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A comparison of the effects of HC II-55 and B&L contact lenses on the cornea

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A comparison of the effects of HC II-55 and B&L contact lenses on the cornea

Abstract
Pachometry of the central cornea and endothelial cell photography were used to compare two lenses, Hydrocurve II (55% water) and B&L U-4, (38.6% water), Six subjects were used with each wearing both types of lenses, Five other subjects could only wear one type of lens. For each lens baseline data was compared to findings found after full time daily wear, and after full time wear combined with four hours of sleep While wearing the lenses. Two weeks were allowed between lenses during which time no lenses were worn. All findings were compared with paired data t-tests. The results showed that higher oxygen transmissability as found in HC II-55 lenses caused little corneal compromise with full-time daily wear but had no effect on results from lens wear with sleep. It was also shown that B&L U-4 lenses had significant amounts of edema present under normal wear conditions with little further change occurring with sleep. Endothelial cell count was shown to be too variable for clinical use. Corneal striae were shown to be a possible diagnostic tool for the success of extended wear.

Degree Type
Thesis

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A COMPARISON OF THE EFFECTS OF HC II-55
AND
B&L U-4 CONTACT LENSES ON THE CORNEA

A THESIS
PRESENTED TO THE FACULTY
OF
PACIFIC UNIVERSITY
BY
NADA LINGEL RICHARDSON
TERRY P. TOBIN

IN PARTIAL FULFILLMENT
OF THE REQUIREMENT FOR THE DEGREE
DOCTOR OF OPTOMETRY
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ADVISOR

LYNN J. COON, O.D.
A COMPARISON OF THE EFFECTS OF HC II-55
AND
B&L U-4 CONTACT LENSES ON THE CORNEA

BY

TERRY P. TOBIN

NADA LINGEL RICHARDSON

Accepted by the faculty of the College of Optometry,
Pacific University, in partial fulfillment of
the Doctor of Optometry Degree

A
Midterm Grade

Lynn J. Coon, O.D.
Thesis Advisor

A
Final Grade
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Further thanks to our eleven subjects for giving us their time and patience so willingly.
Pachometry of the central cornea and endothelial cell photography were used to compare two lenses, Hydrocurve II (55% water) and B&L U-4, (38.6% water). Six subjects were used with each wearing both types of lenses. Five other subjects could only wear one type of lens. For each lens baseline data was compared to findings found after full time daily wear, and after full time wear combined with four hours of sleep while wearing the lenses. Two weeks were allowed between lenses during which time no lenses were worn.

All findings were compared with paired data t-tests. The results showed that higher oxygen transmissibility as found in HC II-55 lenses caused little corneal compromise with full-time daily wear but had no effect on results from lens wear with sleep. It was also shown that B&L U-4 lenses had significant amounts of edema present under normal wear conditions with little further change occurring with sleep.

Endothelial cell count was shown to be too variable for clinical use. Corneal striae were shown to be a possible diagnostic tool for the success of extended wear.
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INTRODUCTION

The endothelium of the cornea is a single layer of cells lining Descemet's membrane. If the endothelium is damaged by any means, swelling of the corneal stroma occurs. This swelling in turn causes a loss of corneal transparency. Swelling occurs much more rapidly and is more pronounced than that found with epithelial damage. These facts indicate that the endothelium is important in the maintenance of corneal deturgescence. Currently there are two theoretical mechanisms for this function. One involves the endothelium acting as a barrier to the aqueous while the second possible mechanism is the presence of a bicarbonate ion pump. In fact, it may be a combination of both. In both mechanisms the corneal endothelium plays an important role in corneal physiology.

