
<td>0.18</td>
</tr>
<tr>
<td>4</td>
<td>0.26</td>
<td>0.06</td>
<td>0.20</td>
</tr>
<tr>
<td>5</td>
<td>0.42</td>
<td>0.30</td>
<td>0.12</td>
</tr>
<tr>
<td>6</td>
<td>0.64</td>
<td>0.52</td>
<td>0.12</td>
</tr>
<tr>
<td>7</td>
<td>0.44</td>
<td>0.26</td>
<td>0.18</td>
</tr>
<tr>
<td>8</td>
<td>0.82</td>
<td>0.88</td>
<td>-0.06</td>
</tr>
<tr>
<td>9</td>
<td>1.18</td>
<td>1.02</td>
<td>0.16</td>
</tr>
<tr>
<td>10</td>
<td>0.88</td>
<td>0.72</td>
<td>0.16</td>
</tr>
<tr>
<td>11</td>
<td>0.16</td>
<td>0.02</td>
<td>0.14</td>
</tr>
<tr>
<td>12</td>
<td>0.22</td>
<td>0.06</td>
<td>0.16</td>
</tr>
<tr>
<td>13</td>
<td>1.48</td>
<td>1.48</td>
<td>0.00</td>
</tr>
<tr>
<td>14</td>
<td>1.38</td>
<td>1.34</td>
<td>0.04</td>
</tr>
</tbody>
</table>
Figure 1. Corneal topography maps from a patient who wore the lens normally in the right eye and inverted in the left eye for thirty days continuously.
Figures 2-15. Corneal topography difference maps, in tangential view, for each eye after 12 hours of lens wear. The maps on the left (fig. 1-14 A) are for the eye that wore the lens normally, and the maps on the right (fig. 1-14 B) are for the eye that wore the lens inverted.

**Figures 2A, 2B**  
Subject: E.S.  
Fig 2A: OS, Normal  
Fig 2B: OD, Inverted

**Figures 3A, 3B**  
Subject: M.S.  
Fig 3A: OS, Normal  
Fig 3B: OD, Inverted

**Figures 4A, 4B**  
Subject: C.P.  
Fig 4A: OD, Normal  
Fig 4B: OS, Inverted
Figures 5A, 5B
Subject: L.K.
Fig 5A: OD, Normal
Fig 5B: OS, Inverted

Figures 6A, 6B
Subject: S.B.
Fig 6A: OS, Normal
Fig 6B: OD, Inverted

Figures 7A, 7B
Subject: M.H.
Fig 7A: OD, Normal
Fig 7B: OS, Inverted
Figures 8A, 8B
Subject: K.K.
Fig 8A: OD, Normal
Fig 8B: OS, Inverted

Figures 9A, 9B
Subject: R.B.
Fig 9A: OS, Normal
Fig 9B: OD, Inverted

Figures 10A, 10B
Subject: M.K.
Fig 10A: OD, Normal
Fig 10B: OS, Inverted
Figures 11A, 11B
Subject: Z.K.
Fig 11A: OS, Normal
Fig 11B: OD, Inverted

Figures 12A, 12B
Subject: J.P.
Fig 12A: OD, Normal
Fig 12B: OS, Inverted

Figures 13A, 13B
Subject: F.T.
Fig 13A: OD, Normal
Fig 13B: OS, Inverted
Figures 14A, 14B
Subject: M.W.
Fig 14A: OS, Normal
Fig 14B: OD, Inverted

Figures 15A, 15B
Subject: T.H.
Fig 15A: OS, Normal
Fig 15B: OD, Inverted