Endothelial changes have been reported with many kinds of corneal injury and stress, including hard and soft contact lens wear. These changes, called blebs, appear clinically as black areas among the endothelial cells. These blebs have been reported in the literature as representing acellular areas, areas where cells are out of focus due to edema, or areas of cells so large that their cytoplasm is too thin to see. Endothelial cells very seldom, if ever, undergo mitosis. Instead, endothelial integrity is maintained by remaining cells sliding and
spreading to fill in areas where cells have died. Therefore, even if these blebs are acellular it is unlikely that they will remain that way permanently. (7,8,15,22) The mechanism of cell sliding is supported by findings of decreased numbers and density of cells in older patients and those with corneal trauma.(6,7) Laule, A., et al. have demonstrated that very few acellular areas exist on eye bank eyes stained with Toluidine Blue O. They also feel that the areas appearing cell-free with the biomicroscope are artefactual.(7)

Zantos and Holden report endothelial blebs occurring within ten minutes after insertion of soft contact lenses.(24) They found these changes to be transient, with the endothelium returning to normal "rapidly" after lens removal. In their study, however, Holden and Zantos, who used unadapted subjects, did not report how long the contact lenses were worn, nor what time period they considered to be a "rapid" return to normal. Unadapted contact lens wearers, as used in Holden and Zantos' study, are known to develop as much as 3 or 4% corneal swelling with initial wear.(8) It is therefore probable that these endothelial blebs are related to corneal edema.
The following study will explore two different hydrogel lenses and their effects on the endothelial cell counts and corneal swelling during full-time and closed eye wear. The two lenses compared will be Hydrocurve II (55% water content) and B&L U-4 (38.6% water content). These lenses were chosen because they represent two different schools of thought. Hydrocurve II-55 have a very high water content and, although they are thin in the center, have fairly thick edges. Bausch and Lomb U-4 lenses are uniformly thin but only contain 38.6% water. Both lenses were readily available and were being used fairly extensively at Pacific University Optometric Clinic. The thinnest Bausch and Lomb lenses, 0-4's, were not yet available when this study was started. Actual oxygen transmissability for the lenses, along with manufacturers' lens specifications can be found in table 1. Corneal stress will be attempted by having the patients wear the hydrogel lenses under closed eye conditions. Even without lenses corneal thickening of approximately 4% occurs with sleep.\(^{(9)}\) The effect of soft contact lenses worn under these conditions is of clinical importance because of the recent FDA approval of contact lenses for cosmetic extended wear.

The effects of this stress on central corneal thickness will be measured by pachometry. The instrument to be used is an Electronic Digital Pachometer, Model 6090, manufactured by Diagnostic Concepts. According to Schoessler and Barr the level of accuracy is slightly less
than 1% (16). Corneal endothelial cell changes will be monitored by slit lamp photography. The changes found will be used to compare the effects of the two hydrogel lenses on corneal physiology.
<table>
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<tr>
<th>Lens</th>
<th>HC II-55</th>
<th>B&amp;L U-4</th>
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<tr>
<td>Water Content</td>
<td>55%</td>
<td>38.6%</td>
</tr>
<tr>
<td>Center Thickness</td>
<td>0.05 mm</td>
<td>0.07 mm</td>
</tr>
<tr>
<td>Actual Oxygen Transmissibility</td>
<td>22.7</td>
<td>7.8</td>
</tr>
<tr>
<td>$DK/L \times 10^{-9}$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Diameter</td>
<td>14.0 mm</td>
<td>14.5 mm</td>
</tr>
<tr>
<td>Base Curve</td>
<td>8.6 mm</td>
<td>Varies with power</td>
</tr>
</tbody>
</table>
PROCEDURE

Eleven subjects were chosen for this study. All subjects met the criteria of Miller, Coon and Meier as modified below (12):

1. no binocular problems present
2. correctable to 20/20 or better in each eye with conventional spectacles
3. no structural abnormalities of the eyes or anexa present
4. no clinical evidence of active ocular pathology present
5. no history of ocular disease
6. taking no ocular medications
7. normal intraocular pressures
8. correctable, by contact lenses, to visual acuity acceptable to the subject and the examiner

Any subjects who were currently wearing lenses were required to discontinue wear for at least two weeks before baseline findings were taken. Baseline data included endothelial photography and pachometry.
After baseline data was taken, all subjects were fit with new lenses. The lenses were fit following the criteria of Miller, et al., as follows (12):

1. The lens must move freely with blinking and look loose. One to three millimeters of movement is desirable. On upward gaze the lens may displace three to four millimeters.

2. The lens edge must overlap the limbus at least one mm. Slight decentration is acceptable if this criterion is met.

3. If more than one base curve/size relationship appears to meet the above criteria, the "loosest" lens must be used.

Following these criteria six subjects were able to wear both HC II-55 and B&L U-4 lenses. Four subjects were fit with only B&L U-4’s because the HC II-55 parameters did not allow a suitable fit. In all four patients the lenses folded and would not remain on the eye with blinking. One subject was able to wear only the HC II-55 lenses because the B&L U-4 lenses were not received from the manufacturer in time to be included.

After fitting, the subjects built up their wearing time following manufacturer’s recommendations until full time daily wear was achieved. Those subjects able to wear both types of lens chose one brand randomly. Subjects were required to wear their lenses full time for one week before further experimental data was gathered. After this wear was achieved, endothelial photographs were taken and pachometry performed. Contact lens progress exams were also done at
this time. The criteria of Miller et al. had to be met before sleeping was allowed. The lenses were required to (12):

1. be comfortable
2. provide good, stable visual acuity throughout the wearing period
3. be wearable throughout all waking hours
4. have had no detrimental effect on ocular health status

If these criteria were met the subjects remained under closed eye conditions for one hour. After this hour patients were again examined to insure that no adverse reactions had taken place. Any responses that were considered harmful to the subject precluded the use of that patient for longer periods of lens wear under closed eye conditions. Responses considered harmful would include corneal abrasion, circumcorneal injection, or subjective symptoms, any of which persist for more than fifteen minutes after contact lens removal.

One week later the subjects were examined again after eight to ten hours of contact lens wear. If all criteria were met, the subjects, while wearing their lenses, were placed under closed eye conditions for four hours. Four hours was chosen because literature shows that corneal edema reaches its maximum amount after no more than three to four hours of closed-eye wear. (8) Significant amounts of edema have been found with as little as one half hour of sleep.
while wearing hydrogel lenses. After this closed eye period, photographs and pachometry were again performed.

The six patients who were fit with both lenses were once again taken out of contact lenses for two weeks. The entire procedure was then repeated for the second pair of lenses.

The endothelium was photographed with a 35mm Nikon single reflex camera mounted behind a 10x eyepiece of a Nikon biomicroscope. This allows 35x magnification. The photographs were taken using Kodachrome 64 ASA film. To insure that the photographs were taken of a constant corneal location, an alignment system was employed. It consisted of a head brace and fixation light. The fixation light, the illumination system of the biomicroscope, and the camera were always set at a constant angle as described by Holden and Zantos. All photographs were taken by one experimenter, with one instrument.

With the electronic pachometer, a fixation light that allows a constant area to be measured is provided. Only one experimenter took the pachometric measurements throughout the study. These alignment systems will allow decreased experimenter variability for both the photographic and pachometric measurements.
The electronic pachometer is also equipped with a computer that takes the mean and standard deviation of three consecutive readings. To be accepted as a valid corneal thickness the standard deviation must be less than .009.

After all photographs were available, the cells were counted by an experimenter who did not know under what conditions the photographs were taken. This avoided biasing the results. Only one experimenter counted the cells, once again to decrease experimenter variability. To be counted, the photographs of the corneal mosaic were projected onto a grid of 48 squares. (Figure 1) The grid was constructed by photographing a hemacytometer slide. The hemacytometer slide, like the subject's cornea, was photographed at 35x. It was also photographed in the same plane as the subject's cornea. When projected, each square of the grid will represent 1mm. The actual cell count is multiplied by 100 to give cells/mm².

At least four pictures of each eye were taken in each situation. Many of the photographs of the endothelial cells were not readable. When the slide was projected on the grid not all of the squares were countable. The total number of squares counted appears under # on table 3. Only those cells inside squares or touching the left or bottom borders were counted. Those cells touching the top and right borders were not counted. This will help to insure a precise measurement. (19) To further insure that no cell is
counted twice, and to provide a written record, the cells were dotted on the grid as they were counted. For each individual in each experimental situation a mean and standard deviation for all squares counted was computed.

Statistical analysis was carried out by using a student's t-test on the pachometric data. This was done with matched paired data points so that the same subjects are compared in each group. Because there was so much variability within groups an f-test as well as a t-test was performed on cell numbers. Pachometric and photographic, baseline findings were compared to the data gathered from all other sessions. Also compared was the data derived from the same situations for the two different lenses and each lens in different situations.
RESULTS

Pachometric and cell count data can be found in tables 2 and 3, respectively. Analysis of the pachometric findings was done with the use of the student’s t-test. In this analysis eight t-tests were performed. Baseline findings were compared to all other findings for each lens. The findings for the B&L U-4 lens after full time wear were compared to those after four hours of sleep. This was also done for HC II-55. The findings from each lens in the same situation were also compared.

No significant difference between the means of corneal thickness for the two groups was found when baseline findings were compared to HC II-55 lenses worn for eight to ten hours. There was also no significant difference between the means of B&L U-4 lenses worn for eight hours and B&L U-4 lenses worn for eight hours followed by four hours of sleep. Also, when B&L U-4 lenses worn eight hours followed by four hours of sleep were compared to HC II-55 lenses worn under the same situation there was no significant difference between the mean corneal thicknesses.
Significance at the $\alpha = .005$ level was found for corneal thickness comparing the following means:

1. baseline when compared to HC II-55 lenses worn for eight hours followed by four hours of sleep* (HC II 8+4).
2. baseline when compared to B&L U-4 lenses worn for eight hours* (B&L 8).
3. baseline when compared to B&L U-4 lenses worn for eight hours followed by four hours of sleep* (B&L 8+4).
4. HC II-55 lenses worn eight hours (HC II 8) vs HC II 8+4*
5. HC II 8 vs B&L 8*

In each of the compared groups the mean of corneal thickness was larger for those conditions marked with *.

The average amount of corneal swelling from baseline was also calculated for each situation. The HC II 8 findings showed an increase of approximately 1.4% in corneal thickness. After four hours of sleep this same group showed an average swelling of 5.4%. The B&L 8 group had an average of 4.9% corneal swelling which increased to 5.9% with the four hours of sleep.

Corneal striae were found in three patients after four hours of sleep. Two patients, A.R. and D.G., developed striae with both HC II-55 and B&L U-4 lenses. One patient, S.G., developed them only when sleeping with B&L lenses. The percentage of corneal swelling was computed for each of these patients. (table 4).
One patient, C.H., experienced tightening of the B&L U-4 lenses after one hour of sleep. This caused decreased lens movement and increased ocular irritation. Because of this the subject did not meet our criteria for sleeping with the lenses and was not used in B&L 8+4.

Data analysis of the cell counts is less straightforward. All groups show very large amounts of variability. Significant differences in the mean number of cells/mm² were found when comparing baseline* to HC II 8, B&L 8 to B&L 8+4*, and B&L 8+4* to HC II 8+4. Significance was at the level of $\alpha = .05$, .005 and .025 respectively. F-test analysis of endothelial cell counts revealed two significant comparisons. These are B&L 8 when compared to B&L 8+4* at $\alpha = .01$ and HC II 8+4 when compared to B&L 8+4* at $\alpha = .05$. The starred items had larger cell counts and greater variability as found with mean and standard deviation.

Cell count data was further complicated by the fact that many pictures did not turn out. (See table 3). Out of 86 photographic situations, one for each eye in each situation, five were determined to be edematous. This referred to photographs that appeared to be in focus, because one or two cells could be seen clearly with the remainder of the photograph unclear.
One subject, V.T., was particularly prone to this, with two edematous photograph situations for each eye. Another four photographic situations were considered nonreadable due to improper focus of the camera.
<table>
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<th>Subject</th>
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<th>BASELINE</th>
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<th>B&amp;L U-4</th>
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<td>8 hrs wear</td>
<td>4 hrs sleep</td>
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* Data was not obtained because lens fit failed to maintain the wearing criteria.
### TABLE 3

**ENDOTHELIAL CELL COUNTS IN CELLS/MM²**

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<tr>
<th>Subject</th>
<th>Eye</th>
<th>0 hrs wear</th>
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<td>1877 9</td>
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<td>2130 10</td>
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<td>*</td>
</tr>
<tr>
<td>CS</td>
<td>OD</td>
<td>1587 8</td>
<td>*</td>
<td>*</td>
<td>1600 2</td>
<td>1983 6</td>
</tr>
<tr>
<td></td>
<td>OS</td>
<td>2014 7</td>
<td>*</td>
<td>*</td>
<td>1620 5</td>
<td>1985 7</td>
</tr>
</tbody>
</table>

NR: Cells were unreadable due to improper focus of the camera.
ED: Cells were unreadable due to edema.
* Data was not obtained because lens fit failed to maintain the wearing criteria.
TABLE 4

PERCENTAGE OF CORNEAL SWELLING FOUND IN PATIENTS WITH CORNEAL STRIAE.

<table>
<thead>
<tr>
<th>Patient</th>
<th>HC II 8+4</th>
<th>B&amp;L 8+4</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.R.</td>
<td>O.D.</td>
<td>2.53%</td>
</tr>
<tr>
<td></td>
<td>O.S.</td>
<td>0.61%</td>
</tr>
<tr>
<td>D.G.</td>
<td>O.D.</td>
<td>9.26%</td>
</tr>
<tr>
<td></td>
<td>O.S.</td>
<td>0.00%</td>
</tr>
<tr>
<td>S.G.</td>
<td>O.D.</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>O.S.</td>
<td>X</td>
</tr>
</tbody>
</table>

X No corneal striae were present.
DISCUSSION AND CONCLUSIONS

Many conclusions can be derived from the pachometric data. With normal eight to ten hour lens wear, corneal thickening is significantly less for HC II-55 than for B&L U-4 lenses. In fact, the wearing of HC II-55 shows no significant corneal edema changes when compared to baseline.

Although both HC II-55 and B&L U-4 lenses show significant thickening with sleep as compared to baseline, there is no significant difference between the two lenses under these conditions. Finally, B&L U-4 lenses show no significant changes when worn for four hours of sleep as compared to full time wear. HC II-55 lenses, however, show a dramatic increase in corneal thickening with sleep as compared to full time wear.

These results lead us to conclude that HC II-55 lenses would be less likely to interfere with corneal physiology during daily wear. Under closed eye conditions, however, neither lens showed a more positive response. This is especially interesting when transmissability of the lenses is compared. Within the range used in this study, lens transmissability seems to have no effect on corneal physiology under closed eye conditions.
This apparent lack of effect of transmissability is also evident from the occurrence of corneal striae. Under stress both HC II-55 and B&L U-4 lenses were related to striae.

Literature generally suggests that corneal striae only occur with edema of 5-7% or greater. Yet, Polse, Sarver, and Harris found vertical striae in 7 out of 25 hydrogel lens wearers with 0-4% edema. Our findings also show that striae can occur without significant edema as measured by the pachometer. One possible reason for this is that vertical striae may be localized areas of excessive edema. Unless the corneal thickness is measured directly over the striae the cornea may show little or no swelling.

Endothelial cell counts seem to be very difficult to work with in the clinical setting. One possible source of error for cell counting is a 12% greater peripheral magnification experienced with the projection of a photographic image. It may be more important clinically to qualitatively evaluate the ability to see the endothelial mosaic than to quantitatively count endothelial cells.

For those clinicians interested in fitting extended wear lenses it is interesting to note that considerable differences were found between individuals even while wearing the same lens type. For this reason, success of extended wear lenses may depend more on the individual than the lens material as long as the lens is reasonably fit.
Also important is the possibility of using a period of four hours of sleep as a diagnostic tool for success of extended lens wear. This is especially significant if giant corneal striae are found after only four hours of sleep. Whether the patient experiences any subjective symptoms or not, corneal striae indicate some interference with corneal physiology. For any patient this must be considered a poor prognosis of successful extended lens wear.


